S. HRG. 107–404

Senate Hearings

Before the Committee on Appropriations

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations

Fiscal Year 2002

107*th* CONGRESS, FIRST SESSION

H.R. 3061/S. 1536

DEPARTMENT OF EDUCATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENT OF LABOR
NONDEPARTMENTAL WITNESSES

Labor-HHS-Education Appropriations, 2002 (H.R. 3061/S. 1536)

S. HRG. 107–404

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON

H.R. 3061/S. 1536

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2002, AND FOR OTHER PURPOSES

Department of Education
Department of Health and Human Services
Department of Labor
Nondepartmental witnesses

Printed for the use of the Committee on Appropriations

Available via the World Wide Web: http://www.access.gpo.gov/congress/senate

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U.S. GOVERNMENT PRINTING OFFICE

70–756 PDF WASHINGTON : 2002

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

TUESDAY, MARCH 6, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:39 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

WORK SAFETY AND THE ERGONOMICS RULE

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed.

The hearing on ergonomics has been convened on very short notice, as we have not had much notice that the issue would be on the Senate floor, which it is today, and I thought it would be useful to hear from parties in the field, the representatives of the factions which are in opposition to the current ergonomics regulation, representatives in favor of the regulation, and from the Associate Solicitor of Labor for OSHA, the Agency which had the responsibility for promulgating the regulation.

I had a brief informal meeting with the parties in my office. We will proceed now to try to address a number of the critical issues. I would start with the question as to the views of the witnesses, and I welcome Mr. Joseph M. Woodward, Esq., who is Associate Solicitor of Labor for OSHA, and Baruch Fellner, Esq., a partner at Gibson, Dunn & Crutcher, practicing employment law with emphasis on occupational safety and health, and Lynn Rhinehart, Esq., associate counsel of the AFL–CIO. We will start with the baseline question as to whether there ought to be any regulation at all. Mr. Fellner, let me start with you on that first.

STATEMENT OF BARUCH A. FELLNER, ESQ., PARTNER, GIBSON, DUNN & CRUTCHER, LLP

Mr. FELLNER. Based upon the science, the law, and medicine as we presently know it, the regulation which OSHA has promulgated is beyond the mark and is fatally flawed.

Whether there should be any regulation of ergonomics will and should depend on the proper nonrush to judgment evaluation of this extraordinarily complex area, and Secretary Chao in her confirmation hearings has emphasized precisely that, and that is, these are issues which are inordinately complicated, both from an economic as well as a scientific and medical perspective, and given that, given the time frame that it took between proposal to final in this instance, a time frame which the head of the OSHA effort, Marthe Kent, referred to as a miracle if OSHA could promulgate this standard in time—and by in time, we all know that that meant before the close of the last administration.

Senator SPECTER. Then you are essentially saying there could be a regulation, but it has to be properly formulated. What would you recommend as the course to formulate such a regulation?

Mr. FELLNER. We would recommend what we recommended to OSHA during the course of the hearings, and it was a recommendation that was echoed by the Chief Administrative Judge, Judge Vittone, and that was, first, given the complexity of the issues involved, the medical and scientific issues, it would be appropriate, it would be absolutely necessary to get into the same room the major medical and scientific minds on both sides and let them have, over a period of 2 or 3 days, or however long it took, with appropriate overview from the Department of Labor, a full and free discussion of what the science shows.

Senator SPECTER. Who should those people be?

Mr. FELLNER. We represent the National Coalition on Ergonomics and a number of other petitioners in the lawsuit against this litigation, or against this regulation. As part of that lawsuit, we submitted statements from 21 of the world's greatest experts, amongst whom is Alf Nachemson. Alf Nachemson from Sweden, is viewed as the greatest authority on low back pain, period, full stop. He has submitted a statement into the OSHA record indicating that this standard is so ill-advised from an economic, a medical and a scientific perspective, that it should not be promulgated. Alf Nachemson, N-a-c-h-e-m-s-o-n, and there are many others.

Senator SPECTER. How many such experts would you recommend representing your side of the issue?

Mr. FELLNER. I would suggest, Senator Specter, that it might be slightly premature to get into those specifics, but at least a half-a-dozen, half-a-dozen to a dozen experts from our side I would suggest, respectfully, from the appropriate medical side, and I would also remind the chairman that two august medical bodies, the American College of Occupational and Environmental Medicine, representing over 100,000 occupational doctors, supporters of ergonomic principles from day 1, have written a specific letter opposing this final standard. They should be represented. Two, the American Academy of Orthopedic Surgeons submitted a comment into the record opposing this proposed regulation. They should be represented, and if the other side wants to bring in their ergonomists to represent their position insofar as what the medical and scientific issues reflect, by all means let them do so, but if I might add, when we made that suggestion of a full and free discussion

with regard to these issues, OSHA declined, and declined in writing. That issue has to be redressed.

STATEMENT OF LYNN RHINEHART, AMERICAN FEDERATION OF LABOR-CONGRESS OF INDUSTRIAL ORGANIZATIONS

Senator SPECTER. Before taking up, Mr. Fellner, with your specific objections to the regulation, let me ask Ms. Rhinehart what her view is of such an interchange among experts.

Ms. RHINEHART. Well, Senator, I think that is a fine idea, but in fact it has already happened. It has already happened a number of times, the most recently the National Academy of Sciences recently issued a comprehensive report, and that was ordered by Congress as part of the appropriations process 2 years ago.

The NAS issued a comprehensive report after reviewing all of the literature on ergonomics, and this was a gathering of major scientific minds. As Mr. Fellner put it, this was a gathering of major scientific minds, the National Academy of Sciences, and they came out with a comprehensive report in January that found not only is there a strong association between worker exposure to ergonomic risk factors in the workplace, and development of ergonomic injuries, but also that interventions reducing those exposures was effective at reducing worker injuries.

Senator SPECTER. Did the National Academy of Sciences support this regulation?

Ms. RHINEHART. The NAS, their job was to look at the science and to make conclusions about what the science says at this point. They were very explicit that they were not making policy recommendations, that their job was to look at science, not policy, so they did not take a specific position on the ergonomics regulation. However, their findings clearly support an ergonomics regulation. They found that, as I said——

Senator SPECTER. Well, they clearly support regulation, but the focused question is whether they support this regulation.

Ms. RHINEHART. They were not asked to support this regulation, so they did not comment on this regulation.

Senator SPECTER. They were not asked to comment about this regulation?

Ms. RHINEHART. Correct. They were asked to look at the science, and they did, and they found the science supports ergonomic interventions.

STATEMENT OF JOSEPH M. WOODWARD, ASSOCIATE SOLICITOR OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

Senator SPECTER. Mr. Woodward, is it true, as Mr. Fellner says, that OSHA specifically rejected a convocation of experts on both sides?

Mr. WOODWARD. I believe he is referring to a letter that was written during the course of the rulemaking proceedings for this standard. In order to promulgate a standard, we have to follow certain procedures, which include public hearings and an opportunity for comment. We were engaged in following those proceedings at that time, which are all on the record and subject to certain requirements, so I believe it is correct that at that time we did not take up that opportunity.

If I could make a few other points, first of all, I am here in a technical capacity to try to help describe the rule and the issues in the rule. I am not here to advocate a particular policy solution here.

Senator SPECTER. Well, are you here to advocate the rule?

Mr. WOODWARD. I would like to note that the Agency has finalized a rulemaking, and that it found on the record that the criteria for issuing an OSHA standard, in the agency's view, as of last November, were satisfied. Those criteria are: is there a significant risk of harm; is the harm material; and is there a feasible way to reduce the harm. That was the finding that was made in November.

Any approach to ergonomics, if it is in a regulatory approach, would have to follow the criteria that Congress has laid down, and also the procedures. Since we issued the rule, a number of people have filed lawsuits. Thirty-one lawsuits have been filed. A lot of objections have been raised to the rule. The Secretary has said that these are very complicated issues that she wants to study carefully. We are aware of the fact that many people have objected to the provisions of the rule.

Senator SPECTER. Well, you give the reasons why you rejected the idea of having experts on both sides come in, because, as you describe it, you are in the middle of a rulemaking process. Do you think that Mr. Fellner's suggestion is a good one, if you are going back to the start again?

Mr. WOODWARD. We always think it is a good idea to meet with different people who have different viewpoints, and hear what they have to say, because certainly you can learn something that way.

Senator SPECTER. Is that a yes answer?

Mr. WOODWARD. Yes. A meeting or a discussion is a good thing. If the idea is to do a rulemaking, eventually you have to go through the procedures I mentioned, and you have to make your decision on the basis of the evidence.

Senator SPECTER. Do those procedures allow at some stage to have the expertise that Mr. Fellner described convened and discuss the matter?

Mr. WOODWARD. Certainly. There are public hearings where people can come in and say what they want and question each other.

Senator SPECTER. I do not think he is talking about a public hearing, although it could be open to the public. Well, you can call it a public hearing.

Mr. Fellner, coming to the substance of this regulation, what, in your view, is wrong with it?

Mr. FELLNER. If I may be given a couple of minutes to address that, Senator Specter, rather than a relatively brief period of time.

Senator SPECTER. Take whatever time you need, Mr. Fellner.

Mr. FELLNER. I appreciate it immensely. It is important to reflect, obviously, the perspective from which I come. I am an attorney. I represent the National Coalition on Ergonomics, and some 106 out of 136 petitioners in this matter and, in the interest of an open record, it is important to recognize that I am an attorney reflecting those clients.

Having said that, and if you would allow me a personal digression, I have been practicing occupational safety and health law for

30 years. In my formative years as a lawyer I was in charge of OSHA enforcement for a period of approximately 10 years, and it is with a great deal of sadness and mixed emotion that I am here today, speaking against a regulation from an agency for which I have enormous respect and an agency which I believe has a very, very important task in this country. It has gone too far insofar as this particular regulation is concerned.

And let me emphasize, Senator Specter, what we are not opposed to. We are not opposed to the voluntary application of ergonomic principles in the workplace. Ever since the wheel was invented, man has understood that it is preferable to use a wheelbarrow to move rocks than it is to do it on his back. That is pure, sensible, logical, you want to make the job as comfortable——

Senator SPECTER. Mr. Fellner, it does not advance the issue much to say that you are in favor of voluntary compliance. Of course, if it is voluntary, who would have any objection to that. The issue moves from that as to whether you need something more.

Mr. FELLNER. That is right, and the question is whether this—not whether you need, with all due respect, whether you need something more, in the context of your first question to me, any regulation. The issue before us this morning, with respect, is this midnight regulation that we are talking about.

Senator SPECTER. Precisely. That is why I am asking you what is wrong with it, in your view.

Mr. FELLNER. It is the most intrusive, most far-reaching micromanagement of American industry in the history of the Department of Labor. It is, to put it bluntly, bad law, bad economics, bad science, and bad medicine, and if I could touch on all of those four briefly this morning, I can give what I would think would be a complete response.

Senator SPECTER. That is fine. To the extent you can be specific as to what there is in the regulation which is costly, which is inefficient, and which does not move to protect worker safety, we would appreciate it.

Mr. FELLNER. Thank you. The final standard we are talking about, Senator Specter, does a 180 from the proposal. The proposal as a result of 2½ months of hearings in which I participated, cross-examined OSHA's witnesses. That proposal, I dare say the agency concluded was vague to the point of being unconstitutional and, instead of going with the proposal, they went with a final standard which was not the logical outgrowth, could not be anticipated from that which was proposed, and let me give you one or two examples, if I may.

The final standard contains nine mathematical formulas which include basic screening tools and hazard identification tools to tell the employer how to act, how to lift, what to move, what constitutes repetition. The final standard defines repetition as two motions performed within 1 minute over a 2-hour period of time. One minute is interminable. I would challenge——

Senator SPECTER. Two motions?

Mr. FELLNER. Within 1 minute, which are repetitive. A repetitive cycle is two motions within 1 minute over 2 hours.

We do not have the time this morning to take out a stop-watch, and if you take out a stop-watch and determine how slow 1 minute

is, and how few two motions are, that is the stately pace that OSHA would want American business to function at.

Senator SPECTER. I would like to have Ms. Rhinehart's comment. We will come right back to you.

Ms. RHINEHART. Thank you, Senator. I hesitate to guess exactly what Mr. Fellner is talking about, but I believe he is talking about the triggers that OSHA included in its final rule, triggers which simply tell an employer, hey, your worker may be exposed to a hazard here, and you need to do a job analysis, fully analyze the job, and see if your worker is exposed to a hazard.

Nowhere in this rule does it say that workers, or that employers have to restrict workers to doing a motion less than two times a minute. That simply does not appear anywhere in this rule.

Senator SPECTER. Mr. Fellner.

Mr. FELLNER. Yes. I would like to read page 68848 of the Federal Register document.

Senator SPECTER. We will include that page in the record at this point.

[The information follows:]

Table W-1 - Basic Screening Tool

You need only review risk factors for those areas of the body affected by the MSD incident.

		Body Part Associated With MSD Incident			
Risk Factors This Standard Covers	**Performing job or tasks that involve:**	Neck/ Shoulder	Hand/ Wrist/ Arm	Back/ Trunk/ Hip	Leg/ knee/ Ankle
Repetition	(1) Repeating the same motions every few seconds or repeating a cycle of motions involving the affected body part more than twice per minute for more than 2 consecutive hours in a workday.	√	√	√	√
	(2) Using an input device, such as a keyboard and/or mouse, in a steady manner for more than 4 hours total in a workday.	√	√		
Force	(3) Lifting more than 75 pounds at any one time; more than 55 pounds more than 10 times per day; or more than 25 pounds below the knees, above the shoulders, or at arms' length more than 25 times per day;	√	√	√	√
	(4) Pushing/pulling with more than 20 pounds of initial force (e.g., equivalent to pushing a 65 pound box across a tile floor or pushing a shopping cart with five 40 pound bags of dog food) for more than 2 hours total per day;	√	√	√	√
	(5) Pinching an unsupported object weighing 2 or more pounds per hand, or use of an equivalent pinching force (e.g., holding a small binder clip open) for more than 2 hours total per day;		√		
	(6) Gripping an unsupported object weighing 10 pounds or more per hand, or use of an equivalent gripping force (e.g., crushing the sides of an aluminum soda can with one hand), for more than 2 hours total per day.		√		

Mr. FELLNER. This is table W–1, which is the basic screening tool. The left-hand column reads, "risk factors this standard covers." The first one is repetition. In that first definition it says, repeating the same motions every few seconds, or repeating a cycle of motions involving the affected body part more than twice a minute for more than 2 consecutive hours in a work day. That is OSHA's definition of what it calls a risk factor this standard covers, which is repetition.

We always wanted during the course of this hearing for OSHA to tell us how much is too much. They have, in their own words. This is their definition of repetition, and while we are on this page,

Senator Specter, it also contains a definition of lifting 75 pounds once. It also contains definitions which say, if you lift 25 pounds below the knee, above the shoulders, or at arm's length more than 25 times per day—25 pounds, 25 times a day—that constitutes force, and on and on.

These are OSHA's definitions of its risk factors. I would suggest that economically the impact of these risk factors, were these to trigger the kinds of job hazard analyses that Ms. Rhinehart indicates, the impact of these risk factors on our retrenching economy would be devastating.

Moreover, there is not a scintilla of scientific evidence or medical evidence to support these exercises in false precision.

Senator SPECTER. Mr. Woodward, how about it? What is your view of what Mr. Fellner is arguing?

Mr. WOODWARD. I would like to clarify a couple of things here. This table here, which we refer to as a screen, its only function is to tell an employer whether it needs to take a look at a job. There are no limits in here of the kind that would say you have to have fewer repetitions than what is in the table.

The function of this table is, if an employee is injured, and you, the employer, determine that that injury was because of work, then look at this table and determine if there is at least that much exposure to risk factors here. The next step is to do a job hazard analysis to try to figure out whether there is a hazard. You can use any reasonable method to do the hazard analysis.

In other words, if your employee is injured and he has acquired, say, carpal tunnel, and you look at the job and yes, he does have 2 consecutive hours of repeating the same motion over and over again, then you have to go further and look at the job in more detail to see whether or not it is actually a hazardous job. Put another way, if it is less than that, you stop. You do not even inquire. You say, well, if there is less than 2 hours of exposure, I clearly do not need to worry about this.

Now, let me qualify that. There are certain provisions of the standard, not the control provisions, that are triggered when you exceed this amount of exposure. A medical referral for a medical evaluation and then possible work restrictions is triggered, and training is triggered, but in terms of whether controls are triggered: no, the only requirement is to perform an analysis to try to determine whether there is a hazard.

Just to clarify one other point, the definition is not twice per minute. It says, repeating the same motions every few seconds, or repeating a cycle of motions involving the affected body part more than twice per minute, so there are two concepts in here. One is, you are doing the same thing every few seconds for 2 hours in a row without stopping. The other is a cycle that is a combination of body motions, and whether you complete that cycle, go through the full cycle more than twice a minute.

To go back to the other issue that was raised as to whether people have an opportunity to comment on this, that is one of the issues that will be in the litigation. What the proposal said was that if somebody was injured and if they were working, if they were exposed for a significant amount of time to repetition, for example, then you should look at the job, but that phrase, significant

amount of time, was not defined in the text of the proposal, so I think that is the point he is referring to.

There was some discussion in the preamble about scientific evidence indicating that the 2- and 4-hour level is something worth looking at, but there was not anything particular in the text of the proposal.

Senator SPECTER. Let me come back to the basic point here on what this means. Risk factors this standard covers, and then we have the specifics. Are you saying, Mr. Woodward, that even if the employee's activities fall within those definitions, that there is not necessarily a violation?

Mr. WOODWARD. Correct. This is a tool that is part of a process.

Senator SPECTER. It is a tool as part of the process, but that triggers an inquiry as to whether there is inappropriate work required of the person?

Mr. WOODWARD. That is correct, whether there is a hazard.

Senator SPECTER. Then what comes next to make a determination as to whether, if that is done, there is a hazard?

Mr. WOODWARD. Then what the standard says is that the employer should do a hazard analysis.

Senator SPECTER. What about a hazard analysis?

Mr. WOODWARD. It says if these levels are exceeded, the employer must do a hazard analysis, and it says that there are several different methods an employer could use to do a hazard analysis. One method is to hire a professional, a safety and health person who is knowledgeable in the area and knows something about ergonomic principles. Another method is to use one of the enumerated tools that are listed in the standard, and I think Mr. Fellner was referring to these tools as well as something that he believes the public needed more opportunity to comment on, but these are tools that are in the nature of safe harbors. If you want to use any one of these tools to conduct a hazard analysis you can do that, that is allowed. Finally, you can do any other approach that is reasonable.

Senator SPECTER. Mr. Fellner, your point is that these factors occur, then a hazard analysis is triggered, and there has to be a determination as to whether there is a hazard which is unacceptable, is that your point?

Mr. FELLNER. Yes, in part. If I could expand on that a bit, Senator Specter, and that is, first of all let me address one of the things that Mr. Woodward said insofar as this screening out injuries. The word injury is not used in the standard. It is a musculoskeletal disorder incident.

That term is defined in the context of a list in the standard of subjective symptoms, including pain, simply pain, tingling, cramps. That constitutes an MSD incident. Then question is whether any of these screening criteria which we refer to in table WD–1 screen anything out. The answer is no. That, in turn, triggers a job hazard analysis.

The job hazard analysis and its consequences, which is the mandated use of nine tools that have not been associated in any way, shape, or form scientifically with eliminating ergonomic risk factors or eliminating MSD incidents, those nine tools have to be used, and you have to constantly implement engineering controls, reengineer

your workplace in compliance with these mandated tools, so the process, soup to nuts, is the identification of these hazard screens, these action triggers, which in turn——

Senator SPECTER. I am going to come back to that. Ms. Rhinehart has not had a chance to respond, and I see her anxiously edging forward toward the microphone. Ms. Rhinehart, what is your view?

Ms. RHINEHART. Thank you. I would just like to back up, if I could, and put some of this in a little bit of context. OSHA in this ergonomics rule essentially codified an approach to ergonomics that many companies are already following, that the General Accounting Office has recommended as an effective approach to ergonomics, that NIOSH recommends as an effective approach to ergonomics, that the NAS in its recent report suggests is an effective approach to ergonomics.

It is a very broad and very flexible approach to ergonomics that has employers follow very basic program elements of job hazard analysis, hazard identification and control, involves their workers in that process, provides some basic training. These are elements that have been out there and in use ever since at least the 1990's, the late 1980's, the 1990's, when the Department of Labor put out its guidelines for addressing ergonomic problems in meat-packing plants.

These basic elements that are in the final rule were part of those red meat guidelines. They have been part of settlement agreements that OSHA has reached with many companies. Many companies have voluntarily adopted ergonomics programs centered around these principles, and there is a reason why they have, because they work.

There are countless examples in the rulemaking record, Senator Specter, where companies that have implemented ergonomic programs centered around these principles have found that not only are they able to reduce worker exposure to hazards, they have reduced worker injuries, and they have reduced the costs associated with those injuries in terms of Workers Comp costs, lost productivity, other health costs, not to mention the sparing workers and their families the impact that these injuries have.

These are serious, debilitating injuries that occur at a rate of about 600,000 serious injuries per year, and the impact of these injuries on workers and their families is simply devastating.

There are effective, known measures centered around these broad principles contained in the final rule to address this problem and to reduce that suffering, and save employers money in the process, and that is why we think that it is important that we have a final ergonomics standard on the books that frankly has been—it has been 10 years in the making. It has been a long time coming. It is no rush to judgment. But fortunately, finally the time has come, and we do have these ergonomics protections on the books that we strongly support.

Senator SPECTER. Mr. Fellner, your position is what? What about Ms. Rhinehart's statement that these standards represent a great many practices which have been accepted in the industry and by these other agencies?

Mr. FELLNER. This standard did not receive 10 years of scrutiny. It did not receive 10 minutes of scrutiny insofar as notice and comment is concerned. This standard as a regulatory requirement, which on pain of penalty from compliance officers, taking this standard out and enforcing it has not been part of anybody's ergonomics program.

Senator SPECTER. Is there a pain of penalty if somebody has the repetitive motion of more than twice per minute for more than 2 consecutive hours in a work day? Is there a pain of penalty for some employer who permits that kind of work to go forward?

Mr. FELLNER. If some employer permits that kind of work to go forward without undertaking the job hazard analysis and the mandated tools, in Appendix D–1 the answer is absolutely yes. It is those action triggers that start the ball rolling.

Senator SPECTER. Now, the job-mandated analysis on specified tools, elaborate as to what that means exactly, and why you are opposed.

Mr. FELLNER. Job hazard analysis—and we are opposed to that because we have seen this in the context of OSHA having issued over 550 general duty clauses—citations under its omnibus authority for ergonomics issues.

The job hazard analysis and what OSHA has required pursuant to those citations have involved everything from reengineering the workplace, slowing the pace of the workplace, hiring more workers, reducing the weight, changing the entire configuration of conveyer systems.

There are comments in the record, Senator Specter——

Senator SPECTER. Mr. Fellner, what would you recommend, or the ancillary question is, do you believe that there is not a problem if someone has to do more than twice a minute the same activity more than two consecutive hours in the work day? Do you think that is not a problem, or an indicator of a problem which requires further analysis to decide whether it is a hazard?

Mr. FELLNER. That is correct.

Senator SPECTER. You do not think that means anything?

Mr. FELLNER. I would suggest, with all due respect, that that indicates how far OSHA has gone if they honestly believe that repetition is doing something twice a minute, twice a minute for 2 hours, and that that triggers—the word they use is action trigger, that that triggers action, including the worker removal protection, which is independently triggered by that.

Senator SPECTER. What is the worker removal test?

Mr. FELLNER. The worker removal protection is 90 days at 90-percent pay if one has a subjective MSD incident that I described earlier.

Senator SPECTER. 90 days at 90-percent pay in some other job?

Mr. FELLNER. No, sitting at home doing no other job. 90 days at 90-percent pay. We are talking about the most favored injury clause. If you compare this with any other injury, an amputation would not yield the same——

Senator SPECTER. Okay, I understand your point.

What kind of repetitive activity do your experts think would be hazardous?

Mr. FELLNER. That is an extraordinarily complex question, as complicated as the human being is, and I would respond——

Senator SPECTER. It is up to a man of your experience to answer.

Mr. FELLNER. I would respond by saying, with respect, look at the answer of sports medicine. Sports medicine teaches you that repetition is not bad, but good. Repetition strengthens the human body. The basic medical premise on which ergonomists have based this standard is that we are a series of ball-bearings, we human beings, and that we are going to wear out over time.

If anyone has an aged parent, if anyone is dealing with recovery from injury, we know that motion is not bad, but repetitive motion, and difficult repetitive motion, is good for the human body, striking that balance. It is a difficult balance.

Senator SPECTER. Mr. Fellner I am trying to zero in on issues which I think will be of concern not only to me but to my colleagues. Are you saying that there is no problem with repetition no matter how much repetition there is?

Mr. FELLNER. I am saying that that is a question for free and open debate amongst the experts.

Senator SPECTER. What do your experts say? You must know what they say on the subject. If you are disagreeing with the standard, what is the standard?

Mr. FELLNER. Again, we are not in the position to draft a standard in this hearing room, and I would not be in a position to condense the experts' views in this hearing room.

Senator SPECTER. I was thinking of providing 6 to 12 persons on each side to come into this room and have a discussion about it.

Mr. FELLNER. That is not a bad idea.

Senator SPECTER. When you come down to this next one, lifting more than 75 pounds at any one time, or more than 55 pounds more than 10 times a day, or more than 25 pounds below the knees or above the shoulders or at arm's length more than 25 times a day, I think about my experience in my father's junkyard. At 17, I could lift 100 pounds, but it was tough, and we had joints of 2-inch casing, tubing, 25 feet long, which three of us threw on a truck, and more than 100 pounds was tough.

What happens with women? Are women called upon to lift 75 pounds in their jobs? Are they, Ms. Rhinehart?

Ms. RHINEHART. Absolutely, Senator. One of the industries with the highest rate of back injuries and other ergonomic injuries is nursing homes. Nurses' aides and other workers in nursing homes are required to lift patients who often weigh more than 100 pounds, and often they are required to lift these patients on their own, and as a result of that, the rate of injuries in that industry is rampant.

Can I just go back for 1 second to the repetitions?

Senator SPECTER. Stay with nursing homes for a second. What is to be done? Is someone to be with the employee at all times to help them lift the patient?

Ms. RHINEHART. There are a couple of things that were discussed extensively in the rulemaking hearings, either that you have somebody assist you in lifting a patient, or there are actually mechanical devices that are out there and in use in hospitals and in nursing homes and in other settings that assist a worker in moving a

patient, and which takes some of the weight and some of the load off of the worker while still permitting the patient-handling that needs to be done to occur. So those devices are out there.

Senator SPECTER. You had another point you wanted to make.

Ms. RHINEHART. I just wanted to, on the point of repetition and how much repetition is too much, I would just refer you—and I would be happy to provide this for the record—to some of the very compelling testimony during the OSHA rulemaking hearings from poultry workers, who have birds coming past them on a line at a rate of 70 birds per minute, and they have to pull these birds down and make motions and cuts on those birds, 70 birds a minute, every minute, every hour, and I would suggest that when you take that repetition and combine it with the effect of that repetition on workers, the skyrocketing rates of injuries, that is too much.

Senator SPECTER. I am trying to figure out how to get there from here. I do not know what the repetition standard ought to be, and I do not know what the weight-lifting standard ought to be, but the question, Mr. Fellner, is how we get there, and you do not like what is being done here, and if you convened experts in all of these fields who give their testimony, then you would leave it up to OSHA to make a judgment as to which expert testimony was correct, and they would then make up a chart like this one on risk factors this standard covers. Then there would be an opportunity for the parties to comment, and then OSHA would consider those comments and come to a final conclusion. That is what you are suggesting, Mr. Fellner?

Mr. FELLNER. That is—definitely, assuming that the new OSHA concludes that one can segregate the physical factors, which is what we have talked about, and limited our discussion this morning, from the myriad of other factors acknowledged by the World Health Organization, the National Academy of Sciences, and others, including psychosocial factors, social factors, cultural factors, gender, genetics, and a variety of other factors, all of which contribute to these MSD incidents that we talked about before.

And assuming that the new OSHA concludes, as well, that it is in a position to distinguish that which takes place in the workplace from that which is caused outside of the workplace, especially since there is so much of a conglomeration, if you will, of these factors together.

Assume that all of these pieces can be appropriately understood by the new OSHA, and assume that physical factors can be segregated from all of the rest which have been acknowledged even by the experts that Ms. Rhinehart relies on. Then what you have described is an entirely appropriate way of approaching the issue, but the assumptions are not yet well understood.

Senator SPECTER. Let us go to the issue of cost. What has OSHA estimated the cost to be, Mr. Woodward?

Mr. WOODWARD. OSHA estimated the cost of this standard at roughly $4.5 billion per year. This is an annualized cost; there are several components to that estimate. There is the cost of the program elements. In other words, you have to train employees according to this standard. That takes time. That is a cost. There is the cost of the controls that you would have to put in if you find that there is a hazard that needs to be controlled. There is also the cost

of the work restriction protection, maintaining an employee's earnings, if you determine the employee is injured and that he cannot perform his normal duties.

Senator SPECTER. How do you come to the figure? What is your methodology?

Mr. WOODWARD. The biggest single part of it, according to OSHA, is the program cost. Those were roughly $2 billion, a little more than that.

Senator SPECTER. How do you determine that?

Mr. WOODWARD. The current standards requires employers to do various things. They have to set up a system by which employees can report their injuries to them. They have to give employees information about these type of injuries. They have to train them. They have to do hazard analysis. What OSHA did is to list those activities and then try to figure out how much time it typically would take an employer to do that. That computation was in the final rule largely based on testimony about existing ergonomics programs.

People testified about their ergonomics programs. For example, it takes us *x* hours to train our employees, and other people had a different estimate, and they said, it takes us *y* hours. The agency reviewed those estimates and came out in the middle. Basically, that was how OSHA calculated the program part of the cost.

For the work restriction protection part, OSHA received from BLS an estimate of how many workers are currently off work due to this type of injury. Then OSHA made an adjustment because they think there is underreporting, and that the real number, after this standard goes into effect would be greater since more people would be reporting their injuries.

Then OSHA looked at what BLS says is the median amount of time people are out of work because of these injuries. I think it is 7 days for musculoskeletal disorders as a whole, although it varies depending on which type of disorder you are talking about.

That was how OSHA calculated the number of days, and then they looked at the earnings in different industries and occupations and made an adjustment for the fact that some of this is currently being covered by Workers' Compensation. OSHA subtracted that amount from the cost, since that was already being borne, and from that they obtained an estimate of $600 or $700 million a year. I believe it was an estimated $630 million a year.

Then there was the control cost presented, what OSHA termed it, difficult issues related to costing. What OSHA did was convene a panel of practicing ergonomists and asked them to estimate what they thought, based on their experience, on average, it would cost to fix a hazardous job in a particular occupational grouping. Based on that, the experts then tried to estimate, how many people are in that occupational grouping in different industries and obtained an estimate.

Senator SPECTER. Was there a calculation as to benefit as a result of the regs to offset the cost?

Mr. WOODWARD. Yes.

Senator SPECTER. What was that figure?

Mr. WOODWARD. OSHA estimated 4.6 million disorders would be prevented over the first 10 years, and there was a partial monetary

value assigned to that. In other words, OSHA did not try to cost pain and suffering, but they did estimate that there was about $9.1 billion of other value from the rule.

Senator SPECTER. What is the total value, Mr. Woodward, calculated by OSHA?

Mr. WOODWARD. $9.1 billion, I believe.

Senator SPECTER. What do you think about those figures, Mr. Fellner?

Mr. FELLNER. Those figures make this the most expensive regulation in OSHA's history, and those figures are minuscule compared to what the real figures are. The litmus test for what this standard will cost American industry lies in the citations that OSHA has issued over the last 10 years on ergonomics. These are citations that will be issued by the same compliance officers using the same measures, the same tools, and the same requirements for fixes.

We have for a number of clients taken a look at the specific recommendations that OSHA has made to fix these risk factors that we have talked about earlier, and we put a price tag on them. That price tag is anywhere between $100 billion and $1 trillion, and lest that be viewed as an exaggeration, we must continue, we in industry, under this standard which is the subject of this hearing, we must continue to experiment and force technology until we are down to the screening tools, so that the action triggers are no longer activated, because we know we are going to get those MSD incidents. We know we are going to get complaints with regard to back pain.

So consequently the process by which—for example, there is a comment filed by Federal Express in the record which, simply put, states that next-day delivery will cease if the OSHA standard is promulgated. There is testimony in the record, as you can well imagine, from funeral directors indicating that burials will no longer take place if the precise kinds of requirements in this standard are, in fact, effectuated.

Senator SPECTER. When you say burials will not take place, do you mean they will be delayed?

Mr. FELLNER. No. I am suggesting to you, Senator Specter, you cannot lift a human body, unless it is wasted down to below 75 pounds, and that is what I am suggesting, and that is what the testimony in an uncontradicted fashion indicates in the record.

Senator SPECTER. What about that, Mr. Woodward?

Mr. WOODWARD. There is nothing in the rule that says you cannot lift a person who is more than 75 pounds. I do want to acknowledge that, as the Secretary has said, these are very complicated issues. Many issues have been raised about the way the current rule is structured, and we acknowledge that, and we are in litigation. No briefing schedule has been set, no oral argument set, but we acknowledge that a number of issues have been raised about it.

Senator SPECTER. Mr. Fellner, how do you get to your calculation of $100 billion to $1 trillion in cost?

Mr. FELLNER. If one were to take across the vast array of American industry the specific requirements, and we are not talking about the hours it would take to absorb. I am not sure whether Mr.

Woodward said it takes 1 hour or 2 to absorb this 608-page standard, together with its preamble.

We are not talking about the number of hours that it takes to study and understand an incomprehensible regulation. We are talking about the nuts and bolts, as I indicated to you earlier, that it would take to comply, after the job hazard analysis, with this regulation. This is not a matter of putting a phone book under a desk, which some of our union friends have indicated.

This is not simply a matter of simple, quick fixes. This is experimenting with pace, with employees, with automation, and the bottom line here, the great irony here is that our friends in the labor movement, who are very, very much behind this standard—and I acknowledge the good faith with which they approach the arguments favoring this standard, as I did 2 weeks ago when Lynn and I were on an ABA/OSHA subcommittee panel together discussing the very same issues.

The issue is not that good faith. The great irony is that this standard will push two things, one, jobs going abroad, and two, automating employees out of jobs, because robots do not complain about low back pain.

Senator SPECTER. Mr. Fellner, can you come to grips a little more directly with the way you come to the computation of cost of $100 billion to $1 trillion?

Mr. FELLNER. The Employment Policy Foundation has submitted a detailed document indicating that the range is $100 billion without relying on the specific numbers for implementing these 5(a)1, these general duty clause citations.

Senator SPECTER. What is the basis of that computation?

Mr. FELLNER. The basis of that computation is using a more realistic analysis of the hours, the time, and the implementation of job hazard controls.

Senator SPECTER. They say $100 billion?

Mr. FELLNER. They say in excess of $100 billion, and that is part of the record.

Senator SPECTER. Do they say as much as $1 trillion?

Mr. FELLNER. They do not say as much as a trillion. That reflects an extrapolation from specific 5(a)(1) citations, which I indicated earlier.

Senator SPECTER. Who made that extrapolation?

Mr. FELLNER. We did, in the context of our submissions to the OSHA record.

Senator SPECTER. Mr. Woodward, what do you think about that? Your $4.5 billion compared to their $100 billion?

Mr. WOODWARD. OSHA explained its reason in some detail, and OSHA concluded that most of these fixes were relatively inexpensive, more in the range of $800 to $1,000, to fix a hazardous job. That was based largely on testimony of what people currently do to abate a hazard. There is a huge range, so we are talking about an average. Some people disagreed with that.

One reason some of the other estimates are so high is because they interpreted the provisions of the standard differently than OSHA interpreted them. For example, one requirement is to provide your employees information about musculoskeletal disorders—what are they, what they should be aware of—so they can report.

One of the cost estimates was based on the idea that it would take 60 hours with each employee to convey that information, whereas OSHA's interpretation of the requirement, was that you could simply provide a written explanation to the employee of what to look for. So I think there are some differences in how the standard was interpreted. That is one of the factors.

Because we were in rulemaking, the estimates were directed toward the proposed rule, and there were some differences with the final rule. I think that also is a factor here.

Senator SPECTER. Mr. Fellner, did your computations take into account a benefit contrasted or similar to what Mr. Woodward has testified to? When he says there were $4.5 billion in cost, he says there were $9.1 billion in benefits. Did your analysis take into account the benefit factor?

Mr. FELLNER. In point of fact, our analysis indicates that the benefits are largely overdrawn. The BLS statistics upon which they are based are roundly criticized by the National Academy of Sciences, which is seeking properly a much more sophisticated analysis of the so-called MSD incidents. The BLS statistics are much too rough a tool.

Senator SPECTER. Is there no benefit?

Mr. FELLNER. As a matter of fact, the initial—as OSHA concedes, the initial stage of this ergonomics standard will be iatrogenic, and by that I mean it will increase the number of MSD incidents that are reported in the workplace, because to a certain extent we are teaching employees how to be sick, and in the context of heretofore having coped with musculoskeletal pain and discomfort, and overcome it, as all of us do, OSHA would turn the tables on that particular point, and so in many respects the benefits that OSHA has indicated are illusory, and if I may further add, Senator——

Senator SPECTER. Is that a no answer?

Mr. FELLNER. No, it is not a no answer. We do acknowledge that there may be some benefits, as there would in the so-called Hawthorne effect. Turning your attention to any problem will, from a variety of different perspectives, potentially ameliorate those problems, and that is a psychosocial aspect of that amelioration.

But let me, if I may——

Senator SPECTER. You may, but first tell me if you have a figure on benefits. You say that there may be benefits. Do you have a figure on benefits?

Mr. FELLNER. I do not.

Senator SPECTER. You were pretty fast on $100 billion to $1 trillion, but no figure on benefits?

Mr. FELLNER. If I were to accept, which I do not, the $9 billion number that OSHA has put forth in the context of the standard, it is swallowed up by the costs, so as we see them and as they are demonstrated clearly in the record, i.e., $9 billion in benefits, even assuming that were accurate, is more than swallowed up by their $100 billion to $1 trillion in costs.

So under the circumstances benefits is a negligible factor in this equation, particularly, if I may, if one looks at what Mr. Woodward has indicated is one of the methodologies of determining benefits, which is getting their selected ergonomists in a room with a huge range, insofar as the benefits and the costs that they determine of

this standard, a huge, inconsistent, subjective range, if their way of coming up with benefits of interventions is, as one of the case studies, quote-unquote, which they rely on, which is a Continental Air magazine——

Senator SPECTER. I think I have your point.

Mr. FELLNER [continuing]. Which was taken out of a seat. That is the way they determine benefits.

Senator SPECTER. With $4.5 billion in costs and $9.1 billion benefits estimated by OSHA, and your figures of $100 billion in costs ranging up to $1 trillion. I am trying to find some basis for rational congressional evaluation of what is going on here and it is a swirl. It is an absolute swirl.

I do not understand much of what Mr. Woodward says as to his $4.5 billion in costs, and I understand less from what you have said of the range of $100 billion to $1 trillion. That is a pretty big range, and if we go through the rulemaking process again, how is there going to be an evaluation?

One of the things I asked in a meeting that I held informally that you did not attend, Mr. Fellner, was the possibility of bringing the contestants together to see if something could be worked out, to see if there could be some agreement.

When the telecommunications bill was passed with all its complexities, the parties finally got together, and we do facilitate that from time to time. Is there any possibility of doing that, Mr. Fellner, so that experts can draw the lines of disagreement and compromise?

Mr. FELLNER. In the context of this regulation the answer is no.

Senator SPECTER. How about the next regulation, if there is one?

Mr. FELLNER. The answer is yes, obviously, if there is one.

Senator SPECTER. This massive regulation, which I have heard described as 300 pages, and then I have heard it further described, and correct me if I am wrong, Mr. Woodward, as nine pages of regulations, 16 pages of fact sheets in support, and the balance of public comments, is that accurate, Mr. Woodward?

Mr. WOODWARD. That is correct.

Senator SPECTER. Is that accurate, Mr. Fellner?

Mr. FELLNER. That is inaccurate.

Mr. WOODWARD. The rest of the package is what we call the preamble. It is an explanation of the rule, and it is a justification in terms of the evidence, the scientific evidence that was presented, and the economics.

Senator SPECTER. But you are saying there are only nine pages of regulation.

Mr. WOODWARD. The regulatory text, yes, that is correct.

Mr. FELLNER. Any employer, if I may interrupt, any employer who would attempt to take action based upon 9 pages of standard and 16 pages of fact sheets without knowing what is in the preamble, given my experience insofar as OSHA standards are concerned, with much shorter preambles than this, is engaged in a very risky business.

To understand the standard is to understand OSHA's interpretations in its preamble. Indeed, we will not know what OSHA means by this standard until it comes out with its enforcement directive,

which it has declined to do up until now, because there is extraordinary confusion as to what this standard means.

Senator SPECTER. How about that, Mr. Woodward? How about the enforcement directives?

Mr. WOODWARD. We normally do issue what we call a compliance directive. As I said, the Secretary has noted that these are complicated issues, and that the entire standard has been under review. We have not issued a compliance directive yet. The compliance directive does not change the meaning of the nine pages of text. It cannot do that. But any of these materials can interpret the rule and, to that extent, provide guidance.

Senator SPECTER. The issue has been raised as to whether any new regulation, if this one falls under the Congressional Review Act, will be fatally inhibited by the provision in the statute which precludes a new rule, if it is reissued in substantially the same form. Is there any problem at all, as you see it, Mr. Fellner, in having a new regulation which will be permitted under the Congressional Review Act, and not prohibited by being substantially in the same form by the rule prohibiting a regulation: "reissued in substantially the same form"?

Mr. FELLNER. This being the first time that the CRA will be tested, we are clearly in uncharted waters as to what substantially the same form means, so let me very carefully and very gingerly respond to your question, Senator Specter, and suggest that a standard that contains the kind of very specifically mandated formulae and definitions that this standard contains, and would hold employers to those definitions and to those requirements, and I am specifically talking about W–1, which we talked about earlier, as well as appendix D–1, that that kind of standard may very well fall in the substantially similar rubric, as outlined by the CRA, but we do not know that, and we will not until good lawyers like Lynn and hopefully myself test it in the courts.

Senator SPECTER. So there is some possibility that there might be some litigation?

Mr. FELLNER. After the next standard comes out, that is correct, there may very well be.

Senator SPECTER. Do you think there is any conceivable possibility there would not be enormous litigation?

Ms. RHINEHART. Two years ago at an ABA meeting I promised——

Senator SPECTER. Wait a minute. I want to hear his answer.

Mr. FELLNER. Do I think it is——

Senator SPECTER. Do you think there is any possibility at all, any remote, contingent possibility that there would not be litigation that a new regulation is barred by the substantiality requirement I just read?

Mr. FELLNER. The answer is, if we all do our jobs, and we come up with a consensus, there is a good chance that litigation could be avoided.

Senator SPECTER. Ms. Rhinehart, you wanted to say something.

Ms. RHINEHART. I did. I just wanted to——

Senator SPECTER. I did not want to let you come in before Mr. Fellner had a chance to answer.

Ms. RHINEHART. And the fact that they may not sue OSHA over a subsequent standard is welcome news indeed. I just wanted to say that the AFL–CIO is very concerned about the impact of passage of a resolution of disapproval under the Congressional Review Act on the agency's ability to issue a standard in this area in the future, and I think what we have just heard from Mr. Fellner is evidence as to why we are right to be concerned.

OSHA made some modifications in this final rule to be a little more specific, and to give employers some more guidance because the employers asked for it. Now we are hearing from Mr. Fellner that they do not like that specificity, and they want to go back to a broad, more general standard. Well, that is what they had, and they did not like that, either.

The fact of the matter is that many trade associations and a large part of the employer community has vociferously opposed any ergonomics regulation, so the notion that if Congress were to pass this resolution of disapproval and send OSHA back to the drawing board, that there would be a change of heart and all of a sudden we would all be collaborating and embracing a new rule in the future seems a bit far-fetched, in our view, and so we are very concerned about the effect of passage of a resolution on OSHA's future ability to act.

We would like to believe they could act. We obviously are very interested in there being a good, strong ergonomics standard to protect workers, and we will do everything we can toward that end, but we are very concerned.

Thank you.

Senator SPECTER. Does anybody care to comment any further? Additional statements for the record will be included at this point, including a letter from Secretary Chao.

[The statements follow:]

PREPARED STATEMENT OF LPA, INC.

Mr. Chairman and Members of the Subcommittee: LPA is pleased to submit testimony opposing the Occupational Safety and Health Administration's (OSHA's) final ergonomics standard, which has been estimated by the Employment Policy Foundation to impose annual costs on employers of as high as $126 billion, probably making it the most expensive workplace regulation in history. The final standard, which OSHA completed in less than 11 months, was less an attempt to promulgate a sound workplace regulation than the fulfillment of a political promise by President Clinton to organized labor. Politics should give way to reasonable regulation, and thus Congress should invalidate the standard using the Congressional Review Act, allowing OSHA to try again.

LPA, Inc., is an association of the senior human resource executives of more than 200 leading corporations in the United States. LPA's purpose is to ensure that U.S. employment policy supports the competitive goals of its member companies and their employees. LPA member companies employ more than 12 million employees, or 12 percent of the private sector workforce. If the final ergonomics standard remains in effect, it will cover nearly all of our member companies and virtually all of their employees.

In short, LPA supports the application of ergonomic principles to the workplace. However, it opposes the final ergonomics standard because it covers ergonomics disorders caused by non-work activities, is not based on sound science, ensures that most employers will be required to set up ergonomics programs, and creates unacceptable conflicts with state workers' compensation laws. Instead, LPA supports the Senate joint resolution of disapproval sponsored by Sen. Don Nickles (R-OK), S.J. Res. 6, which would invalidate the final standard and allow OSHA to regulate workplace ergonomics in a more reasonable manner.

Final standard covers non-work-related disorders

OSHA's final ergonomics standard fails to substantially narrow the definition of work-related musculoskeletal disorder (MSD). The final standard purports to cover workrelated MSDs, but broadly defines that term as those that work caused, contributed to, or for pre-existing MSDs, significantly aggravated. The Preamble defines "significantly aggravated" as having an injury already "but because of the employee's exposure to identified risk factors in the workplace, the MSD has progressed to the extent that medical treatment is now necessary." Reading between the lines, this means that if work exposure played any role in an employee-reported MSD, then the MSD is work-related.

NAS study shows that final standard not based on sound science

One of the key arguments in opposition to the final ergonomics standard is that OSHA has failed to conclusively prove that work factors cause MSDs. The National Academy of Sciences (NAS) study completed in January 2001 was intended to solve this debate. The study reviewed existing scientific literature in order to determine whether science has affirmatively linked injuries to workplace exposures. However, it only demonstrated that more research was required in this complex area.

The NAS panel concluded that "[n]one of the common musculoskeletal disorders is uniquely caused by work exposures," that there are no comprehensive national data on medically defined MSDs, and that the available data is mostly based on employee reporting, not a diagnosis from a health care provider. It cautioned that often it is difficult to scientifically distinguish work exposures that may cause MSDs from other life exposures that cause them because 80 percent of the population works, further complicating research on the issue. The panel concluded that significant additional research is needed in this area.

The NAS panel also noted that MSDs are affected by many non-work factors, such as age, gender, healthy lifestyles, and the effect of other diseases such as diabetes. The panel spent a considerable amount of time discussing how psychosocial factors, such as high perceived stress, low job satisfaction, monotony, and low social support increase the chances of developing an MSD in the lower back.

Despite the unspoken preference for unanimity in such reports, the NAS panel drew a rare dissent from panel member Dr. Robert Szabo. Dr. Szabo criticized the panel for using inaccurate scientific literature, particularly regarding carpal tunnel syndrome. He highlighted the studies that indicated that personal factors, age, lifestyle and sex as more predictive of carpal tunnel syndrome than job exposure. He also noted that the cited studies only demonstrate that job controls reduce the symptoms of disease but do not address whether they reduce the underlying soft tissue disease. Taken as a whole, the evidence cited by Dr. Szabo with respect to carpal tunnel syndrome casts doubt on the remainder of the NAS conclusions.

Triggers easily met

Once an employee has reported a work-related MSD, an employer must set up a full ergonomics program if the reported MSD meets two "triggers" or tests set under the standard. The first stage of the trigger is met if the MSD involves days away from work, work restrictions (such as the inability to work scheduled or mandatory overtime) or medical treatment beyond first aid. It is also met if an employee feels tingling or other MSD symptoms in his or her arm for seven consecutive calendar days. Given that it in not unusual for employees to experience symptoms or to request work restrictions occasionally, the first trigger is often met.

Once the first stage of the trigger is met, the employer must determine whether the employee's job exceeds certain action thresholds. In many cases these thresholds are also easy to meet. For example, an administrative employee who regularly works steadily at his or her keyboard for four hours or more per day would trigger a full ergonomics program for all people performing similar jobs, if he or she reported a work-related MSD and was unable to work overtime for one day.

Taken together, the overbroad definition of work-related and the low job task thresholds mean that the standard will cause most jobs to be covered by the ergonomics standard.

Standard interferes with State workers' compensation laws

The final ergonomics standard would require employers to provide 90 days paid leave at 90 percent of an employee's gross earnings to any employee who has been determined unable to work by a health care professional. This requirement, called "work restriction protection," is a blatant violation of section 4(b)(4) of the Occupational Safety and Health

Act (OSH Act), which states that an OSHA standard may not "supercede or in any manner affect" any state workers' compensation law.

The ergonomics standard will interfere substantially with state workers' compensation laws in several ways, including:

—preempting the exclusive remedy provisions;

—invalidating state standards on injury and causation;

—undermining the return-to-work incentive; and

—increasing state costs because of increased claims and benefit duration.

Although OSHA has proposed and enforced work restriction protection provisions in other, narrower standards, it has never attempted to apply it in a wide-ranging standard that applied to virtually all general industry employees. Because the ergonomics standard would apply to most employees of most employers, significant conflict between the work restriction protection requirement in the OSHA standard and state workers' compensation laws is a virtually certain, and thus, illegal.

LPA urges support for congressional resolution of disapproval

Mr. Chairman, because OSHA's final ergonomics standard is fundamentally flawed, LPA recommends that Congress invalidate the current standard by passing S.J. Res. 6, the joint resolution of disapproval introduced by Sen. Nickles. If the Senate and the House of Representatives both approve the resolution by a simple majority vote, and it becomes law, the ergonomics standard is invalidated.

Contrary to the assertions of organized labor and other opponents of the resolution, a successful resolution would not prevent OSHA from issuing an ergonomics standard. Rather it would preclude OSHA from re-issuing the current standard or one that is substantially similar. LPA believes this is a reasonable and measured step to take given the great costs to the economy, employers, employees and states imposed by the existing standard.

CONCLUSION

OSHA's final ergonomics standard is unworkable because it applies to disorders that are not related to work, is based on inadequate science and would cause a substantial conflict with state workers' compensation laws. LPA endorses the attempt to pass a congressional resolution of disapproval to rid the country of this flawed standard and to allow OSHA to pursue a more reasonable approach.

Thank you for the opportunity to present our views.

PREPARED STATEMENT OF THE AFL–CIO

NATIONAL ACADEMY OF SCIENCES/INSTITUTE OF MEDICINE REPORT SUPPORTS THE OSHA ERGONOMICS STANDARD

The National Academy of Sciences and the Institute of Medicine recently released their long awaited report on Musculoskeletal Disorders and the Workplace. The report, requested by industry groups and conservative Republicans who opposed an OSHA ergonomics standard, finds that there is strong scientific evidence showing that exposure to ergonomic hazards in the workplace causes musculoskeletal disorders and that these injuries can be prevented. Prepared by some of the world's top scientific and medical experts in ergonomics, the report calls MSDs an important national problem and strongly supports the approach that OSHA took in its final Ergonomics Program Standard, released November 14, 2000.

This is the third comprehensive review of the scientific literature over the past four years that has come to the same conclusions. The National Institute for Occupational Safety and Health (NIOSH) published a comprehensive review of the data on the relationship between MSDs and the workplace in 1997. The NAS also came to similar conclusion in an earlier report published in 1998.

The NAS report puts to rest, once and for all, the claims by some industry groups and conservative Republicans that there is no scientific evidence that workplace exposures cause musculoskeletal disorders. It shows without question that OSHA's new ergonomics standard is needed and justified.

Musculoskeletal disorders are an important national health problem

The NAS report confirms OSHA's estimates of the scope of the problem, citing an even larger number of workers losing time from work than OSHA. The NAS estimates that one million people lose time from work each year due to these disabling injuries, compared with OSHA's more conservative estimate of 600,000. The NAS also confirms OSHA's estimate that ergonomic problems cost the economy around $50 billion each year. The report warns that MSD-related problems are expected to increase in the future due to the changing nature of work, the aging of the workforce and rising numbers of women entering material handling and computer jobs.

The report also finds that existing national data sources conclude that construction and agricultural workers, who were not covered in the OSHA standard, also suffer higher rates of work-related MSDs than overall industry.

"There is no doubt that musculoskeletal disorders of the low back and upper extremities are an important and costly national health problem . . . In 1999, nearly 1 million people took time away from work to treat and recover from work-related musculoskeletal pain or impairment of function in the low back or upper extremities. Conservative estimates of the economic burden imposed, as measured by compensation costs, lost wages, and lost productivity, are between $45 and $54 billion annually." (Page ES–1)

"The consequences of musculoskeletal disorders to individuals and society and the evidence that these disorders are to some degree preventable justify a broad, coherent effort to encourage the institution or extension of ergonomic and other preventive strategies." (Page ES–6)

"As the workforce ages and as more women enter the workforce, particularly in material handling and computer jobs, evaluation of work tasks, especially lifting, lowering, carrying, prolonged static posture, and repetitive motion, will be required to guide the further design of appropriate interventions." (Page 11–2)

Science strongly supports the fact that there is a strong relationship between workplace physical tasks and the risk of MSDs

The NAS found a strong and consistent pattern of evidence from both epidemiologic studies (studies of groups of people experiencing similar exposures), as well as "biomechanical" evidence (the actual damage that ergonomic stress does to muscles, tendons and nerves.) The report cites the same workplace risk factors that OSHA cites in its standard—heavy lifting, repetition, force, frequent bending and twisting (awkward postures) and vibration. The report actually goes beyond the OSHA standard, including whole body vibration as a risk factor for back injuries, where OSHA only regulates hand-arm vibration.

While more research and better quality studies are clearly desirable, the NAS report finds that the consistent overall pattern of evidence from existing studies clearly confirms the relationship between workplace physical exposures and MSDs.

"The basic biology and biomechanics literatures provide evidence of plausible mechanisms for the association between musculoskeletal disorders and workplace physical exposures." (Page ES–6)

"The panel's review of the research literature in epidemiology, biomechanics, tissue mechanobiology, and workplace intervention strategies has identified a rich and consistent pattern of evidence that supports a relationship between the workplace and the occurrence of MSDs of the low back and upper extremities." (Page ES–3)

"The panel concludes that there is a clear relationship between back disorders and physical load; that is, manual material handling, load movement, frequent bending and twisting, heavy physical work, and whole-body vibration. For disorders of the upper extremities, repetition, force and vibration are particularly important work-related factors." (Page 11–10)

"Occupations that involve repetitive lifting, e.g. warehouse work, construction and pipe fitting, particularly when that activity involves twisting postures, are associated with an increased risk for the complaint of low back pain and, in a few studies, an increased risk for lumbar disc hemiation." (App. A–6)

"Low back disorder risk has been established through epidemiologic studies of work that involves heavy lifting, frequent bending and twisting and whole body vibration, as well as other risk factors . . . . Biomechanical studies reinforce the epidemiologic findings." (Page ES–3)

"The pattern of evidence for upper extremity disorders, as for the low back, also supports an important role for physical factors, particularly repetition, force and vibration. The most dramatic physical exposures occur in manufacturing, food processing, lumber, transportation and other heavy industries, and these industries have the highest rates of upper extremity disorder reported as work related." (Page ES–4.)

"There is strong support across these bodies of work that high force and repetition are associated with musculoskeletal disorder of the upper extremities; basic biology data provide evidence of alteration in tissue structure." (Page ES–4)

"These exposure-response associations persist when adjusted for individual factors that may increase vulnerability, such as age, gender and body mass index." (Page ES–4)

"The BLS and workers' compensation data are sufficient to (1) confirm that the magnitude of the work-related musculoskeletal disorder problem is very large; (2) demonstrate that rates differ substantially between industries and occupations con-

sistent with the assumption that work related risks are important predictors of musculoskeletal disorders." (Page 2–17)

Science strongly supports the fact that workplace interventions based on ergonomic principles can reduce the risk of MSDs

The report also confirms the fact that using ergonomic principles to reduce exposure to risk factors reduces the risk of MSDs. Changing the design of tools and workstations, rotating jobs and other ergonomics interventions such as lift tables and vibration dampening seating devices that reduce ergonomic risk factors have been shown to reduce the risk of MSDs of the low back and upper extremities.

"The weight of the evidence justifies the introduction of appropriate and selected interventions to reduce the risk of musculoskeletal disorders of the low back and upper extremities." (Page 11–2)

"The intervention literature supports the efficacy of tool and workstation design changes, job rotation, and other interventions that directly address these risk factors with regard to upper extremity symptomology." (Page ES–4)

"Intervention studies have shown how lift tables and lifting hoists are effective in mediating the risk of low back pain in industrial settings. Since risk is lowered when the load is changed from a heavy lift to a light lift, this finding is also consistent with the rigorous epidemiologic finding." (Page ES–3)

"Based on the current evidence, modification of the lifting can reduce symptoms and complaints. Specific successful strategies, which include ergonomic interventions (such as the use of lift tables and other devices and matching the worker's capacity to the lifting tasks), administrative controls (such as job rotation), and team lifting, appear successful. Despite enthusiasm for their use, there is marginal or conflict evidence about lifting belts and education programs in reducing low back pain in the population with heavy lifting requirements." (Page App. A)

The NAS report supports the main elements included in the OSHA standard

The NAS Report found that employers with effective-ergonomics programs use a programmatic approach that OSHA adopted in its standard. The OSHA standard requires employers to include several basic program elements in approaching ergonomic problems: Management Leadership and Employee Participation, Job Hazard Analysis and Control, Training, Medical Management and Program Evaluation. These are the same common elements that the NAS report found in successful ergonomics programs. This programmatic approach provides a framework for employers; it does not dictate how employers are to address the problems. The standard fully allows and anticipates that employers will tailor their programs to meet the own specific needs of their workplace and work organization. The NAS report found this approach to be effective in small and large companies from a variety of industries.

"To be effective, intervention programs should include employee involvement, employer commitment and the development of integrated programs that address equipment design work procedures and organizational characteristics." (Page ES–6 and 11–2)

"The complexity of musculoskeletal disorders in the workplace requires a variety of strategies that may involve the worker, the workforce, and management. These strategies fall within the categories of engineering controls, administrative controls, and worker-focused modifiers. The literature shows that no single strategy is or will be effective for all types of industry; interventions are best tailored to the individual situation. However, there are some program elements that consistent recur in successful programs:

"1. Interventions must mediate physical stressors, largely through the application of ergonomic principles.

"2. Employee involvement is essential to successful implementation.

"3. Employer commitment, demonstrated by an integrated program and supported by best practices review, is important for success." (Page App. A–6)

"These findings are based on a research and development process that tailors interventions to specific work and workers conditions and evaluates, on a continuing basis, the effectiveness of these interventions in the face of changing workplace and worker factors. It is therefore neither feasible nor desirable to propose a generic solution." (Page ES–5)

PREPARED STATEMENT OF THE AMERICAN HEALTH CARE ASSOCIATION

AHCA PRAISES USE OF CONGRESSIONAL REVIEW ACT TO RESCIND ERGONOMICS REGULATION

WASHINGTON, DC.—The American Health Care Association (AHCA) today praised Senator Don Nickles (R-OK) and Senator Mike Enzi (R-WY) for invoking the Congressional Review Act in their effort to rescind a 600-page ergonomics regulation due to become law unless quick action is taken by Congress.

"Our membership is actively working to help ensure this excessively burdensome regulation does not become law, and we're pleased to work with Senators Nickles and Enzi on this critical issue," stated Charles H. Roadman II, M.D., President and CEO of AHCA. "This ergonomics rule would impose yet another crushing financial burden costing long term care providers $1.2 billion at a time when we are being squeezed on many different fronts. We have to be strong advocates for our patients by being zealous guardians of the scarce resources allocated by the government for long term care."

Late last week, Nickles, Enzi and several other Senators introduced a "resolution of disapproval" under the Congressional Review Act. If the resolution is approved by a simple majority in the Senate and House, and is signed by the President, the ergonomics rule will not become law.

Dr. Roadman reiterated AHCA's position that reducing work-related injuries and protecting employees is best accomplished not through costly new federal regulations, but through ongoing voluntary efforts that are already working. AHCA has supported, created and promoted ergonomic programs to improve workplace safety for the caregivers in long term care for nearly a decade.

"We believe the proposed rule will actually reverse the positive trend toward lower rates of workrelated injuries because it will divert limited resources away from further improvements," said Dr. Roadman. "Just as the federal government has started to correct the errors made in the implementation of federal Medicare cuts, the last thing providers need is a new federal regulation that will drain $1.2 billion of scarce resources out of facilities to implement on a nationwide basis."

COPY OF THE LETTER SENT TO ALL U.S. SENATORS AND HOUSE MEMBERS

March 1, 2001.

[Each Letter was Personally Addressed and Signed to Individual Members of Congress]

On behalf of the American Health Care Association (AHCA), a federation representing over 12,000 non-profit and for profit nursing home, assisted living, subacute and ICFMR providers of long term care nationwide, I am writing to urge your strong support of the Congressional Review Act and your vote for the resolution of disapproval of the OSHA Ergonomic regulation.

Let me state up front that AHCA has supported, created and promoted ergonomic programs to improve workplace safety for the caregivers in long term care for a decade. As caregivers our primary mission is to treat our patients and provide them with a high quality of life. This can only be successfully accomplished if our employees work in a safe, secure, and healthy environment.

The fact of the matter is that the incidences of musculoskeletal disorder (MSD) injuries in long term care have been in decline, and continue to decline. Bureau of Labor Statistics (BLS) data show that from 1993 to 1997 sprains and strains numbers (the number one problem for health care employees) declined by 16.7 percent. BLS data released in December 1999 shows the decline to be continuing. Clearly, current programs and voluntary efforts to reduce MSDs are working. Indeed, AHCA believes that the ergonomics final rule will actually retard and even reverse this positive trend toward lower rates of work-related injuries.

Long term care employers are in a box with no way out with respect to the resources available to them to help pay for this new standard. Medicaid or Medicare pays for the medical care for nearly 80 percent of residents in nursing facilities today. AHCA has estimated that the first year's cost for long term care facilities is almost $1.2 billion. The reality is that there is no way to increase prices to pay for the costs of this standard. The $1.2 billion will have to come from existing patient care resources, with questionable employee safety benefit from the rule's implementation.

We strongly urge you to prevent this regulatory attack on caregiver resources, and allow a more reasoned approach to intelligent safety programs. Thank you for your attention to this critical vote.

Sincerely yours,

CHARLES H. ROADMAN II, MD,
President and CEO.

LETTER FROM SECRETARY ELAINE L. CHAO

SECRETARY OF LABOR,
Washington, March 6, 2001.

Hon. ARLEN SPECTER,
Chairman, Subcommittee on Labor, Health and Human Services, Education, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR CHAIRMAN SPECTER: It is my understanding that the Senate will soon consider a Joint Resolution of Disapproval pertaining to the Occupational Safety and Health Administration's (OSHA) ergonomics standard. As you are aware, the Congressional Review Act of 1996 gives Congress the authority to vitiate this standard and permanently prevent OSHA from promulgating a rule in substantially the same form.

Let me assure you that, in the event a Joint Resolution of Disapproval becomes law, I intend to pursue a comprehensive approach to ergonomics, which may include new rulemaking, that addresses the concerns levied against the current standard. This approach will provide employers with achievable measures that protect their employees before injuries occur. Repetitive stress injuries in the workplace are an important problem. I recognize this critical challenge and want you to understand that the safety and health of our nation's workforce will always be a priority during my tenure as Secretary.

I look forward to working with you throughout the entire 107th Congress.

Sincerely,

ELAINE L. CHAO,
Secretary of Labor.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you very much, Mr. Woodward. Thank you, Mr. Fellner. Thank you, Ms. Rhinehart.

Thank you very much, that concludes the hearing. The subcommittee will stand in recess until 9 a.m., Wednesday, April 25, when we will meet in room SD–192 to hear from HHS Secretary Thompson.

[Whereupon, at 12:15 p.m., Thursday, March 6, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, April 25.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

WEDNESDAY, APRIL 25, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Stevens, Specter, Harkin, Kohl, Murray, and Landrieu.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. This meeting of the Subcommittee for Labor, Health, Human Services and Education will now convene.

We are pleased to have the distinguished Secretary of the Department of Health and Human Services, former Governor of Wisconsin, the Honorable Tommy Thompson. This is your first appearance before our subcommittee on a formal basis, but both Senator Harkin, the distinguished ranking member, and I have had opportunities to meet with you and talk about priorities, your plans, and our inputs into the very very important Department which you are heading.

The Department has discretionary funding under the administration's budget this year for $51.5 billion, which is approximately $2.5 billion above the fiscal year discretionary allowance for the year we are in now. There are a great many very, very, important programs which your Department is administering. You have come up with increases in some very important areas, and there have been some decreases in some important areas which we will want to discuss with you.

In the interest of time, I am going to ask that my full statement be included in the record. As I told the Governor yesterday and again this morning, these days are all busy, and we appreciate you coming over early for a 9 a.m. session. The judiciary committee has a session at 10 a.m., which I expect to Chair shortly after it is con-

vened for Senator Hatch, and I know Senator Harkin has commitments, so we will move right along. I am now delighted to yield to my partner, Senator Tom Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman, and again, it is always a pleasure to work with you in your capacity as chairman of this very important subcommittee. It is my pleasure also to welcome Secretary Thompson today to testify about the 2002 budget.

First of all, Mr. Secretary, I am pleased to see that both NIH and community health centers have received significant increases in the budget. Kudos to you and to the President for that.

I am also glad that you have continued funding for the construction of new laboratories at the Center for Disease Control and Prevention, Atlanta. I understand you visited there yourself and saw how important this work is and how those old buildings need to be upgraded——

Secretary THOMPSON. Thank you very much, Senator.

Senator HARKIN. So I am really happy that you did that.

I am also encouraged that the administration has shown strong support for the real choice system change grants by including them in the President's new freedom initiative for people with disabilities. The chairman and I worked hard to include funds for these grants in last year's bill, and we look forward to working with you on this and other Medicaid reforms that will allow people with disabilities and the elderly to live at home in the community.

I might just paraphrase as an aside here, Mr. Secretary, when the President came and met with the Democratic caucus, we had a Democratic group meeting here a month or two ago or something, and he came and visited us. He said that money ought to follow an individual, not a program. You ought to focus on the individual, and the President is right on that.

When it comes to people with disabilities, that the money——

Secretary THOMPSON. That's true.

Senator HARKIN [continuing]. Ought to follow the person with the disability rather than a program, and if the person wants to live in the community, they ought to be able to do that. And so I said, we need some changes in Medicaid. He took notes on that, so I know that it registered with him. I am glad to see that you are continuing this program and hopefully we will be able to help get the funds for it.

On a little other down note, though, I am disappointed that there are some other public health programs and a number of programs for children that did not fare as well, Mr. Secretary. A few weeks ago on the budget debate, Senator Specter and I worked on an amendment that was passed, that shifted money from the tax cut, mostly to education, but there was also money in there to make sure that kids could get ready to learn.

In 1989, President Bush, then Governor Bush and the Nation's Governors met in Charlottesville, West Virginia.

Secretary THOMPSON. That is correct.

Senator HARKIN. And they came up with some national goals for schools, education. The first goal was that every child should be

ready and able to learn by the year 2000. Last year has come and gone and we have not gotten there. Well, I do not think that we ought to give up on it, we ought to just recommit ourselves to it. So I guess what I'm talking about is Head Start, an early learning fund, and quality child care, programs that come under your purview at your department. There were monies in the amendment to fully fund the Head Start program, and to fund the early learning fund at the authorized level.

Now I have got to tell you that I am disappointed that the budget eliminates the early learning fund, and I hope we can work to get that back in, Mr. Secretary.

The budget also cuts child care funding for infants and toddlers, and there is no expansion for Head Start. Now I am not going to say that this is absolutely certain, but from our initial read of the Head Start funding for next year, it looks as though about 2,500 kids are going to be cut out of Head Start under the budget. Now, if I am wrong, I would like to be proven wrong on that, but from the initial run that we have seen on that, with all of the quality programs and stuff built in there, the discretionary money that is left over will actually serve 2,500 kids less next year.

Take a look at that please. I am not certain that is true, but that is the first kind of run we took. If that is the direction we are going, we have to do more under your purview on that.

So these are priorities that I hope to work with you and other members of the subcommittee on, to do.

Now, one last note, Mr. Secretary.

Secretary THOMPSON. Yes.

Senator HARKIN. In Iowa and in Wisconsin and in a lot of other States, our people are paying as much in for Medicare as any other State in the Nation, but what we get back, our reimbursement rate in Iowa is $2,900, and in Louisiana it is $7,000. I do not know where Alaska falls, but I bet it is down there somewhere.

And so, what I am saying, there is such a huge disparity in our reimbursement rates, I think Wisconsin is probably right down there with us someplace too, I think, so it is unfair to seniors in Iowa and those who live in rural States. If we just looked at the average for the United States and take where Iowa is in that average, we are losing a billion dollars a year that we have by rights coming in to take care of our elderly.

Secretary THOMPSON. Senator, when I was Governor of Wisconsin, I would have changed our reimbursement rate for Iowa. We got treated even worse.

Senator HARKIN. You were worse than Iowa? Well, we are next to last, and I know you are not the last now, so you must be up above us somewhere right now, but you know what I am talking about.

Secretary THOMPSON. I know.

Senator HARKIN. And we are going to introduce legislation to address this and try to get a better national average, and I hope to work with you on this issue. Thank you, Mr. Secretary.

Secretary THOMPSON. Thank you, Senator.

Senator SPECTER. Thank you very much, Senator Harkin. We are joined today by our distinguished chairman of the full committee, Senator Stevens.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Thank you very much, Mr. Chairman. Mr. Secretary, we are delighted you are taking on this task and with your background we are even more delighted, because we know what you have done in your own State. I am really pleased that you have stopped by to visit me, and I am sure you are visiting everyone else to talk over the future of your area.

I want you to know that I am concerned about the progress of keeping our commitment to double NIH funding. I really commend Senator Specter and Senator Harkin for their initiative in carrying this forward. Baby boomers are coming at us fast and if we do not get this science completed in order to deal with their problems in a different way than we have dealt with our generation, I think it is going to be extremely costly for the United States. The investment that we are going to make in health care research I think will pay off great dividends.

I do support your efforts and the administration's efforts—I think Senator Bond has been the leader up here on this concept—to double funding for community health centers. However, I have to tell you that until this year, my state received only $7 million out of the total of $1.1 billion for community health centers. I found that the authorizing legislation and the regulations in your department hinder smaller rural isolated communities like those we have in our state from participating in that program. I hope that the community health center legislation that we develop to reauthorize this program will eliminate those barriers to the participation of frontier communities in America in the community health center program.

Your budget eliminates the funding for what we call our Denali Commission, to build clinics in remote Bush communities in Alaska. There are 271 of those, Mr. Secretary. I hope to get you up to see our state soon, not just to the capital and our major city, but out to the Hooper Bays and the Scammon Bays, and the various areas that have tremendous problems.

Forty percent of the 271 native villages do not have water and sewer systems. And these are communities that have no tax base, they are completely surrounded by federal property. They have unemployment rates in excess of 80 percent on a structural basis. There is no way that they can develop their own funds for health services.

We developed the Denali commission so it could handle funds from several different agencies, merge them together, and do a comprehensive development in each village, instead of going into one village with water and sewer one year, and into another one the next year, and having different concepts coming in from HUD or from EPA. We have tried to put them all together so that when they go to the village, they do a comprehensive job that is less expensive and more productive in terms of producing good benefits.

It is one of the things I hope you really look at, because we put an overhead ceiling of 5 percent on the Denali commission. The overhead at your department is 30-plus percent on monies that go to rural areas. There is just no reason to handle money that way,

particularly when several departments are needed to deal with the problems of one single small rural village.

I think if you take the time to come up, we can show you how you can be of great help and save money in the long run.

The one really sad thing I want to discuss with you, and Senator Harkin has already mentioned that, and that's the initiative I developed which was called the Early Learning initiative. Your budget eliminates $20 million for that. It is not a lot of money, and I do support the first lady's reading program. There is no reason not to have them both.

But the early learning initiative is a comprehensive approach to preparing children for school and I think it is absolutely essential in these times. We listened to the Secretary of Education yesterday concerning the problems of reading throughout the country, and it seems that no matter how much money we put into the Department of Education, the reading levels are not going up. This is one small amount that will, we believe, bring those reading skills up more rapidly than much of the billions of dollars that have been spent in the past, so I urge you to take a look at that.

But again, I welcome you and look forward to working with you, and I am sure that it is going to be an interesting time for you. I appreciate your service. Thank you very much.

Secretary THOMPSON. Thank you very much, Senator Stevens.

Senator SPECTER. Thank you very much, Senator Stevens.

Our practice, Mr. Secretary, is to put your full statement in the record and ask you to hit the highlights and summarize it as you see fit, so the floor is yours.

Secretary THOMPSON. Senator Stevens, before you leave, I would just like to say thank you, and I will be looking forward to traveling to Alaska this summer and discussing it with you, and I hope to be working with you on the Denali Commission.

Senator STEVENS. Let me see if I can develop some of your other skills.

SUMMARY STATEMENT OF HON. TOMMY G. THOMPSON

Secretary THOMPSON. I am not very good at it but I will certainly try, and if the chairman asks me to do it, I will do it.

Good morning, Chairman Specter, and thank you for your kind introduction and your friendship for many years and I appreciate that. And Senator Harkin, thank you for doing the wonderful job you do in the neighboring State of my home State. I have watched you with a great deal of interest and support for many years, and I apologize to you for not being able to get to see you personally, but I will be making every attempt to do so very quickly. I want to meet all the Senators in their office, and I look forward to that.

I am honored, Senators, to appear before you today to discuss the President's fiscal year 2002 budget for the Department of Health and Human Services. I will make this very short, because I know both of you have to leave and I know you want to ask questions and I want to answer them.

But several weeks ago I appeared before the colleagues of the Senate Budget Committee to discuss the President's fiscal year 2002 budget framework. Since that time, much has been written and said about selected portions of our budget. Some unfair and

some inaccurate charges have been leveled against it. That is why I am so very pleased today to have this opportunity to appear before you to discuss our detailed budget proposal. I am confident that a review of the full details of our budget will demonstrate that we are proposing a balanced responsible approach to building a strong and healthy America.

The budget before you today keeps the promises the President has made. It proposes new and innovative solutions for meeting the challenges that face the nation. Our proposal increases support for America's children and families, enhances the ground breaking research being sponsored by the National Institutes of Health, and I want to thank both senators for being so supportive of the NIH.

Again, the modernization of Medicare expands access to health care and reforms the way the department operations are managed. Mr. Chairman, the total HHS request for fiscal year 2002 is $468 billion. The discretionary component totals $55.5 billion, and the amount before this committee totals $300 billion in budget authority, of which $52 billion is discretionary.

I know, Mr. Chairman, you have been very interested in NIH, as I have. I want to tell you that there is just some wonderful things going on up at NIH. And as you know, and you have been up there several times, and we are so close in so many areas, it is truly an exciting time to be Secretary of this Department and be involved.

Senator Harkin, I appreciate your support of CDC. I have been down there. I do not know if you know this, but we are currently renting 22 buildings all over the city of Atlanta. I went down there and looked at it, and it is a crazy way to run it. We have land there, we have got an opportunity to build something that everybody in America can be proud of. And I pushed very hard to get the money of $150 million for new laboratories there. I would like to consolidate the 22 areas into one beautiful college campus that is going to do the things necessary for CDC, and I appreciate your support.

Senator HARKIN. I will back you any way I can.

Secretary THOMPSON. I know that, and I appreciate that.

In regards to women's health, we have put in a great deal of additional money for women's health because it is so important. We also have put a lot of money into children.

PREPARED STATEMENT

I could go on, but I think I would much rather stop at this time, Senators, and Senator Murray, it is a pleasure to be in front of you as well. I know you have lots of questions, and I would just as soon answer your questions, and I will leave the rest of my written remarks for you to put in the record if that would be okay.

Senator SPECTER. That is fine, Mr. Secretary. We appreciate that.

[The statement follows:]

PREPARED STATEMENT OF HON. TOMMY G. THOMPSON

Good Morning, Chairman Specter, Senator Harkin, and members of the Subcommittee. I am honored to appear before you today to discuss the President's fiscal year 2002 budget for the Department of Health and Human Services.

Several weeks ago, I appeared before your colleagues on the Senate Budget Committee to discuss the President's fiscal year 2002 budget framework. Since that

time, much has been written and said about selected portions of our budget, and some unfair and inaccurate charges have been leveled against it. This is why I am so pleased to have the opportunity to appear here today to discuss our detailed budget proposal. I am confident that a review of the full details of our budget—not selected pieces of it—will demonstrate to one and all that we are proposing a balanced, responsible approach to building a strong and healthy America.

Part of this approach involves taking another look at the way we do things on the national level. We must no longer be content to do things a certain way because "that's how we've always done it"; but must instead be willing to reform our business practices and seek innovative ways to manage our programs. And while we know that the Federal Government has an important role to play, we must also recognize that we must look to others—to State, local, and tribal governments, to community and faith-based organizations, to the private sector, and to academic institutions—for new and creative approaches to solving public problems. The President and I share this view, and I am proud to say that it is manifested in the budget he has put forward.

The budget I present to you today keeps the promises the President has made and proposes new and innovative solutions for meeting the challenges that face the nation. Our proposal increases support for America's children and families; enhances the groundbreaking research being sponsored by the National Institutes of Health and protects public health; begins the modernization of Medicare and expands access to health care; and, invests in infrastructure and reforms the way the Department's operations are managed. The HHS budget also reflects the President's commitment to a balanced fiscal framework that puts discretionary spending on a more reasonable and sustainable growth path; protects Social Security, Medicare, and other priority programs; continues to pay down the national debt; and, provides tax relief for all Americans.

Mr. Chairman, the total HHS request for fiscal year 2002 is $468.8 billion (outlays). The discretionary component totals $55.5 billion (budget authority). The amount before this Committee totals $300.7 billion in budget authority, of which $51.4 billion is discretionary. Let me now discuss some of the highlights of the HHS budget.

INCREASING SUPPORT FOR AMERICA'S CHILDREN AND FAMILIES

The HHS budget substantially increases our investment in children. Overall, the President's budget provides nearly $3 billion in increased spending for children's programs in this Department. The budget includes both increases for existing programs and investments in a number of new programs designed to fulfill President Bush's commitment to making sure that no child is left behind. This administration recognizes that America's children and families are its strength, and this budget reflects our commitment to helping them thrive and prosper. Our budget also increases support for the charitable organizations that can make such a difference in people's lives.

After School Certificates

One of the lessons I learned during my years as Governor of Wisconsin was that for people to move from dependency to success in the workforce, you had to be willing to invest in programs that support working families. One of the most important things that we as a government can do to help working families is to assist them in obtaining high-quality child care. Last year the Congress voted to provide a substantial increase in child care funding, and this year we are asking you to take another step to help working parents and their children be successful. The President has requested a total of $2.2 billion for the Child Care and Development Block Grant and has proposed to specifically dedicate $400 million for After School Certificates within the block grant. These certificates would help low-income working parents to pay for the costs of after school care for up to 500,000 children who are less than 19 years old. We expect these after school activities to also have a strong educational component, helping children to achieve success in school.

Promoting Safe and Stable Families and Independent Living

Our budget takes a number of steps to help protect our most vulnerable and at-risk children and to help them live safe and productive lives. First, we propose to create a new $67 million discretionary program within the Promoting Safe and Stable Families program to mentor children of prisoners. This initiative will provide grants through States, to assist faith and community-based groups in providing a range of activities to assist children of prisoners and probationers, including family-rebuilding programs that will help to reunite children and parents once the parent is released from prison if it is in the best interests of the child. Our budget also

proposes a $200 million increase in mandatory funding for the Promoting Safe and Stable Families program, which supports State and Tribal child welfare agencies in carrying out family preservation and support services and adoption promotion and support programs. We also propose an additional $60 million for the Independent Living program. These funds would be used to provide vouchers, worth up to $5,000, to youths who are aging out of foster care so that they can obtain the education and training they need to lead productive lives. Funds could be used to pay for either college tuition or vocational training.

Maternity Group Homes

One of the toughest problems we face in trying to end the cycle of dependency is children having children. These teenage mothers have often suffered abuse or neglect and may not have a safe and supportive family environment in which to raise their babies. To begin removing the obstacles to success that these mothers and their children face, we are proposing $33 million for a new Maternity Group Homes program. This program will support efforts to work with organizations that operate community-based, adult-supervised group homes for teenage mothers and their children, as well as to provide certificates to young mothers to obtain supportive services. These homes will provide a safe and nurturing environment for young mothers while offering the support necessary to help them and their children to improve their lives.

Promoting Responsible Fatherhood

Helping young mothers is an important part of our program to assist America's families, but it is also important that we recognize the critical role that fathers play in the lives of their families. The unfortunate reality is that nearly 25 million children do not live with their fathers, and studies show that these children are far more likely to experience poverty and suffer problems in school than children who live with both parents. Our budget framework includes $64 million to begin an initiative to promote responsible fatherhood by providing competitive grants to faith-based and community-based organizations that work to strengthen the role that fathers play in their families' lives. These funds will be used to support programs that help low-income and unemployed fathers and their families to avoid dependence on welfare, and to fund programs that promote successful parenting and marriage. Of these funds, $4 million will be used for special projects of national significance.

Compassion and Charitable Giving

The President has been a leader in recognizing the important role that charitable organizations play in delivering services to the public, and we are proposing a number of steps to increase Federal support for these groups. First, we are requesting $89 million to establish a Compassion Capital Fund. Through public and private partnerships, these resources will be used to provide start-up capital and operating funds to qualified charitable organizations so that they can expand or emulate model social services programs. Funds will also support research on "best practices" among charitable organizations. Our budget also includes $3 million to establish a Center for Faith-Based and Community Initiatives in the Department in accordance with the President's recent Executive Order. Finally, we have included a proposal to encourage States to provide tax credits for contributions to designated charities that work to address poverty. Under this proposal, States would be allowed to use Federal funds provided through the Temporary Assistance for Needy Families program to partially offset revenue losses that resulted from the tax credits.

Head Start

Head Start is the Nation's largest early childhood education program. The Head Start program helps to ensure that low-income children start school ready to learn and, to that end, provides a range of comprehensive child development and health services. The President proposes to revitalize Head Start by making school readiness skills such as pre-reading and numeracy the program's top priorities. For fiscal year 2002, the budget proposes a total of $6.3 billion for Head Start, an increase of $125 million. These funds will allow Head Start to serve 916,000 children, including 55,000 in Early Head Start, and to maintain a competitive salary for teachers.

ENHANCING SCIENTIFIC AND HEALTH CARE QUALITY RESEARCH

Advances in scientific knowledge have provided the foundation for improvements in public health and have led to enhanced health and quality of life for all Americans. Our fiscal year 2002 budget enhances support for scientific research as well as for research to improve the quality of the Nation's health care system.

Biomedical Research Sponsored by the National Institutes of Health

The National Institutes of Health (NIH) is the largest and most distinguished biomedical research organization in the world. The research that is conducted and supported by the NIH, from the most basic research on biological systems to the successful mapping of the human genome, offers the promise of breakthroughs in preventing and treating any number of diseases. A top priority for this Administration is ensuring that the NIH continues to have the resources necessary to help turn these promises into a reality.

This budget keeps the President's commitment to double NIH's fiscal year 1998 funding level by fiscal year 2003. For fiscal year 2002, we are proposing an increase of $2.75 billion, which will be the largest dollar increase ever for NIH. This funding level will enable NIH to support over 34,000 research project grants, the highest level in the agency's history. NIH will expand its focus on four research areas that show the greatest potential for yielding new scientific breakthroughs: genetic medicine, clinical research, interdisciplinary research, and health disparities.

With any large increase in resources, there also comes the increased challenge of making sure that those resources are managed properly. I take this responsibility very seriously, and NIH will be working to develop strategies to ensure that we are managing taxpayer dollars in the most efficient and effective way.

Patient Safety and Health Care Quality

The Agency for Healthcare Research and Quality (AHRQ) is the Federal agency with primary responsibility for research on the Nation's health care system and is HHS's lead agency for improving patient safety and the quality of everyday health care. The fiscal year 2002 budget provides a total program level of $306 million for AHRQ, an increase of $36 million or 13.5 percent over fiscal year 2001.

AHRQ will devote a total of $53 million to continue the work this Committee first funded in fiscal year 2001 to identify ways to reduce medical errors. These funds will support activities to research the causes of medical errors, develop and test new technologies to reduce medical errors, test reporting strategies, and improve training. Earlier this week, I announced the establishment of a new Patient Safety Task Force within the Department in which AHRQ will collaborate with FDA, CDC, and HCFA to improve existing reporting systems on patient safety. HHS seeks to develop a robust, anonymous database of information on errors and adverse events that can be used to find new and better ways to improve patient safety.

Our request includes a $26 million increase for research on health care quality and cost-effectiveness. Like you and many others, we are reviewing the recent recommendations by the Institute of Medicine for research to improve the quality of health care. Once that review is complete, I expect that an appropriate portion of these resources will be directed toward the recommendations that we conclude should be given the highest priority. I also expect the findings of this and other research on patient safety, which have emphasized the importance of encouraging and rewarding the development of health care systems that encourage safer and higher-quality care, to guide our efforts to improve Medicare, Medicaid, and other government health programs.

IMPROVING MEDICARE AND EXPANDING ACCESS TO QUALITY HEALTH CARE

Of all the issues confronting this Department, none has a more direct effect on the well-being of our citizens than the quality of health care. Our budget proposes to improve the health of the American people by taking important steps to improve Medicare, including the addition of a prescription drug benefit, and by directing funds to various initiatives aimed at expanding access to health care.

Modernizing Medicare

The Medicare program has been the center of our society's commitment for ensuring that all of our seniors enjoy a healthy and secure retirement. Honoring this commitment means not only making sure that the program is financially prepared for the wave of new beneficiaries that the aging of the baby-boom generation will bring, but also ensuring that current beneficiaries have access to the highest quality care. As an interim step, the President has put forward an Immediate Helping Hand (IHH) prescription drug proposal. This proposal provides $46 billion over 5 years to help States provide prescription drug coverage immediately to beneficiaries with limited incomes or high drug expenses. This proposal, which will sunset in fiscal year 2005 or as soon as legislation to strengthen Medicare including a prescription drug benefit is enacted, would provide immediate coverage for up to 9.5 million beneficiaries.

We also believe, along with many members of Congress who have supported and continue to support bipartisan efforts to strengthen Medicare, that we must take

steps to improve Medicare as soon as possible. Inadequate prescription drug coverage is only the most obvious gap in Medicare benefits. Today, Medicare covers only 53 percent of the average senior's annual medical expenses, and the options available to seniors to help them limit these expenditures are declining. In addition, Medicare is facing a looming fiscal crisis. A full assessment of the health of both the Part A and Part B Trust Funds reveals that spending exceeds the total of tax receipts and premiums dedicated to Medicare and that financing gap is expected to widen dramatically. Even without the financing problem, Medicare modernization would be necessary to ensure beneficiaries get high quality health care. President Bush proposes to devote $156 billion (including funding for Immediate Helping Hand) over the next 10 years to a set of improvements in Medicare that are urgently needed. These Medicare modernizations include taking steps to make better coverage options available, to assure that all seniors have affordable access to prescription drugs, to provide better options for high out-of-pocket expenses, particularly for low-income seniors, and to ensure that Medicare has greater overall financial security.

Expanding Community Health Centers

Our budget also proposes steps to strengthen the health care safety net for those most in need. Community Health Centers provide high quality, community based care to approximately 11 million patients, 4.4 million of whom are uninsured, through a network of over 3,000 centers in rural and urban areas. The President has proposed to expand and increase the number of health center sites by 1,200 by fiscal year 2006, and to double the number of individuals without alternative coverage who are served by the centers. As a first installment of this multi-year initiative, we propose to increase funding for Community Health Centers by $124 million. We will also be looking at ways to reform the National Health Service Corps so as to better target placement of providers in areas experiencing the greatest shortages of health professionals.

Increasing Access to Drug Treatment

The problems caused by substance abuse affect not only the physical and mental condition of the individual, but also the well-being of society as a whole. Nationwide, approximately 2.9 million people with serious substance abuse problems are not receiving the treatment they desperately need. To help close this treatment gap, we propose to increase funding for substance abuse treatment by $100 million. Of these funds, $60 million will be used to increase the Substance Abuse Block Grant, the primary vehicle for funding State substance abuse efforts, and $40 million will go to increase the number of Targeted Capacity Expansion grants, which seek to address the treatment gap by supporting strategic and rapid responses to emerging areas of need, including grants to organizations that provide residential treatment to teenagers.

Organ Donation

Our budget supports an initiative very close to my heart. Approximately 75,000 patients are awaiting organ transplants, far above the number of available donors. In fact, organ transplants in 2000 totaled 22,827, an increase of 1,172 over the 21,655 transplants that occurred in 1999. The number of living donors rose from 4,747 in 1999 to 5,532 in 2000, an increase of 16.5 percent, the largest 1-year jump ever recorded. While I am encouraged by the progress that has been made in the last year, there is still a very long way to go. To tackle this problem, I launched a new national initiative, on April 17th, to encourage and enable Americans to "Donate the Gift of Life". I am beginning a national "Workplace Partnership for Life", in which employers, unions and other employee organizations can join in a nationwide network to promote donation. I released a model organ and tissue donor card, incorporating proven elements from today's donor cards and have ordered an immediate review of the potential of organ and tissue registries where donors' wishes could be recorded electronically and made available to families and hospitals when needed. I have also made a pledge to create a national medal to honor the families of organ donors and will create a model curriculum on donation for use in driver education courses, to be offered to states and counties nationwide. And, let me tell you, this is just the beginning. I intend to do everything I can to increase organ donation throughout America and to create the most comprehensive effort ever in our nation regarding donation and transplantation.

INVESTING IN INFRASTRUCTURE AND REFORMING MANAGEMENT

For any organization to succeed, it must never stop asking how it can do things better, and I am committed to seeking new and innovative ways to improve the

management of our programs. But we must also recognize that we do a disservice to all who rely on this Department if we do not provide the resources necessary to effectively administer our programs. In preparing our budget, we began the process of evaluating the programs and business practices of this Department and identifying the areas where we can do a better job of managing taxpayer resources, as well as those areas where new investments are required if we are to successfully administer our operations.

HCFA Management Reform

One of the most important management reforms we will pursue is the improvement of the Health Care Financing Administration (HCFA). I have often referred to HCFA as the agency people love to hate; and I recognize that patients, providers, and States have legitimate complaints about the scope and complexity of the regulations and paperwork that govern the Medicare, Medicaid, and State Children's Health Insurance programs. At the same time, we must recognize that in the last few years HCFA has been tasked with implementing several pieces of major legislation and its responsibilities have grown more complex with each new major healthcare law or budget reconciliation.

Concerns about HCFA's management capabilities have been raised in several General Accounting Office reports, including the High Risk Series: An Update (January 2001) and Financial Management: Billion in Improper Payments Continue to Require Attention (October 2000). HCFA management reform is an Administration priority. HCFA will undertake a major effort to modernize and streamline its operations to effectively manage current programs and implement new legislation. In particular, HCFA's role in a modernized Medicare program needs to be carefully considered. This may require substantial changes in HCFA's mission and structure. My goal is to assure that HCFA's resources are focused as effectively as possible on improving quality and limiting costs for Medicare beneficiaries, limiting burden for providers, and increasing efficiency for taxpayers.

The budget proposes an increase of $109 million, or 5 percent, for HCFA program management. Included in the HCFA program management budget is an increase of $36 million, for a total of $53 million, to support the development of the HCFA Integrated General Ledger Accounting System (HIGLAS). HCFA currently relies on several financial management systems to account for the hundreds of billions of dollars spent on Medicare benefits, and most contractors do not use double entry accounting methods or claims processing systems with general ledger capabilities. This system requires financial statements to be imputed manually, increasing the risk of administrative and operational errors and misstatements. HIGLAS will provide a uniform Medicare accounting system that will help to detect and collect money owed to the Medicare Trust Funds, retain a clean opinion on financial statements without more expensive, alternative efforts, and comply with financial management statutory requirements.

I am also committed to reforming HCFA's antiquated and inefficient contracting system. We are considering a number of options in this area including: allowing carriers who are not health insurance organizations to become Medicare contractors; allowing the Secretary (as opposed to the Part A provider) to contract for and assign fiscal intermediaries to perform claims processing, claims payment, communications, audit functions, renewing contracts, and transferring functions; and replacing current special provisions for terminating contracts with more standard terms and conditions embodied in the Federal Acquisition Regulation (FAR). In addition, I am including in the budget $115 million in new proposed user fees for duplicate and paper claims processing. We will work hard to enact these fees, which will help to improve the efficiency and lower the cost of processing Medicare claims.

Revitalizing Laboratories and Scientific Facilities

It is critical that we invest in the modernization of the laboratories and scientific facilities, for obsolete facilities affect our scientific readiness and compromise our ability to retain the top scientists. Our budget includes funds to continue the revitalization of key facilities at the Centers for Disease Control and Prevention and the National Institutes of Health. We are requesting $150 million for buildings and facilities at the Centers for Disease Control and Prevention, which will support construction of a laboratory facility dedicated to handling the most highly infectious pathogens, such as Ebola, and construction of an Environmental Toxicology Lab. The budget also requests $307 million for intramural buildings and facilities at the National Institutes of Health to support projects such as the construction of the John Edward Porter Neuroscience Research Center and a centralized, multi-level animal facility.

Enhancing Coordination and Reducing Duplication of Operating Systems

The only way that this Department can effectively serve its many clients is if we commit to making the necessary investments in our management and infrastructure. One of the challenges in a large, decentralized Department such as HHS is finding ways to bring together diverse activities and to develop coordinated systems for managing our programs. Our budget provides the resources necessary to begin the process of streamlining our financial management and information technology systems so that we can enhance coordination across the Department and eliminate unnecessary and duplicate systems.

For financial management, we propose to invest $50 million, which includes funding for the new HCFA accounting system, to move toward a unified financial accounting system. The Office of Inspector General has cited problems with the Department's current system structure, which involves five separate accounting systems operated by multiple agencies. We plan to replace these antiquated systems with unified financial management systems that will increase standardization, reduce security risks, allow HHS to produce timely and reliable financial information needed for management decision-making, and provide accountability to our external customers.

In the information technology arena, we are proposing $30 million for a new Information Technology Security and Innovation fund. Currently, the Department's information technology systems are highly decentralized, heterogeneous, and vulnerable to exploitation. Funds would be used to implement an Enterprise Infrastructure Management approach across the Department that would minimize our vulnerabilities and maximize our cost savings and ability to share information. With this approach, we will be able to reduce duplication of equipment and services and be better able to secure our systems against viruses and network intrusion.

As the largest grant-making agency in the Federal Government, this Department will also continue to play a lead role in the government-wide effort to streamline, simplify, and provide electronic options for the grants management processes. As part of the Federal Grant Streamlining Program, we will work with our colleagues across the government to identify unnecessary redundancies and duplication in the more than 600 Federal grant programs and to implement electronic options for all grant recipients who would prefer to apply for, receive, and close out their Federal grant electronically.

Redirecting Resources and Enhancing Flexibility

Being a wise steward of taxpayer resources means not only recognizing where you need to invest but also where resources can be redeployed to more effective uses. In preparing our budget, we carefully reviewed each agency, identified areas where funding could be redirected, and made targeted reductions in selected programs. The fiscal year 2002 budget eliminates $475 million in earmarked projects and $155 million in funding for activities that were funded for the first time in fiscal year 2001. In addition, the budget shifts $597 million from programs that are duplicative, or whose goals are better met through other avenues, to higher priority activities. And, to assist in financing other high priority activities, the budget expands the use of Public Health Service Evaluation funds. These decisions helped to meet our goal of moderating the large increases in discretionary spending that have occurred over the last few years and putting the budget on a more sustainable growth path for the future.

This Administration is also committed to giving States greater flexibility to manage public health grant programs. Our budget proposes to give States expanded authority to transfer funds among public health grants, thereby enabling them to make more efficient and effective use of Federal resources and to target and reallocate funds to public health priorities identified at the State and local levels.

In addition to giving the States greater flexibility, I am seeking to increase my transfer authority from one percent to six percent, to eliminate the restriction that the transfer may not increase an appropriation by more than three percent, and to make it Department-wide. I believe this transfer authority is a valuable tool for managing the Department's resources and will allow me to respond to emergency needs or unforeseen events that would otherwise adversely effect a program or agency.

Continuously Evaluating and Improving Program Performance

The Government Performance and Results Act serves as an important tool for making sure that this Department is not only doing the right things but that we are doing them well. As in previous years, our budget request is accompanied by the annual performance plans and reports. The performance measures and targets

in these reports touch nearly every aspect of the Department's multi-faceted mission and detail a number of notable achievements, including:

—HCFA met its fiscal year 2000 target of reducing the Medicare error rate to 7 percent.

Auditors estimated improper payments at $11.9 billion, compared with $13.5 billion in fiscal year 1999. The error rate has fallen to roughly half of what it was in fiscal year 1996, and HCFA is pursuing increasingly rigorous goals for fiscal year 2001 and fiscal year 2002.

—The Administration for Children and Families (ACF) reported that 42.9 percent of adult recipients of TANF became employed in fiscal year 1999. This is a primary indicator of success in moving families toward self-sufficiency. It improves on the fiscal year 1998 baseline of 38.7 percent and exceeds the target of 42 percent.

—CDC reported a reduction of perinatal Group B streptococcal disease—the most common cause of severe infections in newborns—by 70 percent from 1995 to 1999, exceeding the goal.

These are just a few of the dozens of impressive success stories found in the 13 performance plans and reports. GPRA has been and will continue to be an important part of our effort to improve the management and performance of our programs.

WORKING TOGETHER TO BUILD A STRONG AND HEALTHY AMERICA

Mr. Chairman, the budget I bring before you today contains many different proposals; but, the common thread that binds them all together is the desire to build a strong and healthy America and to improve the lives of the American people. All of our proposals, from enhancing scientific research to modernizing Medicare, from expanding access to care to increasing support for the Nation's children and families, are put forward with these simple goals in mind. I know these are goals we all share.

As you begin to consider our proposals, let me leave you with one final thought. Senator Everett Dirksen said of the legislative process: "You start from the broad premise that all of us have a common duty to the country to perform. Legislation is always the art of the possible. You could, of course, follow a course of solid opposition, of stalemate, but that is not in the interest of the country." Starting from this premise, I am prepared to work with each of you to ensure that we develop a budget for this Department that effectively serves the national interest. I would be happy to address any questions you may have.

CENTERS FOR DISEASE CONTROL PREVENTION

Senator SPECTER. As is our practice, we will commence with 5-minute rounds for each Senator.

I begin, Mr. Secretary, with the issue of the Centers for Disease Control. The Centers have deteriorated just tremendously, and it is a matter of some concern to me that there had not been action by the last administration and a very competent Secretary of Health and Human Services in alerting this subcommittee to the deplorable conditions. I made a trip down there about a year ago, and this subcommittee took the lead in putting in $170 million because the situation was so catastrophic.

My recent meeting with the representatives of the Center found that they want $240 million. You have——

Secretary THOMPSON. $150 million.

Senator SPECTER [continuing]. $150 million, which is $25 million down from our figure last year. And my question to you is, how do you calculate $150 million, and is that really enough, or are the people at the Center really on the right track in asking for about $240 million?

Secretary THOMPSON. Well, I think you can make that argument, Senator, but the truth of the matter is, there are 22 buildings that we're renting, and I think it makes very good fiscal sense as well as scientific sense to be able to consolidate those into one campus.

Senator SPECTER. I went down there, and there is no doubt about the consolidation. Let me ask you to do this. Let me ask you to have your department take a look at the overall program, which is a big one, in excess of a billion dollars as I understand it, and give us a projection as to what we are going to have to spend next year, the year after, so that we can make an evaluation of priorities as to whether we think we need to shift some money.

Secretary THOMPSON. Okay. Well, Senator, I have already done that, and that is why we put in $150 million. It is going to have to be an ongoing $150 million in order to modernize and do it correct. If you want to accelerate it, you could do it at $175 million. We cut back on some planning for the next building and we felt we could do that in the next fiscal year, and we put some labs and so on in this year.

Senator SPECTER. Let us take a look at your specific projections and compare that with what the Center has in mind.

Secretary THOMPSON. Fine.

Senator SPECTER. And with what the other advocates have in mind.

Secretary THOMPSON. My projections are not much different than the Center's.

Senator SPECTER. Well, the figures are a fair amount lower, but let us take a look at the specifics.

Secretary THOMPSON. Absolutely.

STEM CELL RESEARCH

Senator SPECTER. There is not a whole lot of time, so let me move to the issue of stem cells, which is a very important topic, and note just very briefly for the record that when this issue broke in November of 1998, this subcommittee had a hearing within a couple of weeks. We have had seven hearings on the subject and I think it is a fair assessment that the subcommittee, I know that Senator Harkin and I are convinced that the stem cells which come from embryos are vital for medical research.

A point which I think has to be emphasized, and you and I have talked about this informally but just a word or two on the record, is that these embryos are created for in vitro fertilization, there are more created than necessary, and they are going to be discarded. If there were any possibility that these embryos would turn into human life, I would be the last to countenance using them for stem cells. But when they are going to be destroyed, then the alternative is to use them or lose them, in effect.

I know that there is another evaluation of the legal opinion issued by general counsel for the Department of Health and Human Services, which concluded that Federal funds may be used for research on the stem cells, once they are extracted, but Federal funds may not be used to extract the stem cells from the embryos. And speaking as one lawyer to another, lawyers' opinions are not too hard to obtain on any given proposition.

My yellow light is up and so I will conclude the issue by asking you for your perspective and what your plans are on handling this stem cell matter.

Secretary THOMPSON. Thank you very much, Senator. You know this is a very contentious issue and one in which I have been very

much involved in from my prior life as the Governor of the State of Wisconsin.

Stem cells are being evaluated by the Department, both by the general counsel, and other legal opinions are being discussed, but also scientific review is being done by NIH. Both of those reviews will be to me, hopefully, by the first week in June. And as regards to the process that is already in place, there are two applications, and those applications are being reviewed, even if the hearing was not postponed in April, they would not have been able to be funded until next April. That still is possible, if in fact both reviews come back consistent with your point of view, or if in fact Congress decides to change the law, Senator.

Senator SPECTER. My red light is on, so we turn now to Senator Harkin.

REGULATION OF TOBACCO BY FDA

Senator HARKIN. Thank you very much, Mr. Chairman.

Mr. Secretary, I have been pleased to hear your comments about the need for FDA to regulate tobacco. Stick with it.

Secretary THOMPSON. I notice when I looked around, there were not too many people behind me, except you, Senator.

Senator HARKIN. Well, stay out there, you are right on that issue and you are going to get a lot of support because people are on your side on this issue.

The tobacco companies, for example, you know that nitrosamines for example, are highly carcinogenic. They have the technology to reduce that, they are not doing that. That is one of the things that FDA could do. But, I just want to say that, you know, we had—the FDA issued in 1996 these regulations, and the Supreme Court said they didn't have the legislative authority with which to do that.

But they said, the tobacco companies said they were going to voluntarily not market to kids, that they were going to not do that. Well, they have been saying that for a long time. A recent Federal Trade Commission report showed that in the first year after the settlement, tobacco marketing expenditures went up 22 percent to a record $8.24 billion per year, and much of the increase was in marketing efforts that reached kids. Two for one discounts that reduced cigarette prices, payments to stores for high visibility shelf displays, et cetera.

So I tell you, I personally believe the FDA needs to have the ability to rein in the industry and protect our kids. That is what FDA is supposed to do, supposed to protect us are from unwarranted drugs, unsafe foods, and cigarettes.

The regulations that FDA issued included a number of restrictions, including banning of outdoor advertising within a thousand feet of schools, it would have allowed only black and white text appearing in publications with youth readership.

TOBACCO ADVERTISEMENTS

Senator HARKIN. I am going to ask Sabrina to hold this up. This was in Cosmopolitan. 1,463,000 teenagers, they say mostly girls read it, and that is the ad for Virginia Slims, and that is what these young girls are reading. There is no question in my mind now

why lung cancer now has overtaken breast cancer as the most pervasive cause of death among women in America today.

Secretary THOMPSON. Very true.

Senator HARKIN. It is true. And we are finding out more and more that the tobacco companies have been targeting women and young girls, getting them hooked young.

Well, I do not know that I have so much of a question, except just to say, Mr. Secretary, I urge you to continue your efforts, and I do not mean to put you on the spot or anything like that, but I just want to know how you feel about the FDA having that kind of authority to restrict this kind of advertising, to restrict where they can put tobacco on store shelves, all the things that were in the regulations that FDA issued in 1996 which the Supreme Court took out, and which I hope we in Congress are going to address.

Secretary THOMPSON. This is a big issue, Senator Harkin, for me and obviously for you, and I appreciate that. It is amazing that 165,000 women died last year which was directly caused by tobacco smoking, and 30 percent of our teenagers in high school have tried cigarettes—32 percent of our teenagers have tried a cigarette or tobacco in the last 30 days.

Senator HARKIN. How many?

Secretary THOMPSON. Thirty two percent. And the record shows that if in fact you are able to prevent teenagers from smoking, that there is an 80 percent chance that people will not smoke after they reach age 21. So it is obvious that we have to address this problem.

In regards to regulation, really it is going to be up to Congress if they can pass the bill. FDA should have some regulation, should be able to do it, and I would welcome that opportunity, Senator.

Senator HARKIN. I appreciate your forthright statement.

Secretary THOMPSON. Thank you.

Senator HARKIN. My yellow light is on too. I have one question about Medicaid and managed care for disabled, but I guess I will have to wait for my second round.

Senator SPECTER. Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman, and thank you, Mr. Secretary.

Secretary THOMPSON. How are you, Senator?

Senator MURRAY. I am doing great. Good to see you here at our committee, and I look forward to working with you on this very very important piece of our budget.

I have a first question today about the nursing shortage, and I think everyone of us have heard——

Secretary THOMPSON. It is a real problem.

NURSING SHORTAGE

Senator MURRAY. There is a real shortage, I am very concerned about it, and I see that the President proposed to redirect health profession funds from physician education to professions like nursing, which is one step, but in talking to a number of our technical schools and community colleges that do a lot of the initial training on this, they are telling me that the impact has come from welfare reform, which has changed the emphasis and only gives 1 year credit for education, so that there is not an incentive for women and men on welfare to go into nursing, because they don't get the

exemption long enough to get the training that they need. I think it is really important to have some flexibility in the welfare program to provide that education and training, and I just wanted to find out if you would support extending that current 12-month education work standard in order to meet the growing nursing needs in our hospitals and nursing homes.

Secretary THOMPSON. If I could just broaden the question a little bit, I would appreciate it, Senator Murray. Nursing shortage is a severe problem in America and it is going to get worse, especially for the nursing home industry.

Currently, we are 90,000 short for registered nurses, 250,000 short on CDNs, and it is very important that we address it, and I applaud you for your leadership. It is also a big concern of mine and the Department so we want to do something about it.

In regards to welfare reform, TANF is not going to be reauthorized until next year, and I will be more than happy to work with you to find ways on how we can encourage it, but I do not think welfare reform is the cause for the nursing shortage. The nursing shortage is caused by long hours and shortage, in the fact that the working conditions have not been the best for nurses. What we have to do as a Congress, and as an administration, we have to look at ways to encourage that.

I think we also have to consider the possibility, and I know this is not popular, but you are asking my opinion, so I think we are also going to have to look at seeing how we might be able to encourage immigration avenues to encourage people that want to come to the United States to go into the health professions.

I am very concerned about the future of nursing home industries unless we get more CNAs. Projections are that the CNA shortage is going to go from 250,000 possibility up to 400,000 in the near future and that's going to be a very serious problem for you, for me, and for America.

Senator MURRAY. Well, I really appreciate the fact that you understand this and I want to work with you on this.

Secretary THOMPSON. I really want to work with you too. It is an issue that is very near and dear to me.

Senator MURRAY. I agree that wages, long hours is a contributing factor, but in talking to many of the facilities in my home State that train and educate, particularly women obviously, into these professions, there are not women applying, and one of the——

Secretary THOMPSON. They are not, and we have to encourage people to do that.

Senator MURRAY. And I think one way to encourage that and help promote that would be to extend that education work standard for 2 years specifically for a nursing program.

Secretary THOMPSON. I would be more than happy to work with you on that, and I am very supportive of issues like that, and how we can encourage more young people to go into the nursing profession.

CHILD CARE

Senator MURRAY. Very good, okay.

Another quick question. In the President's budget he increases funds for child care for older children, which I am pleased to see,

but I also notice that he cuts Federal support for child care for younger children by $200 million, which seems to go against the welfare reform standards that have been advocated, which require that even women with young children need to be in the work force earning wages. Was there a study that showed that there was a drop in the national needs for child care for younger children?

Secretary THOMPSON. No, but I have to dispute your conclusion. I do not want to be in a position of being confrontational, but the baseline was $2 billion, and the discretionary money. We are putting in 200 million more, or a 10 percent increase, to $2.2 billion for child care in the discretionary fund. And out of that discretionary fund of $2.2 billion, the President says instead of just having a block grant going back to the State, he wants to earmark $400 million of that $2.2 billion, or the 10 percent increase plus the additional $200 million, to allow for children between the ages of 13 and 19 to be able to have after school care. He thinks it is a real serious problem. Instead of a cut, it is going to allow for 500,000 additional students to be taken care of under the program.

The second thing is, there also is the mandatory side of child care, and that is a $150 million increase. So instead of a cut, there has been a $350 increase in child care, a 10 percent, and a total of $4.9 billion totally, and that is $350 million over what it was last fiscal year 2001.

Senator MURRAY. Thank you for that, and I know my time is up. I do want to talk to you at some point about the SCHIP program.

SCHIP

Secretary THOMPSON. Sure, I would love to talk about it.

Senator MURRAY. My question is one that is penalized for where we have gone with that, and I would like to talk to you about some flexibility in that program so my state and others that have been trying to do the right thing are able to fall into that program.

Secretary THOMPSON. Your Governor, I think, has been in to see me on it.

Senator MURRAY. Good, thank you.

Senator SPECTER. Thank you, Senator Murray. Senator Landrieu.

HEALTH CARE

Senator LANDRIEU. Thank you. And Mr. Chairman, this is my first meeting and I want to tell you how pleased I am to be on the committee and to serve with our ranking member and my wonderful friend and colleague, and Mr. Secretary, it is a pleasure to be with you this morning.

Secretary THOMPSON. Thank you, Mrs. Landrieu.

Senator LANDRIEU. Let me follow up on what Senator Murray was highlighting and just associate myself with her remarks, because the issue of health care and child health and the nursing shortage is on everyone's mind and really is at the heart of our efforts to deliver a quality health care system for this nation.

Secretary THOMPSON. Absolutely.

Senator LANDRIEU. I mean, without nurses it cannot be done, with all due respect to doctors and the other health professionals——

Secretary THOMPSON. You are absolutely correct.

Senator LANDRIEU [continuing]. That nurses are really the heart of that whole enterprise, and we have a real, I would almost say crisis in this Nation regarding that, and it is going to take a bipartisan sort of multifaceted effort to try to come up with some immediate solutions.

But, I want to follow up on this additional child care piece that Senator Murray brought out, because I was looking at the numbers too, and want to work with you to increase our investment in child care, recognizing that the current budget underserves millions and millions of communities. And without the child care dollars, particularly for young children, but of course as you mentioned, there are needs for children of all ages after school, targeted to those communities of working families where both spouses are usually having to work not one job but two jobs, child care becomes essential to that family being able to work their way out of poverty, and to build the wealth and assets necessary to provide for their children.

So if the Government fails to meet them halfway on this issue, we are really not living up to, I would say, the minimum that we should do. And I wanted just to point out that the way we have added the numbers, it does seem like there is a cut in this area as opposed to a real increase, because although you are increasing the overall number, you are earmarking a certain percentage for older children, and the only place it can come is from the younger children's discretionary portion.

So, I do not want to argue those numbers this morning, but just to say that I would like to try to get some clarification at a later date if that is not the case, then, because it seems to us that that most certainly is the case.

The second point is the area of foster care and stable families. I want to work with you on that.

Secretary THOMPSON. So do I.

FOSTER CARE

Senator LANDRIEU. Because as you know, governments do a lot of things well, but one thing we do not do very well is raise children, and children are best raised in families, in permanent stable relationships with either one responsible caring adult, preferably two parents, but one responsible adult can and in many instances do beautiful jobs. So we need to try to support children in the biological families to which they are born but if that cannot take place, to try then to find them a real family, not an orphanage, not an institution, not a group home, but a real family.

And so I would just say that throughout the budget, I am going to be focused on all of the programs that encourage reunification where possible, but then a permanency for children to be placed into a family. So with your prisoners initiative, I just wanted to ask and make a point that we want to make sure some of these children can be reunited with parents who spent long time in prison, but if it is not possible for the reuniting, that we should really work to provide another home for children and not take that opportunity away from them to have a family.

I just want to raise that and look forward to working with you on adoption and foster care issues particularly.

Secretary THOMPSON. You have raised several things and I would like to respond to all of them, if I might, Senator Landrieu.

NURSING SHORTAGE

It is really heartening for me to hear, both from you and Senator Murray, about your passion for increasing nursing. It is something, we really have a problem facing us as a country, and if we are going to have a quality health care, we are going to have to find ways to increase the number of people applying for nursing school. I do not know how much more I can tell you than I want to work with you.

It is a very important thing for the department because with all the additional rules and regulations we are imposing upon nursing homes for more nursing care, and we do not have the nurses to staff it, we are going to cause severe problems to that industry as well as taking care of our elderly citizens, our mothers and our fathers, so it is a problem we have to take care of.

CHILD CARE

In regards to the dollars, there is a block grant of $2 billion in discretionary funds for fiscal year 2001. We put an additional $200 million, which is a 10 percent increase; it goes from $2 billion to $2.2 billion.

Now we earmarked $400 million for after school children, because we found, and I found as a governor that we could not use this money to take care of a real serious problem. And those are the freshmen and sophomores, and juniors, seniors could care less, but they should be taken care of as well, but they were not as interested. But the boys and girls schools, the clubs, the opportunities to have athletic programs and educational programs after school is so important. And that's why the President felt that this was something really needed.

So there is a 10 percent increase in it, but $400 million has been earmarked, there is no question about that, I am not trying to hide that. So, I mean, it is a block grant.

Then on top of that, we added an additional $150 million on the mandatory side for child care. You are talking to somebody, you know, when I was a Governor, I went from $12 million to $300 million my last year for child care. And I have told this Senate and I have told the House many times when I was a governor, if you are going to have welfare reform, you have to take care of the children, you have to be able to have child care. We did not have any waiting lists when I left as governor in the state of Wisconsin.

Senator LANDRIEU. You did an excellent job.

Secretary THOMPSON. And so that is a passion of mine, and I want to work with you in the reauthorization of TANF on that, but I really think the figures speak for themselves. There is an increase of $350 million for child care, and there is an attachment, that the money goes for that, but it actually takes care of 500,000 additional children.

FOSTER CARE

In regards to foster care and adoption, all I can say is I agree with you. I mean, we need to do it. But the President has also recognized that the fathers are very important. That is why we have a fatherhood initiative, and you know that. We have to have fathers being reintegrated back into the family, and that is why we put an additional, a new program, $67 million, for fathers to come back in, also $64 million for prisoners to be reintegrated. And prisoners are going to get out of jail, and we want them somehow to have the skills necessary to be reintegrated back into that family.

And so those are two new programs that I think and hope that you would support.

Senator LANDRIEU. Well, I know my red light is on, but let me just say that you have been really one of the leaders in this area, and I want to applaud you. If our Federal budget would reflect the kind of priorities and investments that you made as Governor, we would be a heck of a lot better off in this nation, so God bless you and thank you for all your good work.

Secretary THOMPSON. Thank you, ma'am.

YOUTH VIOLENCE

Senator SPECTER. Mr. Secretary, moving to a number of other subjects, this subcommittee took the lead 2 years ago in allocating almost a billion dollars to the subject of youth violence from existing programs, and we did it in not a low key way, but a no key way, just had working sessions with the three Departments for which we provide appropriations, yours, Labor, and Education, and also the Department of Justice was involved.

I call this program to your attention specifically, although I know you're aware of it. The administration's funding reduced the programs which we have designated here by more than $250 million. I had called Miss Margaret Lamontaine, the domestic counselor, and I mention it at this time for the purpose of asking for your staff review and your review with a view to implementing this program. It has a lot of facets and what we really need to do is to see that these monies are being well spent in the areas to which they are directed, and we will be following up with you.

Secretary THOMPSON. I appreciate that, Senator. As a new Secretary that has been here for 75 days, how can we interact with your office better to develop a coordinated effort in regards to this thing? How can we use your abilities and intellect in this, Senator Specter, as a prosecutor and as a Senator, to do something in the area of youth values and to make sure that the dollars are being well spent to accomplish what you and the other Members of Congress have rightly set up?

Senator SPECTER. Mr. Secretary, I believe that we ought to do it at the highest level with our chiefs of staff and Bettilou Taylor, who is my key executive on the subcommittee, and who is very very experienced, and have a monitoring program. We have to include the domestic advisor to the President, Miss Lamontaine, and what I think we really ought to do is have the three Secretaries and Senator Harkin and myself sit down, and perhaps invite the Attorney General, because the Department of Justice is involved, and really

give it that kind of high level treatment. Because as you well know, when youth violence breaks, then everybody is aghast, and we have not——

Secretary THOMPSON. We have not had a coordinated effort.

Senator SPECTER. There is, as I say, no publicity, it is very quiet, with working sessions, but the way to carry forward would be at the top level and devise monitoring programs with very high ranking people in our offices.

Secretary THOMPSON. Could you call a meeting such as that?

Senator SPECTER. I will. I want to work through, as I say, Miss Lamontaine to get the White House involved in it.

Secretary THOMPSON. Fine.

FAITH-BASED INITIATIVES

Senator SPECTER. Because there is going to have to be a fair amount of their oversight and supervision on it ultimately.

With respect to the faith-based initiatives, Mr. Secretary, with some $89 million for the compassion capital fund in your department, $67 million for supporting children of prisoners and $64 million to promote responsible fatherhood, how do we carry these programs forward respecting the important separation of church and state?

Secretary THOMPSON. We just have to be very diligent, we have to make sure that our programs are set up in such a way that they will not violate the Constitution, and that we have to monitor them on a regular basis to make sure that that doesn't happen. I think Head Start is a prime example. I do not think many people realize this, but almost two-thirds of the funds in Head Start go into faith based organizations, and they do a wonderful job and I do not think there has been any criticism of the Head Start program of money going into faith based organizations. I use that only as an example of one that really is working, and that is the kind of model that I think we should probably try to emulate.

Senator SPECTER. Do you anticipate issuing any regulations to establish the guidelines?

Secretary THOMPSON. Absolutely, sir.

ALTERNATIVE MEDICINES

Senator SPECTER. All right. We will look forward to seeing those.

On the subject of alternative medicine, that is a matter where Senator Harkin and I have been keenly interested and have had a number of hearings on over the course of the past decade. The funding has been increased from $7 million to about $100 million, and I would like to call your attention this morning to a specific program by Dr. Herbert Benson, who is the president of the Mind Body Medical Institute. He has developed some really remarkable research on the benefits of releasing stress through medication and other approaches, and the impact on children.

The red light is on, so I will conclude my portion now by just saying that I am going to be sending over some material to you from Dr. Benson because I think this is worthy of consideration at your level.

Secretary THOMPSON. Fine, thank you. I will be looking forward to receiving it and reading it.

Senator SPECTER. Good. Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I ask a point of personal privilege to ask a question that Senator Byrd wanted to ask, and not be deducted from my time.

Senator SPECTER. Certainly.

Senator HARKIN. Senator Byrd apologizes that he could not be here, but he wanted me to ask this question, Mr. Secretary.

Secretary THOMPSON. Yes.

OBESITY RATES

Senator HARKIN. Why at a time when obesity rates are skyrocketing to the point that two-thirds of adults and a quarter of children are overweight or obese, is the administration cutting funding to the Centers for Disease Control and Prevention's nutrition, physical activity and obesity program by 10 percent, when you should be expanding the program, and what specifically does the administration plan to do to help reduce obesity rates among adults and children?

Secretary THOMPSON. I wish I had an answer to that, and I really do not. It is a problem facing America but it is also a problem facing the whole world. People down at CDC, I went down there to talk to them about diabetes, which is a growing problem, skyrocketing. And the people at CDC tell me, Senator, that 75 to 80 percent of the diabetic conditions can be challenged or changed by two things, watching our diet and exercising.

And I am going to make prevention a real cause for the Department of Health and Human Services, and we are already putting in place and I hope you pass that on to Senator Byrd, and people tell me that diabetes impacts on the Medicare budget by about 4.9 percent. And I do not know if that is correct, and I do not know of the 75 to 80 percent, those were the figures given to me, I think they are both very high, but even if they are close, what we could do for health care, health budgets, and improved quality of life by doing this is something that I want to address.

Now I did not get involved in the budget until very late, and prevention is a cause that I want to pursue, and I am not going to make any other apologies other than I think we have to address it, we have to address obesity because it is a growing concern in America, and I think the Department of Health should be the real model of trying to change that and improve it, and I would solicit your help and that of Senator Byrd in accomplishing that, and hopefully we can.

Finally, I would like to say that the Department is going to do everything possible to put in an initiative, hopefully with the cochairmen, Senator Specter and you, Senator Harkin, on this sometime this year. We have no ideas yet, but we are working on it, and we would like to come to you after we bring something together and talk to you about it.

Senator SPECTER. Senator Harkin, I think Senator Byrd's time is up.

Senator HARKIN. I am going to take off on that now with my time. But Mr. Secretary, one thing I suggest, or I hope that you will work with us on, putting on another hat, I am also ranking on the Agriculture Committee of Senator Lugar.

Secretary THOMPSON. Yes, sir.

NUTRITION PROGRAMS

Senator HARKIN. Our farm bill is up next year. One big part of that is the nutrition program, school lunch, school breakfast, all the feeding programs. And quite frankly, we have to do something about our school lunch programs out there. These kids are getting too much fat in their diets, and the difference between that and the school breakfast program is like night and day.

Secretary THOMPSON. I think we need to add more milk, cheese, and corn.

Senator HARKIN. Skim milk, low fat cheese, and Soy, do not forget Soy, you have to get Soy in there, healthy for the heart and all that.

Also the vending machines problems that we have in schools, things like that. Now that may be out of your purview, but you are a leader in this area, and I thought we had it fixed before about keeping the vending machines off until after the last meal is served in school, but we have to address that problem too, so I hope we can work with you in sort of a cross-track on this with the Agriculture Department on this too in the feeding and the food programs, but I didn't mean to go off on that.

Secretary THOMPSON. No, no, I appreciate it. I think it is something we should do.

Senator HARKIN. We should work together on that.

Secretary THOMPSON. Absolutely. I do not think there is enough cooperation in the Federal Government in regards to this thing, and I would like to see what I can do as a leader.

Senator HARKIN. That is one area where you and Ann Veneman could really work together on that nutrition program.

Secretary THOMPSON. Appreciate that.

MEDICAID PROGRAM

Senator HARKIN. In 1997 Congress made changes to the Medicaid program allowing States to mandate that Medicaid beneficiaries be enrolled in managed care plans, and they included people with disabilities. But we also required that there is a basic set of protections. As a result, HCFA issued guidelines and the guidelines went out, they are critical, especially for people with disabilities, to get the quality of care that they deserve. These regulations lay out standards, continuity of care, all that kind of stuff. In February, the administration announced the delay of this regulation.

I know it was caught up in all these things they delayed. I do not know about the other ones, but on this one I think it is unwarranted. President Bush has called for a patient's bill of rights for those who have private health insurance. How about the Medicaid people that are being put into the managed care plans, especially those people with disabilities, and I just hope that you will push to get this regulation out and get the delay off. I think it was just caught up in all those, but I am asking you to look at it.

Secretary THOMPSON. I appreciate that, and I will. I will look at it before the end of the week and get back to you, Senator.

Senator HARKIN. I would really appreciate that very much.

Lastly, on restraints. We have all these studies that show that a lot of adults and children with disabilities have died as a result of restraints, there have been lots of stories on it. We just had recently two deaths in Iowa of young people being restrained, and these are now being investigated of course, but there are some regulations, again regulations that were supposed to have come out, to provide guidelines for the appropriate use of restraints in Medicaid funded facilities. They were supposed to be effective by March 23, and they are not there yet. The regulations were going to prevent the types of deaths that I just described, the two that just happened in Iowa.

The GAO in September 1999 reported on restraint and seclusion and found conclusively that children are especially vulnerable to this unsafe practice. What is done, it is being used a lot of times just as a means of the caretakers in those facilities, if some kids act up and they do not have time to take care of it, put them in restraints, and it is used as punishment a lot of times too, and those regulations would address that.

And again, second, I hope you take a look at it and see why they are not getting out there.

Secretary THOMPSON. You know, there was an order put out that all these rules and regulations were going to be delayed for 60 days and the one on Medicaid is all wrapped up in the 60-day review period, Senator.

Senator HARKIN. Have all these people that work for you take a look at them.

Secretary THOMPSON. I will, thank you.

Senator HARKIN. Thank you, Mr. Secretary.

FAMILY PLANNING

Senator SPECTER. Mr. Secretary, one final subject, and that is the issue of family planning, birth control, and abstinence only education. This subcommittee has taken the lead in appropriating funds in the past for abstinence only education. The controversy exists that to talk about abstinence only is unrealistic, because facts of life being what they are, unless birth control devices are provided simultaneously, that the abstinence education will not work.

My own view has been that there is room in our budget, room in our society, for both efforts, family planning with their approach, which may include birth control as they protect their programs, but separate programs for abstinence only education, where a large part of our society which feels so strongly that birth control ought not be made available, and ought to have an opportunity with abstinence only education to see if that will provide an answer.

Obviously, this is one of the most contentious issues facing our society with all the ramifications that come from these issues, and I would be interested, the subcommittee would be interested, to know what the administrations plans and your Departments' plans are on family planning and abstinence only education.

Secretary THOMPSON. The President has taken a very strong position that they should be treated equally, and currently there is an underfunding on the abstinence side, about $93 million compared to $135 million on the birth control side. And there is a movement afoot to evaluate our programs to try and make them

equal, and this is something that the President feels very strong about, Senator, and we are working on that.

Senator SPECTER. Mr. Secretary, that is a fair amount of ground, that cannot be comprehensive. And I was just about to sound the gavel until our very distinguished colleague, Senator Herb Kohl arrived.

Secretary THOMPSON. You can never sound the gavel when the distinguished Senator from Wisconsin is here, plus the fact that his Bucks are doing a great job in the championship, and we are pulling for them, and I hope the people in Iowa and Pennsylvania are as well.

Senator SPECTER. I see the ruling of the Chair has been challenged?

And the ruling of the Chair has been defeated, so we will hear from you, Senator, as we always do.

Senator KOHL. What do you want?

Thank you very much, Senator Specter.

Senator SPECTER. Senator Kohl and I have worked together very closely, most noteworthy on the Ruby Ridge hearings, and I have been trying to get him to autograph my copy for 5 years. That is what I want.

Senator KOHL. Done.

Well, it is good to see you.

Secretary THOMPSON. Good seeing you, my friend.

Senator KOHL. Mr. Secretary, Governor.

Secretary THOMPSON. Thank you.

CHILD SUPPORT REFORM

Senator KOHL. Mr. Secretary, you visited my office before your confirmation hearing and we talked about our shared interest in reforming the child support distribution system.

Secretary THOMPSON. Right.

Senator KOHL. At that time you were just beginning your current job, but now that you have had a few months and a budget under your belt, I would like to discuss it just a little bit further. As you know, under current law, a lot of child support money never actually reaches the child. Instead, the state and Federal Governments keep it as reimbursement for their expenses. In Wisconsin, thanks to your leadership, Mr. Secretary, our State——

Secretary THOMPSON. And your support, Senator.

Senator KOHL. That is right. We have a successful waiver program to send more child support money directly to families. I have introduced legislation to give all states the option to follow Wisconsin's example. The bill is included in the bipartisan Strengthening Working Families Act, which includes several other administration supported initiatives to help families succeed.

Given your long history on this issue and the bipartisan support that we have had, can you tell us if the administration will support this initiative?

Secretary THOMPSON. I know I do. I have not talked to the President about it, I am confident that he will, and if you want me to find out how the administration feels, I will be more than happy to, but I strongly support it because it is the right thing to do.

We pioneered that in Wisconsin, and the beauty of it is it gets more money to the mother and to the children and it just makes, you know, common sense. And so I am, I cannot say 100 percent that the administration is in favor of it, but I am, and I will do everything I possibly can to convince them if they are not, but I would dare to say if we can get your bill introduced, you are going to find this administration fully behind you support of it, Senator, and I hope that you push it hard and I would love to be able to be called to testify on it if and when there is a hearing on it.

Senator KOHL. Thank you, that is very encouraging.

Secretary THOMPSON. And I also want to thank you again for the great job you are doing with the Bucks. It is great.

NURSING HOME INITIATIVE

Senator KOHL. Thank you very much, Mr. Secretary. I would like to ask a question on nursing home enforcement. I have been fighting for several years to increase funding for nursing home inspections. Although most nursing homes do a good job, we still have way too many nursing homes with serious problems, including malnutrition, dehydration and bed sores.

In response to these problems, the Clinton administration launched a nursing home initiative which has had bipartisan support. This included mandates on State inspecters to make their inspections less predictable, to respond more quickly to complaints, and to refer deficiencies for immediate sanctions.

The Federal Government is the primary source of funding to the states to carry out these duties. Unfortunately, the President's budget flat lines this funding. If we know that substandard care is a serious problem in our country and if we are all serious about improving care, and I am sure you are, then we really have to invest in the inspection process. We have to give states the money they need to protect their residents. How do you expect States to carry out these critical duties if we do not have an increase in funding? In other words, as you well know, the inspections often times get nursing homes to do a better job, and if we do not increase our ability to do inspections, how can we expect nursing homes to do a better job?

Secretary THOMPSON. We are reviewing all those rules and regulations, Senator. I have no definite answer for you at this point in time. I think that sometimes we waste money and time continuing to inspect the good homes, and should be spending more time on the ones that have had violations in the past, got complaints, and so on and so forth, and accentuate the surveys and inspections there, and also do them at different time intervals so that nobody knows that they are coming, and see if in fact we can improve the quality of nursing care for our senior citizens all over.

And so, we are looking at that, and that is the best answer I have for you at this point in time, but I will be more than happy to sit down with you in the future to discuss it in further detail.

Senator KOHL. Okay. Again, I would just make the comment which, I would like to hope you would at least partially agree with, that to the extent that we inspect, we can expect to have some improvement; to the extent that we inspect less, we are in greater peril. And as I said, the money for the inspections comes from us

here in Washington, so I think it is something that deserves attention.

Secretary THOMPSON. Okay.

Senator KOHL. Last question. As you know, Mr. Secretary, for the past 7 years, Wisconsin's nursing homes have been using trained single task workers to help feed residents during busy mealtime hours. This frees up more time for other nurse aides to provide other critical services. Unfortunately, last year HCFA informed Wisconsin that this practice does not comply with federal law. I am concerned that the immediate removal of all single task workers would only worsen the staffing shortages that our nursing homes are already facing.

I have introduced legislation to allow Wisconsin to continue using single task workers as part of an eight-state demonstration project. These workers would have to be trained and supervised at all times, and a thorough evaluation of the project would be done to determine their impact on quality of care.

Would the administration support this kind of demonstration project, Mr. Secretary?

Secretary THOMPSON. Without a doubt, yes, and enthusiastically, I might add, and it is a problem, and I think the rules that were interpreted, the law needs to be changed, so that HCFA can make the right interpretation. And I will be very supportive of it. I know exactly what you are talking about. It is causing a problem not only in Wisconsin, but nursing homes, especially in the midwest and I presume across America, and it is something that needs to be changed, the law needs to be changed, and let us push forward with it as fast as we possibly can.

Senator KOHL. Well, I thank you, that is great to hear, and you are a great guy and I have always felt that way, and since you have been here in Washington, I increasingly feel that way and I look forward to working with you.

Secretary THOMPSON. My privilege, sir, and thank you very much for your kind words, and I feel the same about you.

Senator KOHL. Thank you, Mr. Secretary.

Senator SPECTER. Mr. Secretary, I have been involved in a few of these hearings, none has surpassed all of the complimentary comments about you. You got a lot of praise and a very high standard to live up to.

Secretary THOMPSON. I certainly do.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. And I join all of the complimenters in saying that we are confident that you will do it.

Secretary THOMPSON. Thank you very much, Senator.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTION SUBMITTED BY SENATOR ARLEN SPECTER

FAITH-BASED INITIATIVES

Question. President Bush's Faith-Based plan created five faith-based centers. One of the centers in located in HHS. What will be the role of the center? How will this

center be funded? How will this center interact with the White House Office of Faith Based Programs?

Answer. Established by Executive Order on January 29th, 2001, the Center for Faith-Based and Community Initiatives within the Department of Health and Human Services will coordinate departmental efforts to eliminate regulatory, contracting, and other programmatic obstacles to the participation of faith-based and other community organizations in the provision of social services. To maintain coordination with the White House Office of Faith Based and Community Initiatives (OFBCI), HHS has designated a Center employee to serve as the liaison and point of contact with the White House OFBCI, cooperate with the White House OFBCI, and provide such information, support, and assistance to the White House OFBCI as it may request, to the extent permitted by law.

The President's budget includes $3 million within the Administration for Children and Families to fund the Center for Faith-Based and Community Initiatives in 2002.

Question. President Bush's Faith-Based initiative calls for the expansion of Charitable Choice. What areas of Health and Human Services would benefit from this proposed action?

Answer. Beginning in 2001, the HHS Center for Faith-Based and Community Initiatives will (a) conduct a comprehensive review of policies and practices affecting existing funding streams governed by so-called "Charitable Choice" legislation to assess the department's compliance with the requirements of Charitable Choice; and (b) promote and ensure compliance with existing Charitable Choice legislation by the department, as well as its partners in State and local government, and their contractors.

Question. How will this expansion comport with the Constitutions Establishment clause?

Answer. Charitable choice is often portrayed as a source of new federal financial assistance made available to—indeed earmarked for—religious charities. It is not. Rather, charitable choice is a set of grant rules altering the terms by which federal funds are disbursed under existing programs of aid. As such, charitable choice interweaves three fundamental principles, and each principle receives prominence in the legislation.

First, charitable choice imposes on both government and participating FBOs the duty to not abridge certain enumerated rights of the ultimate beneficiaries of these welfare programs. The statute rightly protects these individuals from religious discrimination by FBOs, as well as from compulsion to engage in sectarian practices against their will.

Second, the statute imposes on government the duty to not intrude into the institutional autonomy of faith-based providers. Charitable choice extends a guarantee to each participating faith-based organization [FBO] that, notwithstanding the receipt of federal grant monies, the organization "shall retain its independence from Federal, State, and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs." In addition to this broadly worded safeguard, there are more focused prohibitions on specific types of governmental interference such as demands to strip religious symbols from the walls of FBOs and directives to remake the governing boards of these providers. A private right of action gives ready means of enforcement to these protections of institutional autonomy.

Third, the statute reinforces the government's duty to not discriminate with respect to religion when determining the eligibility of private-sector providers to deliver social services. In the past, an organization's "religiosity," obviously a matter of degree not reducible to bright-lines, was said to disqualify providers found to be "pervasively sectarian." That inquiry was always fraught with difficulties. Now, rather than probing into whether a service provider is thought to be "too religious" as opposed to "secular enough," charitable choice focuses on the nature of the desired services and the means by which they are to be provided. Accordingly, the relevant question is no longer "Who are you?" but "What can you do?" So long as a provider is prepared to operate in line with all statutory and constitutional parameters, then an organization's degree of "religiosity" is no longer relevant.

When discussing Establishment Clause restraints on a government's program of aid, a rule of equal-treatment or nondiscrimination among providers, be they secular or religious, is termed "neutrality" or the "neutrality principle." Charitable choice is consistent with neutrality, but courts need not wholly embrace the neutrality principle to sustain the constitutionality of charitable choice.

The U.S. Supreme Court distinguishes, as a threshold matter, between direct and indirect aid. For any given program, charitable choice allows, at the government's option, for direct or indirect forms of funding, or both. Indirect aid is where the ulti-

mate beneficiary is given a coupon, or other means of free agency, such that he or she has the power to select from among qualified providers at which the coupon may be "redeemed" and the services rendered. In a series of cases, and in more recent commentary contrasting indirect aid with direct-aid cases, the Supreme Court has consistently upheld the constitutionality of mechanisms providing for indirect means of aid distributed without regard to religion. The Child Care and Development Block Grant Program of 1990, for example, has been providing low income parents indirect aid for child care via "certificates" redeemable at, inter alia, churches and other FBOs. The act has never been so much as even challenged in the courts as unconstitutional.

In the context of direct aid, the Supreme Court decision that has most recently addressed the neutrality principle is Mitchell v. Helms. The four-Justice plurality, written by Justice Thomas, and joined by the Chief Justice, and Justices Scalia and Kennedy, embraced, without reservation, the neutrality principle. In the sense of positive law, however, Justice O'Connor's opinion concurring in the judgment is controlling in the lower courts and on legislative bodies.

Before proceeding in greater detail, the controlling principle coming from Mitchell v. Helms can be briefly stated: A government program of aid that directly assists the delivery of social services at a faith-based provider, one selected by the government without regard to religion, is constitutional, but real and meaningful controls must be built into the program so that the aid is not diverted and spent on religious indoctrination.

Based on Justice O'Connor's opinion, when combined with the four Justices comprising the plurality, it can be said that: (1) neutral, indirect aid to a religious organization does not violate the Establishment Clause; and (2) neutral, direct aid to a religious organization does not, without more, violate the Establishment Clause.

Question. The President's budget shows new faith-based budget items under Health and Human Services and proposes the expansion of others. Please share with the subcommittee the details of the following policy items:

—Compassion Capital Fund

—Supporting Children of Prisoners

—Promoting Responsible Fatherhood

Will these programs need new authorization? If not, what is the existing authorization?

Answer. The new proposed discretionary initiatives represent a new Federal commitment in providing social services to those in need. Through these initiatives, the Administration wants to spur new community-level approaches to working with low-income families. The Administration will look to all successful sources of support for those in need—faith-based organizations, charities, and community groups. These groups do not replace Government, but partner with it.

The Compassion Capital Fund will provide start-up capital and operating funds to qualified charitable organizations that wish to expand or emulate model social service programs. The program will also promote research on "best practices" among charitable organizations. Another new program, Mentoring Children of Prisoners, will help children through the time their parents are imprisoned, including efforts to keep children connected to a parent in prison, and increase the chances that the family can come together successfully when the parent is released. The President also proposes a program to Promote Responsible Fatherhood. To strengthen the role of fathers in the lives of families, this initiative will provide competitive grants to faith-based and community organizations that help unemployed or low-income fathers and their families avoid or leave cash welfare, as well as to programs that promote successful parenting and strengthen marriage.

The President's fiscal year 2002 budget proposes to fund both the Compassion Capital Fund and the Mentoring Children of Prisoners program under existing authority within the Administration for Children and Families. The Administration is proposing new legislation for the Responsible Fatherhood Initiative, and looks forward to working with the Congress on how to best structure this new program.

COMMUNITY HEALTH CENTERS

Question. You propose an increase of $124 million for community health centers. This is less than the increase Congress provided last year, yet the budget justification says that this is the first step in a multi-year strategy that will eventually double the number of patients seen at community health centers. Could you explain your strategy?

Answer. The President's fiscal year 2002 budget for HRSA includes nearly $1.3 billion for Health Centers program, an increase of $124 million above the fiscal year 2001 appropriation. These additional funds in fiscal year 2002 will allow Health

Centers to create 200 new and expanded access points and serve up to 1 million additional patients, almost half of them uninsured. The added funds represent the first installment of the Administration's multi-year initiative, which will eventually increase or expand health center access points by 1,200 over five years and eventually double the number of people served.

RYAN WHITE PROGRAMS

Question. Why are there no increases for the Ryan White programs, not even for inflation?

Answer. The President's fiscal year 2002 budget includes over $1.8 billion for Ryan White activities, the same level as fiscal year 2001. Ryan White activities have increased by over 81 percent, or $812 million, in the last 5 years. By maintaining funding at this level, grantees will be able to manage these significant increases and address the changes included in the reauthorization of the Ryan White CARE Act.

HEAD START

Question. The President's budget increases for Head Start is $125 million—an increase that only accounts for inflation. Last year's budget increase allowed Head Start to serve 60,000 additional children. This year's budget will not allow any additional children to receive Head Start services. Can you explain the rational for this budget?

Answer. The President's budget provides $6.3 billion for Head Start in fiscal year 2002, $125 million increase above the fiscal year 2001 funding level. This funding level will serve 916,000 children, the same number that was served in fiscal year 2001. The program has received significant funding increases in the past few years and has undergone considerable expansion. In fiscal year 2002 we will work to ensure that the program has the opportunity to absorb this dramatic growth while focusing on strengthening pre-literacy and reading skills of the children.

Question. With the Head Start increase only accounting for inflation, can you tell us how many eligible children will not be served in fiscal year 1902?

Answer. In 2002, Head Start will provide preschool services to 916,000 children (including 55,000 children in Early Head Start), or approximately 60 percent of the eligible population of 1.425 million 3- and 4-year old children nationwide.

CHILD CARE AND DEVELOPMENT BLOCK GRANT

Question. You have set-aside $400 million for use by the States to provide certificates for low-income parents to help defray the costs of after-school programs with an educational focus. With only a $200 million increase in the child care block grant, isn't this an effective cut of $200 million in the block grant? Can you explain how this program differs from the Department of Education's 21st Century Learning Centers.

Answer. The President's budget supports child care services for 2.6 million children. This includes child care services for approximately 2.1 million children—the same number supported in 2001—and certificates for up to 500,000 additional children to help parents defray the costs of after school child care programs which have a high-quality educational focus. The certificates will be available for children who are less than 19 years of age.

The block grant is only one portion of the total funds for the Child Care Development Fund. The fiscal year 2002 ACF budget includes $4.917 billion in Federal resources for the child care services. This funding represents a $350 million increase to the fiscal year 2001 level of $4.567 billion.

The After School Child Care Certificate set-aside is designed to help pay the costs of high-quality after school child care by putting money in the hands of parents who need it. As we understand it, the 21st Century Learning Center program provides funds to support after school programs at schools. The After School Child Care Certificate set-aside is directed to assist parents in paying for after school care, whether in a school or other settings.

YOUTH VIOLENCE

Question. In January the Surgeon General issued a report on youth violence which this subcommittee funded. The report was basically a review of existing literature and contained no new research. I continue to be concerned with the troubling outbreaks of violence by our teenagers. Do you plan to conduct new research to help us understand the causes of violent behaviors and ways to prevent and treat it?

Answer. The National Institute for Child and Human Development (NICHD) will support research to understand how interactions between the brain, hormones, and environmental stimuli lead to changes in teen behavior, including youth violence. Researchers will also examine how these processes interact with external factors as peers, family and the community.

The National Institute of Mental Health (NIMH) has learned that prevention programs must target multiple risk factors for youth violence, for example, poor adult supervision, associations with deviant peers, lower verbal intelligence, family conflict, impulsive behavior, depression, social isolation, school failure, and substance abuse. NIMH will continue and expand etiological and risk factor studies and will expand research on youth violence interventions.

Question. Does the Administration have plans to address the role of media in contributing to youth violence?

Answer. From a public health perspective, the Surgeon General's Report on youth violence noted that the role of the media in contributing to youth violence is largely uncharted territory. Few preventive efforts have been studied systematically. Furthermore, not enough research has been done to form a basis for the design of many experimental interventions. Although many violence prevention programs address a complex array of risk and protective factors in the lives of young people, they have not yet addressed the role of the media.

Question. Mr. Secretary, given the unacceptably high rate of youth violence in the United States and the reductions proposed in the budget, how will the HHS fiscal year 2002 budget request support programs that address youth violence?

Answer. The fiscal year 2002 request for HHS Youth Violence activities totals $103 million. Of this amount $90 million is for the Substance Abuse and Mental Health Services Administration (SAMHSA). With these funds SAMHSA will provide grants to schools and community organizations with the goal of building coalitions, establishing prevention programs, and developing curriculum. Also included in the fiscal year 2002 request is $11.6 million for the Centers for Disease Control (CDC). This funding will allow CDC to develop and implement multi-disciplinary research, develop and evaluate collaborative prevention interventions, and develop a training curriculum. Funding in the amount of $1 million for the Office of Minority Health will be used to expand the Family and Community Violence Prevention Program and $400,000 for the Office of Surgeon General will fund a series of community listening sessions on topics highlighted in the Surgeon General's Report.

QUESTION SUBMITTED BY SENATOR TED STEVENS

SPECIAL HEALTH NEEDS OF CHILDREN WITH MENTAL RETARDATION

Question. On March 5, 2001, at the hearing in Anchorage, the Special Olympics officially released the special report on The Health Status and Needs of Persons with Mental Retardation. Specifically, the Health Report found that (1) Although persons with mental retardation need health and health financing programs that are responsive to their particular needs, too often they are forced into general programs that actually can compromise their health. People with mental retardation may not be receiving health services because they are under-insured; (2) The majority of health professional who are otherwise qualified to treat persons with mental retardation fail to do so. This is largely the result of a lack of appropriate, specific training, inadequate reimbursement policies, fear, and prejudice; (3) Existing federal, state and voluntary programs to meet the health needs of persons with mental retardation are inadequate.

Mr. Secretary, what role can you play in training health professionals to address the needs of person with mental retardation?

The report states that the health care system in this nation provides financial disincentives for physicians and other health care providers to work with patients with mental retardation. What can be done to rectify this situation?

Answer. People with special health care needs have been of particular concern to the Department for decades. Within HRSA's Maternal and Child Health Bureau, our concern with mental retardation has been a heightened priority for 50 years. Currently, the MCH Leadership Education in Neurodevelopmental and Related Disabilities (LEND) program improves the health and quality of life of children who have, or who are at risk for developing neurodevelopmental or related disabilities by preparing trainees from a wide variety of professional disciplines to assume leadership roles to ensure high levels of clinical competence. By providing interdisciplinary long-term training, by developing exemplary clinical service models, and by reaching out to the community through consultation, technical assistance, and con-

tinuing education, the LEND program has made and will continue to make significant strides towards developing comprehensive, coordinated services for infants and children with the potential to have, or having developmental disabilities and for their families. For fiscal year 2001, MCHB is providing $18.3 million through 35 grants in support of the LEND program.

In addition, the Administration on Developmental Disabilities, ACF, administers a national network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (formerly known as University Affiliated Programs). There are 61 Centers that receive 5-year grant awards, for fiscal year 2001 the level of funding for each Center is $347,000. These Centers provide for interdisciplinary training, community services, research and technical assistance and information/dissemination activities. The University Centers are affiliated with medical schools, health care centers and hospitals. They are committed in furthering the health care needs of this population. For example, University Centers must now report on the progress they have made on increasing the number of health care providers trained to meet the needs of people with developmental disabilities as a result of program intervention. The interdisciplinary training programs cover such areas as: medicine, nursing, nutrition, physical therapy, speech pathology, social work, audiology, bio-statistics, psychology and education. They also provide community services on behalf of persons with developmental disabilities, including individual assessments through clinical service programs and physician referral programs.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

FEDERAL MENTAL HEALTH FUNDING

Question. Secretary Thompson, President Bush has expressed his interest in increasing Federal support for people with disabilities, including those with mental illness, with the announcement earlier this year of his New Freedom Initiative. How do you reconcile those expressed good intentions with a budget proposal that level-funds and even cuts Federal mental health funding?

Answer. The Department of Health and Human Services is just one of several agencies participating in the New Freedom Initiative, which will help increase access for and integrate individuals with disabilities into the community through assistive technologies, expanded educational opportunities, greater opportunities to enter the workforce, increased access to community-based care and housing, and other strategies. Increasing support for mental health services by leveraging federal mental health dollars through better coordination is one of many components of this initiative.

Other investments in HHS are also furthering the goals of the New Freedom Initiative. For example, the fiscal year 2002 budget for the Office for Civil Rights (OCR) will support an increase in its efforts to work cooperatively with states to implement the Supreme Court's Olmstead decision. OCR, the Health Care Financing Administration (HCFA), the Administration on Aging, the Assistant Secretary for Planning and Evaluation, the Substance Abuse and Mental Health Services Administration, the Administration for Developmental Disabilities and other components within HHS are working together with states to help them ensure that individuals with disabilities, including persons with mental disabilities, are provided with services in the most integrated setting appropriate to their needs. As states implement plans to provide such services, they will be offering individuals with disabilities more opportunities to move from institutional settings to community-based options when community-based care is appropriate.

We are also encouraging States to consider special initiatives for persons with mental illness as they take full advantage of some of the new opportunities from HCFA. These include the grants and the Medicaid Buy-In newly available under the Ticket to Work legislation. They also include the $70 million new "Systems Change" grants announced on May 18, 2001 that Senators Harkin and Specter were instrumental in crafting.

As you know, Medicaid is one of the most important programs for people with a mental illness. As an entitlement program, Medicaid continues to expand as more people need assistance. We look forward to working with you and focusing the attention of the President's National Commission on Mental Health to determine if there are additional things we could do to make Medicaid even more responsive to people with mental illnesses.

The Substance Abuse and Mental Health Services Administration budget includes $766 million for mental health services, a reduction of $16 million primarily for one-

time projects which will end in fiscal year 2001. Even with this reduction, the Programs of Regional and National Significance will have $39 million available for "new activities" as other projects conclude in fiscal year 2001. In addition, two-thirds of the individuals with substance use problems also have a mental illness and many of these individuals will benefit from the President's budget request for an additional $100 million to support a Drug Treatment initiative.

CENTER FOR MENTAL HEALTH SERVICES

Question. The $16 million cut in funding for the Center for Mental Health Services would significantly impact the agency's Best Practices or Knowledge, Development, and Application activities. Could you discuss how the Administration is proposing to address the need to disseminate research findings on best practices in mental health service delivery to practitioners and providers in the field so that the federal dollars devoted to this very important research are not squandered?

Answer. The President's budget includes $55 million in the Center for Mental Health Services to support Best Practices or Knowledge, Development, and Application activities. Within this amount, SAMHSA will have $39 million to award in new and competing grants and contracts for Programs of Regional and National Significance for mental health best practices in fiscal year 2002. The Center for Mental Health Services has a strong commitment to disseminating to state and local communities, providers, consumers and other key stakeholders findings from the evaluation of its knowledge development programs. The Center is also dedicated to encouraging the adoption of those practices that will benefit persons with serious mental and emotional health and substance abuse problems. To achieve this mission, the Center has funded several grant programs and contracts that use health communication and other social marketing strategies that increase awareness of evidence-based practices and encourage the incorporation of these practices into everyday service delivery. Specific activities include national training conferences, workshops, reports, technical assistance meetings, toolkits, mentorship programs, policy and leadership academies and the use of advanced computer technology for dissemination and education.

PRESIDENT'S FISCAL YEAR 2002 BUDGET PROPOSAL

Question. The Community Access Program would be eliminated under the President's budget. This program was designed to link uninsured and low-income individuals with health care services in their communities, including mental health services. The budget summary document points to increases in funding for community health centers (CHCs) as a more efficient approach to the problem of the low-income and uninsured not receiving services for which they are eligible. However, the budget dedicates this increased funding for CHCs to increasing the number of facilities in existence, with a goal of 1,200 new centers. How much of this funding increase will actually be used to address the fragmentation of public health services for the uninsured and under insured and to help providers link their uninsured patients with the services they need. Through the Community Access Program, 76 communities received assistance with improving coordination of care for the uninsured and under insured. How many communities will receive this kind of assistance under the President's proposal?

Answer. The Administration is committed to identifying programs that are carefully designed and proven to bring more Americans who may not have good access to care into the health care safety net. HHS will focus on the President's commitment to expand direct health care services to the uninsured through Community Health Centers (CHC), to which we are adding $124 million, for a total request of approximately $1.3 billion. This multi- year Presidential Initiative will increase or expand Community Health Center and Migrant access points by 1,200 over 5 years and eventually double the number of people served. By targeting our resources to expand CHCs, millions more Americans will have access to high quality health care.

The CAP program was created to provide short term assistance to local communities in order to transition to innovative service delivery approaches in order to ultimately be competitive within their own markets. Grantees were required to demonstrate that they were able to sustain the delivery of services and funding through other public and private sources on a longer term basis. There are existing funding resources that would enable communities to achieve similar goals as CAP. For example, CHC funding already supports the Integrated Service Delivery Initiative, which provides funding to CHCs to support their efforts to integrate functions with other centers and safety net providers in their community. The budget also includes $15 million to support grants to States to develop designs for providing access to health insurance coverage to all citizens of the State.

NATIONAL HEALTH SERVICE CORPS

Question. The Administration has proposed no funding increases for the National Health Service Corps (NHSC), citing that there is no longer a physician shortage. Instead, the proposal is for target reforms to better address the mail distribution and to increase available funds by eliminating the tax on scholarships and loan repayments. Eliminating the taxation and working on better distribution is all well and good, but the Administration appears to have overlooked the fact that the Corps provides funds for nurse practitioners, physicians assistants, dentists, psychologists and other mental health provider. The nation, especially Iowa and the other rural states continue to experience shortages of all of these providers. In Iowa, there remains a shortage of all of these providers. For example, the Corps is only able to meet less than 7 percent of the dental and mental health care needs in Iowa. Furthermore, the nurses in Iowa are going out into the communities to deliver primary care, but we need more of them.

How can the Administration rationalize not proposing a substantial increase in funding for the National Health Service Corps by citing the lack of a physician workforce? How are the Administration's reforms going to meet the needs of the uninsured and most vulnerable Americans?

Answer. The National Health Service Corp Presidential Management Reform Initiative will improve the NHSC's service to America's neediest communities. The initiative will examine several issues, including the ratio of scholarships to loan repayments and other set-asides, and will consider amending the Health Professional Shortage Area definition to include non-physician providers and J–1 and H–1C visa providers practicing in communities. These efforts will enable the NHSC to more accurately define shortage areas and target placements to areas of greatest need. The NHSC reform initiative will also encourage more primary health care professionals to participate in the NHSC by making scholarship funds tax free.

The President's budget includes a request of $126 million, in increase of $1.05 million over fiscal year 2001. These funds support NHSC clinicians serving communities, as well as outreach and development efforts in these communities. The funds will also provide for recruitment efforts: 265 Federal Scholarships, 286 Federal Loan Repayment agreements, 350 Federal Loan Repayment extensions, and 217 State Loan Repayment agreements. Since the program's inception, more than 22,000 clinicians have been providing services to millions of people in underserved areas. Currently, there are nearly 2,400 NHSC clinicians practicing in Health Professional Shortage Areas.

COMMUNITY HEALTH CENTERS

Question. On April 12, 2000, Governor Bush toured the Grace Hill Community Health Center in St. Louis. He used that occasion to propose increasing the number of new community and migrant health centers by 1,200 over 5 years in an effort to double the number of people served by these centers. The administration budget proposal, however, calls for 1,200 new "and expanded" centers and there is no longer a mention of doubling the number of people served. Moreover, the proposed increase of $125 million for fiscal year 2002 falls well short of the mark needed to increase funding by $3.6 billion over 5 years.

Is the Administration still committed to caring for the uninsured and most vulnerable Americans? How is the Administration proposing to reach its budget goal of $3.6 billion over 5 years?

Answer. The President's fiscal year 2002 budget for HRSA includes nearly $1.3 billion for the Health Centers program, an increase of $124 million above the fiscal year 2001 appropriation. These additional funds will allow Health Centers to create 200 new and expanded access points and serve up to 1 million additional patients, almost half of them uninsured. The added funds represent the first installment of the Administration's multi-year initiative, which will eventually increase or expand health center access points by 1,200 over five years and eventually double the number of people served.

The Administration has also proposed a refundable tax credit to make health insurance more affordable for individuals and families not covered by an employer plan nor eligible for public programs.

Finally, the Administration is developing ideas to improve the insurance options available to lower-income individuals. We are working with States to more efficiently utilize Medicaid and SCHIP funding to increase the number of individuals with access to affordable insurance, encouraging the availability of private group health plan insurance coverage where possible.

REAL CHOICE SYSTEMS CHANGE GRANTS

Question. Last year, the Appropriations bill included $50 million for Real Choice Systems Change Grants. These grants had originally been included in MiCASSA (Medicaid Community Attendant Services and Supports Act) to help states reform their long term care systems to allow people with disabilities to live in their own homes and communities. In addition, another $20 million for demonstration projects to achieve this same goal.

HCFA announced the Real Choice funds should be used to develop public-private partnerships to increase services and supports to people with disabilities. Will HCFA ensure that people with disabilities, their representatives and their families are members of the grant-funded state task forces? Answer. We have tried to be very clear that Congress expressed its intent for States to develop their proposals jointly with a consumer task force of broad representation. We will honor that intent, while simultaneously affording states with sufficient flexibility in the methods of involvement that they can get the job done. For example, some states have asked if their existing ADA/Olmstead planning committee could be used. Where such committees include broad-based consumer representation, we have answered affirmatively. HCFA also made the involvement of consumers an important aspect of its review criteria for the grants. Finally, we made $50,000 "Starter Grants" available to states in February in order to help defer some of their initial planning expenses, particularly expenses associated with stronger efforts to involve people with a disability. We hope these efforts are successful in helping states achieve a robust level of consumer involvement.

Question. Would you endorse the continuation of these dollars for the purpose of funding similar grants -and demonstration projects in 2002?

Answer. No. These grants were designed to be one-time grants to assist States in their effort to allow people with disabilities to live in their own homes and communities. We believe that the funding provided in fiscal year 2000 is sufficient to achieve this goal.

COMMUNITY ATTENDANT SERVICES AND SUPPORTS

Question. Secretary Thompson expressed strong support for community-based services for people with disabilities and the elderly during his confirmation hearing. In Wisconsin, he championed the FamilyCare program to provide comprehensive long term care services to people with disabilities and the elderly. In Iowa there has also been an effort to provide more community-based services to people with disabilities and the elderly. Just last week, the Iowa Department of Human Services released a draft of the State's Olmstead plan. And, the state is implementing the Ticket to Work and Work Incentives Improvement Act.

Both of these initiatives reflect a strong policy consensus—both nationally and in Iowa—that people with disabilities should have the opportunity to live in the community and go to work.

In order to provide people with a real choice to live in the community, however, many individuals with disabilities and the elderly need access to attendant services and supports. Many states provide such services through waiver programs, but they are often not Statewide or comprehensive in coverage. As a result, people remain inside institutions or are on long waiting lists for appropriate community services.

There is a strong policy consensus that our long term care system is in need of reform. Senator Specter and I are in the process of drafting a revised version of Medicaid Community Attendant Services and Supports Act that would provide states increased resources for community attendant services and other activities that would ultimately remove the institutional bias of the current Medicaid program.

Is HCFA willing to work with us on this issue? How can the federal government help states create a Medicaid long term care system that allows people with disabilities and the elderly the opportunity to live at home and in the community? Answer. We believe that the stimulus provided by the Congress in the form of "Systems Change" grants to States in fiscal year 2001, coupled with Department's work to more expeditiously process and approve waiver applications, will allow States the opportunity to make additional investments in home and community-based services. Additionally, we anticipate that this work will support the emergence of effectively working systems that provide States the ability to provide cost-effective long-term supports.

QUESTIONS SUBMITTED BY SENATOR HARRY REID

CHRONIC DISEASE TRACKING SYSTEM

Question. Fallon, a small town in my home State of Nevada, is facing a terrible tragedy. In the last 4 years, 12 children have been diagnosed with leukemia, eight of them in a single year (2000), significantly more than would be expected in this small community. The families are angry and scared and have very real concerns that there may be some connection between this cluster of cancer and the environment, but currently neither the Environmental Protection Agency nor the Centers for Disease Control or other involved Agencies in the Department of Health and Human Services can offer any answers. Two weeks ago the Committee on Environment and Public Works held a field hearing in Fallon, and the witnesses, including representatives of the Centers for Disease Control, Agency for Toxic Substances and Disease Control and Environmental Protection Agency, and many State officials, supported my call for comprehensive disease tracking and rapid response capability.

We had report language in last year's bill that requested CDC put together a plan for a chronic disease tracking system that looked at environmental factors. I look forward to receiving and considering CDC's report on this in the near future. And, I especially want to ensure that, as CDC moves toward implementation of its plan, it will do so in an integrated manner, not parcel the disease tracking network up into separate silos. I do not want this to become a battle between fiefdoms, but rather a comprehensive health tracking system to protect the nation's health.

How are you going to make sure that this tracking system is put together in a strategic way and establishes a coordinated and comprehensive network?

Answer. In the fiscal year 2001 appropriations report, CDC was asked to report back to this committee on plans to respond to the findings of the Pew Commission. In response, CDC's National Center for Environmental Health formed three CDC workgroups with membership from across CDC. The workgroups are in the midst of their work. One important next step is to begin a dialogue with our federal, state, local and public partners to further define the core functions of what a tracking system would do and how it would be implemented. A second step would be to begin planning to develop guidance and protocols for responding to disease clusters that may be related to the environment. CDC will work closely with State and Local Health Departments, professional organizations, e.g. CSTE, ASTHO, to develop these protocols and guidance.

Question. Is this a priority? I heard at the hearing last week that Fallon is not alone, that there are many other communities in the country that are facing unexplained disease clusters.

Answer. CDC is working diligently with existing funds to define core functions and develop guidelines so that CDC can provide leadership to the main organizations who would be involved in this effort.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you very much, that concludes the hearing. The subcommittee will stand in recess until 9:30 a.m., Thursday, April 26, when we will meet in room SH–216 to hear from the Secretary, Department of Labor, Elaine L. Chao.

[Whereupon, at 10:08 a.m., Wednesday, April 25, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, April 26.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

THURSDAY, APRIL 26, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SH–216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Harkin, and Landrieu.

ERGONOMICS

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The Hearing of the Appropriations Subcommittee on Labor, Health, Human Services and Education will convene. This special hearing has been set on the subject of ergonomics.

Preliminarily, I want to note that we had an enormous group in the corridor. I have not seen a line that extends so far to Constitution Avenue since Bill Gates Junior came to a hearing here a couple of years ago. And I was a little mystified to walk in and see the seats empty here and all of the taxpayers in the corridor.

And I asked why people hadn't come in and I was told you were looking for an invitation. Well, let the record show you don't need an invitation to come to a public hearing. You don't even have to show your tax receipts.

I'll just take judicial notice or senatorial notice that you are all taxpayers.

Today's hearing is on a very complicated subject. It has been convened to try to move the process forward as expeditiously as possible. I had thought that the issue of ergonomics was resolved in our conferences on this subject, which go back many years where we delayed the promulgation of a regulation and had an enormous number of arguments until the regulation was supposed to have been final.

But as George Schultz once said, nothing is final in Washington. And we have what I consider to be an area of necessary governmental action.

We held an ergonomics hearing when the matter was listed for revocation. Those Senate floor proceedings came up on short notice, so we had a hearing with a number of witnesses and found that

the subject was very, very complicated and required a lot more inquiry.

We have a great many witnesses today. What we are going to try to do is focus in on questions, with concise testimony from panelists. We welcome the new Secretary of Labor, Secretary Elaine Chao. My distinguished colleague Senator Harkin has arrived, so I will turn to him for an opening statement.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman and Secretary. It is good to see you again. I am glad to see we have a good turnout here today for this hearing because this is an extremely important hearing. And I thank you, Mr. Chairman, for holding this hearing.

I want to thank also AFL–CIO and the National Academy of Sciences and all who are here from the science and labor community for coming to testify today.

First, I want to make as clear as I possibly can how disappointed I was that Congress and the President took the extreme action of repealing this very important worker safety standard.

More than 2 million American workers each year report work-related MSDs and half of them lose time because of these injuries. The ergonomic standards would have cut those numbers drastically. And we are talking about cashiers, nurses, cleaning staff, assembly workers in manufacturing and processing plants, computer users, clerical staff, truck drivers, and meat cutters.

And this is not just a labor issue, it is a women's issue because women are the hardest hit. Women make up 47 percent of the workforce. But in 1998, they accounted for 64 percent of the repetitive motion injuries and 71 percent of reported carpal tunnel syndrome cases.

A good example is Gloria Boyd from Waterloo. She worked 9 years on the assembly line in a pork processing plant. She has got carpal tunnel so bad she can hardly pick up anything heavier than a cup of coffee. Tell her, tell her that we do not need an ergonomic standard. Someone tell her and tell her family that, would they.

This is a 15-page rule. And I have seen pictures of people waving huge stacks of paper around. I have seen pictures of them holding up big stacks of paper saying, Oh, this is how burdensome this was; when this is it, 15 pages; 15 pages, not 200.

Second, this was a complaint-based rule and very flexible according to each workplace and job as a result of exhaustive studies we know of over a decade. Some of my colleagues kept calling for more studies of ergonomics and repetitive stress disorders.

What did we do? We kept authorizing more studies. Another National Academy of Science has studies in 1997, after two more before that. Then we continued to want to delay the rule. Well, the NAS study of the studies, the study of the studies came out in January.

Once again, the National Academy of Science has found there is strong scientific evidence that workplace exposures cause musculoskeletal disorders and they can be prevented. So I am glad that the National Academy of Science is here today to present these findings.

What more do we have to do to prove that America's workers are suffering from these repetitive stress disorders and that there are reasonable ways to prevent them.

With the attitude that seems to be prevalent around this town today, I doubt if we could get a hard hat rule through like we did 30 years ago, no, 40 years ago, 30-something years ago, get a hard hat rule through. Probably could not even get that today.

Well, yesterday, Madame Secretary, I understand you received a petition signed by labor unions, civil rights organizations, women's groups, occupational health and safety groups, that urged the Administration to make it a priority to issue a new ergonomics standard.

It should not be that hard. We have studied it for over a decade. We have got all the scientific basis on it. The work has been done.

Madame Secretary, I am told that you yourself said that work-related repetitive strain injuries account for more than a third of job injuries. And I think this is a quote from you. I did not hear it but I read it, that we need a solid comprehensive approach to new ergonomics rules.

Well, that is an encouraging statement. I want to know why the standard that was issued was not solid and was not comprehensive. And I would like to know what you are going to do and how soon you are going to do it.

It is not enough, I do not think, to say that we are going to look at this some more. I would like to know a deadline. I would like to know when. And that is a question I am going to be asking you is when are you going to set a deadline for having a new rule.

We have gone long enough. Many of our women, our workers, are suffering lifetime injuries because we delay and we delay and we delay and we delay. And we shove it under the carpet, refuse to deal with it.

So if there are some things wrong with the last rule, I am more than willing to listen, more than willing to take into account any problems that may have been in it. But I do not want to see this as an excuse to delay and delay and delay longer.

If things need to be fixed, let us fix them. I know the chairman. He believes in worker health and safety as much as anyone around here. And I know that we would work together. I think we could work bipartisanly up here, but not if it just means we are just going to dribble along year after year after year and not get anything done.

If we have a deadline and you have got solid suggestions, we are more than willing to take a look at it. It is 2001. It is time to put this sad chapter, this very sad chapter in ignoring the legitimate rights of our people to have a rule that will protect them, that will encourage businesses to make the modest minor changes necessary to cut down on repetitive motion disorders, musculoskeletal disorders in the workplace.

With that, I thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Let us refrain from applause. Let us not have any displays here. Let us approach this hearing on a scientific basis and try to figure out what the facts are and what the public policy ought to be.

Let us not have any teams on one side or another. Secretary Chao, we welcome you here. We are going to limit very strictly the witnesses because we have enough to occupy more than the day. Our general rules are 5 minutes. We look forward to what you have to say.

STATEMENT OF ELAINE L. CHAO, SECRETARY, DEPARTMENT OF LABOR

ACCOMPANIED BY JOSEPH WOODWARD, ASSOCIATE SOLICITOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Secretary CHAO. Thank you, Mr. Chairman and Senator Harkin, and other members of the subcommittee. Thank you for inviting me to testify about the need to reduce musculoskeletal disorders in America's workforce.

With me today is Joseph Woodward. He is the Associate Solicitor for OSHA, the Occupational Safety and Health Administration.

When I testified before the Senate Health, Education, Labor, and Pensions Committee at my confirmation hearing about 3 months ago, I spoke about the challenges of preparing America's workforce for the emerging realities of the 21st century workplace.

The Department of Labor must remain in step with the dramatic changes in our economy to fulfill its responsibilities to our workforce. And to meet this goal, I have established five priorities for the Department.

One, is to ensure the safety of every workplace; Two, to guarantee an honest day's pay for an honest day's work; Three, to fight discrimination; Four, to protect workers from coercion and intimidation; and Five, to make sure that workers' compensation and pensions are protected.

That first goal listed above, to ensure the safety and health of every workplace, is my top priority. And it will remain so throughout my tenure as Secretary of Labor.

But I am also committed to bringing the workforce of the 21st century in step with the needs and realities of our modern economy. And it is clear that the workplace of today is very different from the workplace as it existed when the Department of Labor was created in 1913.

Today's employees are better compensated, better treated and work fewer hours. They are also better trained, more productive and more knowledgeable. And we must continue training a more productive workforce in order to continue producing a better compensated workforce.

And so in that vein, I cannot resist a brief commercial for the Department's upcoming 21st Century Workforce summit to be held at the MCI Center on Wednesday, June 20 of this year. You are all invited to join us as what is supposed to be and what promises to be an extremely productive and rewarding day to talk about training and development for the 21st century workforce.

The workforce of the 21st century today is not only better off financially than it was a century ago, it is also far better off from a safety perspective. In 1913, the year the Department was founded, the Bureau of Labor Statistics, part of the Department of Labor, documented 23,000 industrial deaths among a workforce of 38 million people. This is equivalent to a shocking 61 deaths per 100,000 workers.

In 1999, the latest year for which figures are available, the Bureau of Labor Statistics reported 6,023 deaths among a workforce of 134 million people or fewer than 5 deaths per 100,000; fewer but still too many.

These numbers demonstrate that we have made great strides in improving worker safety over the last century. And the Department of Labor as well as our Nation as a whole should be commended for its commitment to improving worker safety.

But these improvements also demonstrate that the new century and the new workforce require a new approach to the safety needs of the American workforce, an approach based on collaboration and prevention rather than the antiquated adversarial approach of years past.

OSHA has a finite budget of $425.4 million in fiscal year 2001. Securing the cooperation of employers and employees can help us to leverage the effectiveness of our resources.

For example, several employers recently shared with us how they have implemented their own ergonomics programs in collaboration with their workers, and some with the assistance of OSHA's consultative services.

The administration asks that OSHA place a greater emphasis on preventing injuries through compliance, assistance and cooperation, such as education, training and technical assistance programs, rather than relying on command-and-control enforcement.

Because we are in a new century and facing a new kind of workforce issue, it is very important that the Department of Labor proceed carefully on the ergonomics question. As we begin this new century, it is important to bring the stakeholders together, work on creating a common knowledge base and a clear recognition of the need for a consensus approach to this issue.

Since the Department has seemingly been looking into this issue for so long, I think it might be helpful to lay out some of the history to give everyone a sense of the time line, and the controversy.

Senator SPECTER. Madame Secretary, we are interested in the history but the time is very short. The red light has been on. Could you summarize. Your full statement will be made a part of the record.

PREPARED STATEMENT

Secretary CHAO. My full statement will be made a part of the record, as you requested. And I will be more than happy to answer any questions you have.

[The statement follows:]

PREPARED STATEMENT OF HON. ELAINE L. CHAO

Mr. Chairman, Members of the Subcommittee, thank you for inviting me to testify about the need to reduce musculoskeletal disorders in America's workforce. With me today is Joseph Woodward, Associate Solicitor for Occupational Safety and Health.

When I testified before the Senate Health, Education, Labor, and Pensions Committee at my confirmation hearing three months ago, I spoke about the challenges of preparing America's workforce for the emerging realities of the 21st Century workplace. The Department of Labor must remain in step with the dramatic changes in our economy to fulfill its responsibilities to our workforce.

To meet this goal I have established five priorities for the Department:

—to ensure the safety of every workplace;

—to guarantee an honest day's pay for an honest day's work;

—to fight discrimination;
—to protect workers from coercion and intimidation; and
—to make sure workers' pensions are protected.

That first goal listed above, to ensure the safety and health of every workplace, is my top priority; it will remain so throughout my tenure as Secretary of Labor. But I am also committed to bringing the workforce of the 21st century in step with the needs and the realities of our modern economy. It is clear that the workplace of today is so very different from the workplace as it existed when the Department of Labor was created in 1913. Today's employees are better compensated, better treated, and work fewer hours. They are also better trained, more productive, and more knowledgeable. We must continue training a more productive workforce in order to continue producing a better-compensated workforce. In that vein, I cannot resist a brief commercial for the Department's upcoming 21st Century Workforce summit, to be held at the MCI Center on Wednesday, June 20 of this year. You are all invited to join us at what promises to be an extremely productive and rewarding day.

The workforce of the 21st century is not only better off financially today than it was a century ago; it is also far better off from a safety perspective. In 1913, the year the Department was founded, BLS documented 23,000 industrial deaths among a workforce of 38 million people—equivalent to a shocking 61 deaths per 100,000 workers. In 1999, the latest year for which figure are available, BLS reported 6,023 deaths, among a workforce of 134 million people, or fewer than 5 deaths per 100,000. Fewer, but still too many.

These numbers demonstrate that we have made great strides in improving worker safety over the last century. The Department of Labor, as well as our nation as a whole, should be commended for its commitment to improving worker safety. But these improvements also demonstrate that the new century, and the new workforce, require a new approach to the safety needs of the American labor force, an approach based on cooperation and prevention, rather than the antiquated, adversarial approach of years past.

OSHA has a finite budget of $425.4 million in fiscal year 2001. Securing the cooperation of employers and employees can help us to realize a substantial return on our resources. For example, several employers recently shared with me how they have implemented their own ergonomics program—some with the assistance of OSHA's consultative services. The Administration asks that OSHA place a greater emphasis on preventing injuries through compliance assistance and cooperation, such as education, training and technical assistance programs, rather than relying on command-and-control enforcement.

Because we are in a new century and facing new kinds of workforce issues, it is very important that the Department of Labor proceed very carefully on the ergonomics question. As we begin this new century, it is important to bring the stakeholders together, work on creating a common knowledge base and a clear recognition of the need for a consensus approach to this issue.

TIMELINE

Since the Department has seemingly been looking into this issue for so long, it might be useful to lay out some of the history, to give everyone, the Congress and the American people a sense of the timeline, the controversy, and the activities over the last twenty years. As you all know, last month, under the Congressional Review Act, Congress repealed OSHA's ergonomics standard. In signing the repeal, the President emphasized that this Administration supports activities that will address the critical challenge of reducing musculoskeletal disorders.

The repeal is only the latest action in the Department's two-decade history with this issue, dating back to the hiring of the Department's first ergonomics specialist back in 1979. You may be interested to know that that individual remains a valued Department of Labor employee.

Since then, OSHA has been working steadily to determine the best possible position for the Department of Labor to adopt in order to ensure the health and safety of the American worker. As the history shows, the Department and Congress have been operating on a collision course for a number of years now, and this movement forward without a consensus has put us in the predicament we are in today. At this point it would be appropriate to submit into the record a timeline covering some of this history.

The timeline I have just submitted is very useful in laying out the history of the ergonomics standard. This history helps demonstrate why the original standard failed—the rush to action, the lack of consensus, and the continual forward movement despite repeated congressional expressions of disapproval. This history makes

it clear why we need to take our time and to achieve a greater level of consensus before proceeding.

WHY ERGONOMICS FAILED

It is vitally important that we avoid a repeat of the last ergonomics standard. It would be wise to consider the factors that preceded last month's vote by Congress before charting a new course. OSHA should not rush when producing a new, comprehensive approach to ergonomics.

Last year, OSHA was asked to complete promulgation of the previous standard in an unreasonable period of time. Many have stated that this was a standard that began in the late 1980's under former Secretary of Labor Elizabeth Dole. Now, we know that the Department actually began looking at this issue in 1979. We also know, however, that the new proposed rulemaking was announced in November 1999 and made final in November 2000. Within that same 12-month period, OSHA received over 11,000 written comments on this rule, making up 188,547 pages. Piled on top of each other, these comments and supporting documents would be 78 and a half feet high. In fact, standing on top of this stack without a safety harness would probably constitute an OSHA violation.

These thousands of pages of documents include complex scientific and mathematical analyses that only experts can understand. As you can see, this display illustrates just how complex this issue really is, and how much interest was generated by the last proposal. The rush to make the standard final, however, forced OSHA to rely heavily on contractors to assist in the review of these documents. The government has a responsibility to listen to the people, especially the regulated community.

Cost, scope of coverage and state jurisdiction were also concerns of the previous standard. The disparity between OSHA and private sector cost estimates approached $100 billion. As a result, the Department will consider having future cost estimates reviewed by an independent entity. The previous standard attempted to cover a large number of businesses. The Department could help lower the overall cost by focusing on high-risk occupations. State jurisdiction should also be preserved by permitting States to administer workers' compensation programs without Federal intervention by OSHA.

DEPARTMENT ACTIVITIES SINCE CRA

In determining how best to proceed from this point, it is best to take advantage of the expertise and experience of all parties involved in the issue. Since becoming Secretary, representatives of unions, employers, safety and health professionals, Congress, and members of the medical and scientific communities have all come to the Department to share their thoughts on how to develop an effective strategy to further reduce—and eventually eliminate—these injuries. The OSHA career staff also provided a brief on the tools currently available under the Occupational Safety and Health Act. I look forward to continuing discussions about the best method for balancing the needs and concerns of management and labor while improving the health and safety of America's workers.

Some of the groups with whom we have met regarding this issue during my short tenure as Secretary of Labor include:

—The president & workers from the United Commercial and Food Workers Union
—The AFL–CIO
—The Service Employees International Union
—The United Brotherhood of Carpenters & Joiners
—The United Brotherhood of Teamsters
—The Hotel Employees & Restaurant Employees International Union
—The Frozen Food Association
—The American Occupational Therapy Association
—The Food Marketing Institute
—The American College of Occupational and Environmental Medicine
—The American Society of Safety Engineers

In addition, we have also had extensive and multiple briefings with the dedicated career staff at OSHA to discuss the Department's activities and options on ergonomics.

Finally, I would add that I am especially pleased to appear here before you today. I consider meeting with Congress to be an important part of listening and learning process on this subject.

One thing is clear from these meetings: there is no consensus on the ergonomics issue. The stakeholders who have come to the Department of Labor to discuss ergonomics are coming from completely different positions, ranging from those who

want no action to those who thought that the previous rule did not go far enough. In fact, after my testimony, you will hear from a number of other witnesses who I expect will demonstrate the full range of these widely divergent points of view. And therein lies the problem. This diversity of opinion suggests that precipitous action is not the wisest course at this time. If we want to find more common ground on this issue, we will need to engage in more discussion and analysis, and we will need more data.

PRINCIPLES

That said, we still do know a lot, and enough to begin thinking about the kinds of approaches that could work, and more importantly, the starting point from which we want to launch further activities. If we are to find common ground, it is important that there is at least general agreement on certain facts and philosophies before we reengage in the process that was reversed last month with the passage of the CRA resolution. A great deal of resources, both in and outside the Department, went into creating the ergonomics standard. Under the CRA, the Department is now precluded from producing any standard that would be "substantially the same." Before we expend valuable—and limited—resources on a new effort, we should agree on general principles that the Department will follow in creating a new ergonomics approach that fits the new 21st century workforce. These principles will provide a vital starting point for common understanding, a point from which we can hope to find common ground:

1. Prevention.—Everyone can agree that reducing occupational injuries is our top priority. Fortunately, there is good news on this front. Recently, the Bureau of Labor Statistics (BLS) released new data on job-related injuries and illnesses for 1999. The data show that there has been a continuing decline in musculoskeletal disorders that result in employees missing time from work. Employers reported 582,300 such injuries in 1999, down from 592,500 in 1998 and from more than 763,000 in 1993. This 25 percent decline has occurred even though more Americans were in the workforce. While I'm encouraged by this progress, I also recognize that musculoskeletal disorders remain nearly one-third of all work-related injuries. The Department should examine why these rates continue to decline, even in the absence of a specific ergonomics standard and while the number of annual OSHA inspections remains steady.

Clearly, more needs to be done to address the hazards that cause these injuries. My goal is for the Department to develop an approach that will focus efforts on preventing injuries before they occur, rather than simply reacting after workers are hurt. We would much rather prevent an injury than fine an employer in the aftermath of that injury.

OSHA has a finite budget of $425.4 million in fiscal year 2001. It is impossible to inspect every workplace with this limited budget. This money is more effectively spent, and protects more workers, if it is focused on prevention efforts. Prevention, education and training are the most effective methods for providing the maximum amount of protection to the greatest number of workers.

2. Sound Science.—Any Departmental action should be based on the best available science and research. In the previous Administration's rush to issue an ergonomics standard, they acted before the completion of a National Academy of Science study that would have provided all stakeholders with more information on the ergonomics standard. In the future, the Department should make sure that it makes determinations based on the best available science.

3. Incentive-Driven.—OSHA has stated that 95 percent of employers are acting in good faith. Employers understand that best safety practices are good for business and are in the best interests of their workers. Any approach should be centered on cooperation between OSHA and employers, rather than an adversarial relationship.

OSHA's efforts with the meatpacking industry over the last 10 years demonstrate how successful a voluntary approach to ergonomics can be. In 1990, OSHA published ergonomics guidelines for the red meat industry, "Ergonomics Program Management Guidelines for Meatpacking Plants." One of the reasons the Agency chose to publish guidelines for this industry was the unacceptably high injury rate to its workers—20.2 cases per 100 employees. Many of these injuries were musculoskeletal disorders.

Many firms in the meatpacking industry used these guidelines and voluntarily implemented programs in an attempt to decrease ergonomic injuries and lower their annual workers' compensation premiums. Over the last 10 years, the case rate of total recordable injury cases dropped 39 percent, from 20.2 cases per 100 full time workers in 1989 to 12.3 per 100 full-time workers in 1999. The case rate for injuries

involving days away from work also dropped substantially over this period, from 6.5 per 100 full-time workers to 2.0—a decrease of 70 percent.

Although these guidelines initially arose from an OSHA enforcement action, this experience does demonstrate the potential effectiveness of voluntary, industry-specific ergonomics suggestions, especially in industries where the prevalence of musculoskeletal disorders is greatest.

4. Flexibility.—We must recognize the unique nature of individual workplaces—avoiding an unworkable one-size-fits-all approach. The comments DOL has received demonstrate that one of the biggest weaknesses of the failed standard was its universal nature. Every workplace is different and will need different tools and approaches to prevent ergonomic injuries.

5. Feasibility.—Small businesses complained that the cost of the previous standard, estimated by the Department at upwards of $4 billion, and by private sources at up to $100 billion, would have imposed a crushing burden on them. Small businesses need the Department to recognize the costs of compliance and the economic constraints faced by small business.

6. Clarity.—The ergonomics standard took up over 600 pages, including preambles and appendices in the Federal Register. While the standard represented only a portion of these, small business owners faced with the entire 600 pages of supporting documents were understandably frightened. Small business owners lack the legal resources to understand what is required to comply with complex regulations. As a result, any approach to ergonomics must include short, simple, and common sense instructions for employers and their employees.

WHAT'S NEXT?

The Department of Labor understands that there is some Congressional interest in addressing ergonomic injuries through legislation. We ask for your patience. This is a new Administration. We have made it our priority to review and understand this issue by taking the time to meet with stakeholders, listen carefully to their concerns and construct principles that guide us to a comprehensive resolution. While the Department is making significant progress, it will take time for us to effectively complete our goal.

Defining the best, comprehensive approach for ergonomic injuries is not a simple process. Occupational physicians explain that ergonomics involves soft tissue—including tears, scarring or inflammations, which can all be generated in places other than the workplace. While the Department is focused on addressing ergonomic injuries acquired on the job, determining where a worker developed a tissue strain is still subject to much debate. There is no set formula. No table exists. There is no equation that permits us to simply plug in a worker's injury and instantly determine its history. Because of the great difficulty of identifying many ergonomic injuries and establishing causality, these kinds of cases can require more investigative resources than traditional workplace injury cases.

The Department of Labor wants to work with Congress in charting the best course of action. The Department is here today because it is committed to providing necessary protections to workers against ergonomic injuries. We applaud you, Mr. Chairman, for holding this hearing, and look forward to working with you and hearing any suggestions you have for providing a sufficient remedy.

Senator SPECTER. Well, in the interest of brevity and to move on to the substantive witnesses, I am just going to ask you one question with two parts. When do you anticipate having a regulation finished, and what are the appropriate monitoring steps during the course of the time line from now until the date you expect to conclude?

Secretary CHAO. Mr. Chairman, I would love to give you a time line and a deadline. A time line we have a better handle over. A deadline I do not think would do any one of us any particular good in trying to accomplish the goal of reducing ergonomic injuries.

We have seen in the past an artificial deadline unreasonably imposed would in fact not bring about the result that we all share. We are all in favor of reducing injuries. I totally agree with you——

Senator SPECTER. Well, can you give us a time line? You say you have a handle on a time line but cannot give a deadline.

Secretary CHAO. Well, I think any regulation that goes through OSHA depending on the scope, the complexity, whatever the particular——

Senator SPECTER. Secretary Chao, would you take a look at the scope and complexity and the history and give us a deadline or a time line.

Secretary CHAO. I am not able to do that, sir. I am sorry. I am unable to do that. I don't think that is a responsible way to proceed.

Senator SPECTER. Senator Harkin?

Senator HARKIN. Madame Secretary, I guess what I am hearing is that this is just going dribble on for another 10 years. Is it going to be 10 years or 5 years?

Secretary CHAO. No, I do not have that kind of plan in mind.

Senator HARKIN. 2 years?

Secretary CHAO. Sir, with all due respect, I know that you would like for me to say a specific deadline. I would be more than glad to do that if that were a responsible course of action.

Unfortunately, that is not a responsible course of action in my eyes. I want to do what is right. And the Department is unable to come to a definitive deadline. And maybe what we can do is I will ask, if I could, and I hate to put him on the spot, but Mr. Joe Woodward is the Associate Solicitor.

Senator SPECTER. We do not want to put anybody on the spot and we do not want to have a protracted debate about it.

Secretary CHAO. Fine.

Senator SPECTER. There is a deadline on my term. It is 6 years. There is a deadline on the President's term. It is 4 years. And I do not think it is asking too much when this subcommittee asks you for a deadline.

What I want you to do, if you will not interrupt me, Madame Secretary, is to go back to the drawing boards and see if you can give us some estimate as to when it is going to be concluded.

Secretary CHAO. I will do that. May I just add a few words please?

Senator SPECTER. Of course.

Secretary CHAO. In my testimony, and I wish that people would read the testimony, because the testimony was put together with a great deal of thought and care, not for the purpose of delaying. Because this testimony really lays out in depth our concern with the subject, our desire to move forward in a responsible fashion.

I think one of the problems that has occurred in the past is that there has not been consensus. And despite repeated appeals from Congress to the Department on acting in a way that is responsible to them, those steps have not been taken. And I am not saying anything bad about the department professionals. I am saying that there were other forces at work.

And so I think if we were to proceed again without due consideration of all the various interest groups that are involved, I do not think we are going to be crafting something that will be sustainable and that will be longstanding.

Senator SPECTER. Madame Secretary.

Secretary CHAO. We are going to end up exactly where we were prior to March 20. And that is not what I want. I want to do what is right.

But I think a consensus of some sort has to be brought together. I have met with all different kinds of groups. And the diversity of opinions is truly vast. We have people on one spectrum who do not want to do anything.

Senator SPECTER. Madame Secretary.

Secretary CHAO. I do not agree with that.

Senator SPECTER. You are repeating yourself. And we do not have time for that. Consensus is fine, if you can get it. Consultation is what you have to do. That can be accomplished in a time frame.

Around here, we all work under time pressures. We work on a budget under a time pressure, and we work late, and we have a vote-a-rama, and we have a schedule on appropriations, and we have a fiscal year, and we have to meet deadlines.

And consensus is great if you can get it, but there are many regulations. Most regulations are issued without consensus. If you could come to consensus, you would not need to have a Department of Labor or a subcommittee or proceed with these hearings.

I want to proceed to call the first panel of witnesses. Senator Harkin, you want one more question. OK.

Senator HARKIN. Madame Secretary, since you say you are going to pursue this——

Secretary CHAO. Yes, of course.

Senator HARKIN. I had my staff look at your budget.

Secretary CHAO. Yes.

Senator HARKIN. How much is in your budget that you have devoted to this effort?

Secretary CHAO. We have a total OSHA budget of $425 million.

Senator HARKIN. I know what your total budget is. I want to know how much you have devoted to an expeditious review of and culmination of the effort to issue a new standard.

Secretary CHAO. I do not have that number with me. I will be more than glad to get it for you.

Senator HARKIN. And would you submit that to this Appropriations Committee.

Secretary CHAO. I certainly will.

Senator HARKIN. I would like to see how much money and resources you are devoting to this specific effort.

Second, I have read your statement over. And what I do not see in your statement, I do not see anything in your statement that says here is what was really wrong with the rule that was promulgated, point by point, and here is how we fix it.

Now, could you submit that also for the record. I want to know precisely what it is in this 15 pages of rules that you think are wrong and that need to be corrected. Could you submit that for the record?

Secretary CHAO. The Congressional Review Act was the action that nullified the rule making.

Senator HARKIN. I understand that. I understand that.

Secretary CHAO. That is not our department. We did not nullify the rule making. In fact——

Senator HARKIN. But you are supporting that. And you are saying that that was the correct course of action to take. You are saying it was correct to have thrown this rule out. That is what you are saying.

Secretary CHAO. Well, the rule has been deemed null and void.

Senator HARKIN. Yes.

Secretary CHAO. That does not mean that a new rule——

Senator HARKIN. But you are saying you support that, do you not? You support that.

Secretary CHAO. The administration supports that and I support that. Yes. Because I think a consensus, some kind of consensus is necessary for us to be able to move forward. Because if we do not find some commonality of interests, the Congressional Review Act will once again be invoked. And any new rule will be void and nullified.

Senator HARKIN. I think——

Secretary CHAO. I am concerned about the workers. If we want to really find a solution to reduce the injuries, we have to be able to find——

Senator SPECTER. I regret interrupting but we have a lot of witnesses. And I think you have asked an appropriate question as to what the Secretary disagrees with in the regulations.

We all know what the Congress did. If you would care to respond to that, we would appreciate it. But we are not going to have a political debate here.

Secretary CHAO. You are right.

Senator SPECTER. That is what we are not going to do. What we are going to do is try to identify what can be done to protect workers. And we have experts here on a wide variety of subjects that is just staggering, including: work-related musculoskeletal disorders, work-related MSDs and interventions, cost benefits and feasibility of economic standards and options for new ergonomics standards.

You have expressed yourself on consensus, Madame Secretary. We understand that. Speaking only for myself, if you can get consensus, that is wonderful. If you cannot, you are going to have to make a decision as the Secretary of Labor, and then Congress is going to review that. Those are our procedures.

I would like to call the second panel now: Mr. Fellner, Dr. Bigos, Dr. Hadler, Miss Seminario, Mr. Evanoff and Ms. Eberhardt.

Let us begin, Mr. Fellner, with a question as to what are musculoskeletal disorders, if any, which require Department of Labor regulation.

STATEMENT OF BARUCH A. FELLNER, ESQ., PARTNER, GIBSON, DUNN & CRUTCHER, LLP

Mr. FELLNER. Senator Specter, it is a pleasure to be before the committee this morning and to participate in this important hearing. If I may, before I get to your question, may I put it in the context of the 5-minute statement that it was my impression we all had an opportunity to give this morning. And with respect——

Senator SPECTER. Yes, you may.

Mr. FELLNER. I will certainly respond.

Senator SPECTER. It would be the committee's preference that you focus on the subject matter for Panel 1 which I have just articulated.

Mr. FELLNER. And with pleasure. I will focus on that, but I would like to put it in the context of my statement with your kind permission, sir.

Senator SPECTER. I have already given you that. Proceed.

Mr. FELLNER. On March 6, the distinguished chairman convened a special hearing to examine the issues surrounding OSHA's now rescinded ergonomics standard.

During the course of that hearing, I suggested that the next step in determining what course the Department of Labor should take should be an open and honest and exhaustive debate on the science and economics, a course of action rejected by OSHA in the prior administration.

We are delighted, we are honored to participate in the beginning of that process and to be part of such a distinguished panel of experts.

Given the scope of the issues, this process obviously cannot begin and end in a single day. We expect that this open dialogue and hopefully consensus will continue in the Department of Labor under the able leadership of Secretary Chao. We do not expect the answers to be easy.

The more one becomes familiar with these issues and their complexity, the more difficult it becomes to find areas of common ground.

And I would like to introduce this debate, Mr. Chairman, by outlining some of the many issues about which there is considerable disagreement first.

The nature of the problem broadly referred to as musculoskeletal disorders or MSDs is poorly defined. And Senator Specter, if I may, the problem and its definition runs the gamut from the definition of the National Academy of Sciences of disorder, and that is what we are talking about today, Senator, musculoskeletal disorders which is an alteration in an individual's usual sense of wellness. That is the NAS definition. That is their amorphous definition.

OSHA, on the other hand, has defined musculoskeletal disorders as injuries and illnesses that affect muscles, nerves, tendons, ligaments, joints or spinal disks. There is not even an agreement on how to define the problem much less to cure it.

Number 2, you will hear extraordinary numbers today from the non-medical witnesses representing the other side, 1.8 million, 650,000 annually. I agree with those numbers, Senator.

If we are talking about an alteration in a sense of wellness, there are millions of those. If we are talking about illnesses, injuries, there are very, very few of those.

Number 3, even the strongest proponents of ergonomics recognize that work and non-work factors contribute to MSDs. Let me suggest in the interest of time that if a picture is worth a thousand words, then I invite the attention of this committee to two pictures, once again from the National Academy of Sciences; two pictures which describe the complexity of the factors and the risk factors that go into musculoskeletal disorders that include the physiology of the human being, the psychology of the human being, the me-

chanical factors to which he is exposed, the socioeconomic factors that the human being finds himself into.

And to suggest that one can pluck one factor, the physical factor out of this kaleidoscope of shards and regulate that one factor is with all respect, Senator Specter, an impossible task based upon the science that we presently know.

And speaking of that science, we do indeed have a distinguished panel. We have brought four eminent medical doctors and researchers, not representatives of the National Association of Manufacturers, not representatives of the Chamber of Commerce, not individuals who are after sound bytes, but rather the folks that know the science and will address the science. And the science is insufficient to support an ergonomic standard as we presently sit.

PREPARED STATEMENT

Moreover, and with this I will conclude, when one is dealing with the single-most expensive regulation in the history of the Department of Labor, and may I suggest with respect the greatest example of microengineering of the workplace in the history of this republic, the science better be sound before we proceed.

Senator SPECTER. Thank you very much.

Mr. FELLNER. With that, Senator Specter, I will conclude.

[The statement follows:]

PREPARED STATEMENT OF BARUCH A. FELLNER

Distinguished Chairman and members of the Subcommittee, I am a partner with the firm of Gibson Dunn & Crutcher. Since OSHA's inception almost 30 years ago, I have practiced safety and health law, having shaped OSHA's enforcement policy in the Solicitor's Office for its first decade and settled over 1,000 OSHA citations in private practice. I am firmly committed to a strong OSHA—one which is actively engaged in preventing accidents, illnesses and injuries in the workplace. On March 6, the Chairman convened a special hearing to examine the issues surrounding OSHA's now-rescinded ergonomics standard. During the course of that hearing, I suggested that the next step in determining what course of action the Department of Labor should take should be an open, honest and exhaustive debate on the science and economics—a course of action rejected by OSHA under the prior administration. We are delighted and honored to participate in the beginning of that process and to be part of such a distinguished panel of experts.

For the past eight years, OSHA has committed enormous resources with a predisposition toward promulgating an ergonomics standard and without objectively evaluating the underlying science, the costs, or the benefits of such a standard. In the recent rulemaking, OSHA hired more than 20 outside consultants to aggressively advocate its position and to criticize dissenting comments. The resulting ergonomics standard was perhaps single greatest experiment in social engineering in the history of the Department of Labor. The costs of the rule would have been staggering, and it had no clear scientific support. That standard is now rescinded.

But now we look to the future. This hearing is the first time there has been open and honest dialogue regarding the scientific foundations and economic implications of an ergonomics rule. Given the scope of these issues, this process obviously cannot begin and end in a single day. We expect that this open dialogue will continue in the Department of Labor under the able leadership of Secretary Chao.

We do not expect that answers will be easy to find. The more one becomes familiar with these issues and their complexity, the more difficult it becomes to find "areas of common ground." I will introduce this debate by outlining some of the many issues about which there is considerable disagreement.

—The nature of the problem—broadly referred to as musculoskeletal disorders or MSDs—is poorly defined. MSDs encompass a variety of perceived maladies and complaints that are not even described with consistent medical terminology. Some define MSDs as objectively diagnosed "injury." The National Academy of Sciences characterizes MSDs as "disorders" that result in "an alteration in an individual's usual sense of wellness or ability to function."

—Efforts to quantify the problem are hampered by the inherent difficulty of categorizing such diverse conditions and complaints. According to the Bureau of Labor Statistics, the bedrock of the claims that an MSD epidemic exists are principally based on 6 million employers interpreting one amorphous category: "sprains, strains and tears." That is a category that encompasses the traumatic and the cumulative, the objective and subjective symptoms, the disabling preexisting condition that has nothing to do with the workplace and the workplace incident that aggravates but does not injure. And almost all of these judgments are made by laymen. This is the stuff of soundbites, not science, as to the catastrophic state of ergonomic injuries.

—Even the strongest proponents of a standard agree that work and non-work factors contribute to MSDs. This NAS table is particularly helpful in showing the complex web of suspected influences. There is sharp disagreement, however, about the relative importance and contribution of these factors. The conclusions of scientific studies are inconsistent and difficult to assimilate because they involve so many different aspects of this multi-faceted issue.

—No single, scientifically validated "exposure-response" relationship exists to provide a quantitative basis for a standard. This is not lead or asbestos, where relative scientific certainty suggests a permissible exposure limit. Without this grounding, would-be regulators struggle between two equally unpalatable alternatives: a vague standard based on general goals such as a "material reduction" or making sure MSDs are not "reasonably likely to occur," and a more specific standard based on quantitative goals that lack scientific support.

—Those who espouse the benefits of ergonomics rely largely on anecdotal evidence. However, there is a dearth of scientifically supportable evidence—particularly scientifically reliable randomized controlled trials—on the effectiveness of ergonomics programs. When we were all in fifth grade, we learned the importance of the scientific method; we seem to abandon that method when we are engaged in social policy or social engineering. Anecdotal evidence of employee complaints is unreliable because it may be tainted by factors unrelated to safety or health. Research must focus on objectively diagnosed medical outcomes.

—Although the benefits of ergonomic controls are speculative, the costs are very real. Even the prior Administration estimated annual costs of more than $4.5 billion, making ergonomics the second most expensive regulation since OMB began its systematic review of regulatory impact. OSHA's estimate, moreover, was based on broad-brush estimates that ergonomic interventions will cost around $150 per job, when the agency had a long track record of seeking interventions costing many times that amount. Industry estimates suggested that the true total cost may exceed $100 billion, perhaps by many multiples.

As we set about for the first time to conduct an objective analysis of the science and economics of ergonomics, it is necessary to proceed without pre-formed notions as to the proper outcome. We hope that the Department of Labor will produce a detailed formal agency analysis that objectively and thoroughly considers all the evidence and comes to a conclusion about the appropriate government response, whether that be a comprehensive standard, a more narrowly targeted enforcement structure, a set of guidelines, or no action at all. The complete analysis and determination could then be published in the Federal Register and subjected to the open notice and comment process necessary to establish it as final agency action. When this process is complete, we believe that OSHA will find the current state of scientific knowledge woefully inadequate to support anything approaching the type of comprehensive standard-setting exercise recently rejected by Congress.

Senator SPECTER. Thank you very much Mr. Fellner. Proceed now to Dr. Stanley Bigos, Professor of Orthopedics, University of Washington. Dr. Bigos, the floor is yours.

STATEMENT OF DR. STANLEY BIGOS, PROFESSOR OF ORTHOPEDICS, UNIVERSITY OF WASHINGTON

Dr. BIGOS. Thank you. It is an honor to be here today to participate in an open examination of a federally mandated ergonomics rule. As a practicing orthopedic surgeon who deals with pain, a researcher and medical school professor, I have studied musculoskeletal problems for years and have engineered some of the principle studies regarding their causes.

Simply, I believe there is no scientific basis for a mandatory ergonomic intervention at the workplace to prevent these nebulous things that have been termed musculoskeletal disorders and we refer to them as MSDs.

The best science regarding musculoskeletal disorders suggests ergonomic proposals would actually be detrimental to the health of American workers by medicalizing many of the undiagnosable things that we in medicine cannot treat specifically. And if you cannot diagnose it, how do you prevent it.

Problems at work are a concern for all of us. We would all like to make them go away. Unfortunately, there is very little consensus about how to define these MSDs and have virtually no reliable data regarding the prevalence.

If we were to rely upon the statistics that OSHA cited in the final ergonomics rule, we would find that the vast majority of MSDs consist of discomfort or pain, generally unavoidable back pain that is a part of life.

I am not saying that this discomfort is imaginary. It is real. It is very real for the people who experience it. I am merely pointing out that when we speak about MSDs we generally are not referring to physical injuries that are associated with tissue damage that can be prevented or medically altered.

This point was recognized in the World Health Organization meeting on January 14, 2000, in a scientific group where all the participants agreed that we cannot continue to include aches and pains as categorized as injury, arthritis or disease because it keeps us away from the real goal of helping our patients.

My point is that many MSDs are nothing more than symptoms without observable tissue damage. We are limited in medicine. And because there is no reliable data regarding the prevalence, it is not at all clear exactly what problem it is we are trying to regulate.

Even if we could identify the nature and scope of the problem, there is no clear-cut science to support an ergonomics intervention. The ergonomics hypothesis is that many MSDs are caused by certain kinds of repetitive motions in the workplace and this can be alleviated by ergonomic controls alone. The problem with this hypothesis is that it is contrary to the best science available today.

The ergonomic hypothesis relies heavily upon studies that only generate clues of association without actually studying the clues to see if there can be an effective mechanism by which the problem can be prevented.

In light of the overwhelming potential cost of an ergonomic intervention, no rule should proceed without some evidence of successful intervention such as based on randomized control trials. No prospective RCTs at this point can guide us in altering the physical work conditions as an ergonomic remedy to the problem.

In fact, the best science available does not support an ergonomic hypothesis. This is especially true for back problems.

I directed the award-winning Boeing study that was summarized in the publications in 1991 and 1992. The study was of 3,020 aircraft workers at the Boeing factory over a 4-year period to look at the report of back problems.

We started with a retrospective study that provided us with clues, and then we studied those clues to see about their impact on

the reported back problems. The non-physical factors outweighed the physical factors in predicting back problems. The study found no correlation between heavy lifting and work activities increasing the report of problems.

In fact, the study found that some employees who routinely performed heavy lifting jobs in the paint shop, lifting 50 pounds with their arms outstretched like this, totally against everybody's ergonomic recommendation, and actually found that because of their—probably because of their high job satisfaction, they were among the least likely to report problems.

I also chaired the HCPR Guideline Panel which found no data through a methodologic process that would support what is being recommended in the rule.

In conclusion, I believe it is imperative for regulators to recognize the past ergonomic proposals are not supported by the best science available.

Let us pretend for a moment that the Food and Drug Administration has suddenly prescribed a specific drug mandatory for the treatment of all patients with a particular problem. Further imagine that the FDA did not know the correct dosage of the drug as we are stuck with, and does not know what side effects it might have, and never subjected it to a single randomized trial. Doctors would then guess the dose or just accept the strong data——

PREPARED STATEMENT

Senator SPECTER. Dr. Bigos, your full statement will be made a part of the record. If you summarize the conclusion, we would appreciate it.

Dr. BIGOS. My point is I doubt that we would do that in medicine. And the whole point is why should an expensive, unproven, potentially damaging approach be permitted simply based upon unfound hypotheses because we are dealing with OSHA science about the work site rather than the FDA science about our clinics and our hospitals.

If we had the solutions, they would already be taken.

[The statement follows:]

PREPARED STATEMENT OF DR. STANLEY J. BIGOS

It is a pleasure to be here today to participate in an open examination of the scientific basis for a federally mandated ergonomics rule. An open discussion of this nature is long overdue. As a practicing orthopedic surgeon, a researcher, and a medical school professor, I have studied musculoskeletal disorders for many years and have engineered some of the principal studies regarding their causes. Based on my extensive experience in this area, I believe that there is no scientific basis for mandatory ergonomic interventions in the workplace. To the contrary, the best science regarding musculoskeletal disorders suggests that the ergonomic proposals we have seen in the past would actually be detrimental to the health of American workers.

Presumably, ergonomics regulation in the workplace is intended to prevent musculoskeletal disorders (MSDs). Unfortunately, there is very little consensus about how to define MSDs, and as a result there is virtually no reliable data regarding the prevalence of MSDs in this country. If we were to rely on the statistics that OSHA cited in its final ergonomics rule, we would find that the vast majority of MSDs consist of discomfort or pain—generally unavoidable back pain—that is a part of life and not accompanied by any observable tissue damage. I am not saying that this discomfort is imaginary; it is very real to the people who are experiencing it. I am merely pointing out that when we speak about MSDs, we generally are not referring to physical "injuries" that are associated with tissue damage.

This point was recognized at the January 14, 2000 "Scientific Group" meeting of the World Health Organization, when the whole conference of 450 participants agreed that musculoskeletal pain is not equivalent to injury, arthritis or disease.

Because many MSDs are nothing more than symptoms rather than observable tissue damage, and because there is no reliable data regarding the prevalence of MSDs, it is not at all clear exactly what the problem is that we are trying to regulate.

Even if we could identify the nature and scope of the problem, there is no clear scientific support for ergonomic interventions. The ergonomics hypothesis is that many MSDs are caused by certain kinds of repetitive motion in the workplace, and thus can be alleviated by ergonomic controls alone. The problem with this hypothesis is that it is directly contrary to the best science that is available today.

The proponents of the ergonomics hypothesis generally rely on studies that are useful in generating clues about associations, but that cannot establish the causes of MSDs sufficiently to prevent it. In light of the overwhelming potential costs of ergonomic intervention, no rule should proceed without some true evidence of successful intervention such as a based on randomized controlled tests (RCTs). No prospective RCTs have ever been conducted to assess the effectiveness of altering physical work conditions as an ergonomic remedy.

In fact, the best science available regarding the causes of MSDs suggests that the ergonomics hypothesis is wrong. I directed The award winning Boeing Study, "termed sentinel science" that was summarized in publications in 1991 and 1992. The Boeing study was a prospective cohort study of the reporting of back injury claims (not merely complaints) among 3020 aircraft workers at the Boeing facility over 4 years following a retrospective analysis of back injury claims. That study found that non-physical factors outweighed physical factors in predicting the report of back problems at work. The study found no correlation between heavy-lifting work activities and increased reporting of back problems at work. In fact, the study found that some of the employees who routinely performed heavy lifting (paint shop) but who had high job satisfaction were among the least likely to report back problems at work.

I also chaired the panel of experts that produced the Agency for Health Care Policy & Research (AHCPR) Guidelines for Low Back Problems, which was published in 1994. The AHCPR Guidelines were produced by a panel of experts brought together under the direction of the U.S. Department of Health and Human Services to conduct an exhaustive methodological review of the existing literature on the back problems. The panel evaluated more than 10,000 abstracts and obtained more than 4,600 studies for methodological evaluation. Based on that review, the evidence suggested that continued activity rather than decreased activity would be helpful in alleviating many types of back problems—a finding that is directly contrary to the ergonomics hypothesis—and the panel found no valid evidentiary support for the use of ergonomics interventions to treat or prevent back pain. The AHCPR Guidelines have since been followed and updated in over 45 countries, including the United Kingdom, Australia, and Israel. Subsequent research has only strengthened many of the key findings of the AHCPR panel.

In conclusion, I believe it is imperative for regulators to recognize that the ergonomic interventions that have been proposed in the past are not supported by the best science available, and there is a considerable body of evidence which suggests that certain ergonomic interventions may actually be physically harmful to American workers and slow their return to productive life.

Let us consider for a moment the Food and Drug Administration, which is explicitly charged with evaluating healthcare interventions. Imagine that evidence-based medicine had demonstrated no support for an expensive experimental class of drugs designed to treat heart disease. Imagine that, nevertheless, the FDA suddenly prescribed a specific drug as the mandatory treatment for all patients. Further imagine that the FDA did not know the correct dosage of the drug, did not know what side effects it might have, and never subjected it to a single randomized control trial. Doctors would guess the dose and accept opinion that strongest data about the issue is wrong? I doubt it! The medical community would never be permitted to do this. Why should an expensive unproven and potentially damaging approach be permitted simply based upon unfounded hypotheses because we are dealing with OSHA's science about the worksite rather than the FDA's science about the clinic or hospital?

Senator SPECTER. Thank you very much, Dr. Bigos. Dr. Nortin Hadler, Professor of Medicine and Microbiology/Immunology, University of North Carolina, Chapel Hill.

STATEMENT OF DR. NORTIN M. HADLER, PROFESSOR OF MEDICINE AND MICROBIOLOGY/IMMUNOLOGY, UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL

Dr. HADLER. Good morning. I want to express my gratitude to the members of the subcommittee for the opportunity to address you today on issues with which I have grappled as a clinician and clinical investigator for over 25 years.

I am a rheumatologist and therefore committed to caring for patients with musculoskeletal disorders. As an academician and clinical investigator, I was drawn early on to improve our understanding of the plight of those amongst us who are otherwise well but in the course of our usual life activities face compromised function because a particular anatomical region such as our low back or arm is painful to move.

I coined the term "regional musculoskeletal disorders" to denote this morbidity nearly 20 years ago. Gainful employment is one realm in which function is placed at risk by a regional disorder. That is the so-called MSD in OSHA's terminology.

But the illness of work incapacity is not the only morbidity, nor is the workplace the only context relevant to the regional disorders. The fact the working capacity from the regional disorders has engendered ergonomic-based regulatory efforts is a social construction that bears very close scrutiny.

We have access to a compelling science that suggests such a social construction deprives the hurting worker of insights that could lead to substantive relief. Hopefully, such an understanding will emerge during the course of today's hearing.

In this, the first of my two presentations, I will focus on the following aspects of the epidemiology of the regional disorders: Who is at risk, how common is the morbidity, what are the options for coping, and what drives the choice amongst the options.

Notice that I continue to use the term regional musculoskeletal disorder. I am willing to specify the region, the knee or low back or neck or shoulder and the like, but seldom am I willing to apply a label that suggests I know what is hurting.

For nearly all the regional disorders, there is no way today to general confidence that any anatomically exact label is valid. Nearly always there is nothing to see or feel. All our wonderful techniques for imaging anatomy seldom shed any light. Either no pathology is demonstrated or that which is demonstrable is nonspecific.

It is commonly found in age matched individuals who are not hurting, is likely to have been present in the person who is hurting before the onset of pain, and likely to persist when the pain has remitted.

Regional musculoskeletal pain is an intermittent and remittent predicament of life for all of us. It is distinctly unusual to live a year without having had to cope with a backache or 3 years without having to cope with arm pain.

We know this from surveys where volunteers keep diaries of the morbidity they experience each day and from surveys where recall of the disorders is elicited. The response varies depending on how the questions are asked, but the message is inescapable. Regional

musculoskeletal pain is an intermittent and remittent predicament of life.

In the past decade, there have been a number of investigations which explore the fashion in which people cope with these episodes. Coping does not occur in a vacuum. Common wisdom and advice abounds, as do many purveyors of putative remedies.

For most of us, most of the time, we can and do cope according to our fashion. For most of us, most of the time, the predicament passes and it is not even memorable. What makes it memorable. What causes us to seek care from a provider. If you think the answer relates simply to the severity of the pain, you need to be disabused.

Aspects of life that confound coping render the musculoskeletal disorders more memorable and less tolerable. Measures of feeling undervalued, of being undervalued, of feeling disaffected, and of self-reported health status associate with the likelihood of remembering and seeking care for back, knee or arm pain. We have known for decades the measures of the severity of the pain itself correlates less well or not at all.

No doubt there is the exceptional person who is faced with a regional disorder of such intensity and persistence that it overwhelms all attempts to cope. Such a person deserves the empathetic care that we would offer anyone with any other of life's morbid challenges such as a severe case of the flu. But these are unusual circumstances.

Most people either on their own or with guidance discover ways to circumvent the painful use of the region that is hurting until in days, occasionally weeks, rarely months, the disorder remits sufficiently that life goes on and the episode is soon to be forgotten.

When someone finds the disorder insurmountable or even unforgettable, it is likely that coping was confounded by the psychosocial context in which the morbidity was suffered. These psychosocial aspects of life operate to render the episode memorable, to cause one to register the complaint to a health officer inside or outside the workplace.

This is not to dismiss the backache or the regional arm pain as trivial or to belittle the effort involved in coping. We will all face such challenges and hopefully we will all have the wherewithal to cope effectively. But I can assure you, if you are trying to cope with a backache and your life is not in order, if there are coincident challenges at home or work, then the backache will seem the last straw.

PREPARED STATEMENT

Senator SPECTER. Dr. Hadler, your full statement will be made a part of the record. Can you summarize in conclusion please.

Dr. HADLER. Yes. The conclusion will come in my second statement. There is absolutely no information as to whether we can alter the likelihood that we will suffer our regional disorder. There have been attempts to alter the likelihood that we will not cope on our own. And the best data we have say such attempts are ineffective. Thank you for your attention.

[The statement follows:]

PREPARED STATEMENT OF DR. NORTIN M. HADLER

When I was a medical student, epidemiologists observed that the risk for Down's Syndrome, trisomy 21, was not uniform in sibships. The youngest child was more likely to be afflicted with this congenital disorder. That lead to hypotheses and research as to what was it about the multiparous uterus that caused the fertilized egg to divide abnormally.

Several years later, epidemiologists returned to this issue to test whether they had missed the real association. The younger the child, the older the mother. Could it be that the likelihood of bearing a child with Downs's syndrome associated more with maternal age than birth rank? The answer proved to be yes. The old hypothesis was superseded and research shifted to the biology of the aging ovary.

Several years after that, epidemiologists again returned to this issue to test whether they had missed the real association. The older the mother, the older the father. Could it be? The answer was yes and no. The likelihood of bearing a child with Down's syndrome associated with both maternal and paternal age. The old hypothesis was superseded and research shifted to the biology of the aging ovary and testis.

Such is the scientific method. We learn from the old hypotheses and the old false starts. And we move on. Today, no one would consider studies of the microenvironment of the multiparous uterus as relevant to the pathogenesis of Down's syndrome.

For over 60 years science has sought associations between the physical demands of tasks and the likelihood of suffering disabling regional back pain. For 30 years, there have been parallel studies between physical demands of tasks and disabling arm pain. Associations have been found, but they are inconsistent and weak. There were hints 30 years ago,[1] but science has really risen to the challenge in the past decade, the challenge of asking whether a more important association was being ignored. I have reviewed this transition in a lengthy editorial in the Journal of Occupational and Environmental Medicine last fall[2] titled "Comments on the "Ergonomics Program Standard" proposed by the Occupational Safety and Health Administration" which I have submitted with the written version of this statement. I review the number of cross-sectional and longitudinal studies that have attempted to probe for associations between disabling regional back or arm pain and aspects of BOTH the physical content of tasks and psychosocial context of work. Designing such studies is demanding. How do you measure either physical or psychosocial exposures given the enormous temporal variability and individual differences? You do the best you can. The result of these multivariate studies is that the associations with the physical content of tasks are weaker and even more inconsistent. The associations with the psychosocial context of work are also weak, but they are more consistent and generally subsume the associations with the physical content of tasks.

I could belabor this new literature; it deserves scrutiny. However, I can not applaud the insistence on relying on the older literature in the systematic reviews that are promulgated by NIOSH and the NRC. Any study that considers only the association between the physical demands of tasks and the likelihood of a disabling regional musculoskeletal disorder is out of date, even if it is on-going or proposed. The state-of-the-science has moved beyond the testing of that hypothesis to newer hypotheses that promise to be more informative.

Let me illustrate first with two small area analyses. There are large companies that have multiple work sites each with similar facilities and similar demographics of the workforce. The incidence of disabling back or arm pain varies from site to site, sometimes dramatically. That offers the opportunity to explore whether measurable differences in task content, demographics or psychosocial context associate best with the variability in the incidence of disabling regional musculoskeletal disorders. Independently, investigators from NIOSH and I performed such a small area analysis in US West directory assistance operations.[3] [4] [5] Neither the NIOSH investigators nor I could explain the site-to-site variability in the incidence of disabling arm pain by any aspect of task content. However, multiple aspects of the psychosocial context of work did associate, fear of redundancy, work pressure, and lack of

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[1] Hadler, NM. Workers with disabling back pain. N Engl J Med 1997;337:341–3.

[2] Hadler, NM. Comments on the "Ergonomics Program Standard" proposed by the Occupational Safety and Health Administration. J Occup Environ Med 2000;42:951–969.

[3] Hadler NM. Arm pain in the workplace: a small area analysis. J Occup Med 1992;34:113–9.

[4] Hales RR, Sauter SL, Peterson M, et al. NIOSH health hazard evaluation report (HETA 1989–299–2230, U.S. West Communications). Washington, DC: Department HSS, PHS, CDCP, NIOSH.

[5] Hales T, Sauter SL, Peterson MR, et al. Musculoskeletal disorders among visual display terminal users in a telecommunications company. Ergonomics 1994;37:1603–21.

decision authority to mention a few. Interestingly, the more overtime and the more hours spent at the computer, the LESS likely the operator was to have found arm pain disabling.

Another small area analysis was performed by UPS. The results were submitted as part of the rules making process regarding OSHA's "Ergonomics Proposed Standard" last year. A detailed ergonometric analysis was performed at a number of UPS hubs where the tasks involve the sorting of parcels. There is not even a hint of an association between physical task demands and the likelihood of recorded disabling arm or back pain.

What do I mean by impugning the psychosocial context of work? What is the human implication of these small area analyses and nearly all multivariate cross-sectional and longitudinal studies that detect associations with the psychosocial context of working[6] [7] [8] [9] [10] [11] and the likelihood of reporting to a health officer in the workplace that your regional arm or back pain is disabling? I do not mean to impugn the veracity or the motivation of any worker so afflicted. Nor am I suggesting that the inflammatory social construction, "It's in your head" pertains. I believe they hurt and I am saddened that their pain is insurmountable. I know that the remedies offered by the providers of today are no matches for this dilemma;[12] [13] at best they are minimally helpful, most are useless and offer the specter of iatrogenesis. However, the science of today forces me to conclude that their back or arm pain is rendered incapacitating because elements of the psychosocial context in which they work impede coping. The frontier for epidemiology is to further define "psychosocial context." That's a daunting exercise.[14] Some of the common threads emerging from studies in the workplace include aspects of job "stress,"[15] "strain,"[16] "allostatic load" and motivational "flow."[17] These measures are sampling such complex psychological functions as satisfaction, autonomy and security on the job as well as perceived psychological demand, motivation, collegiality, and the like. No wonder, associations with "psychosocial" variables are weak, even inconsistent. There may be much that is idiosyncratic. However, that does not diminish the implications. The sad fate of the hurting worker(s) is predetermined if he or she, or they are trapped in a malignant psychosocial milieu.

There are 4 cohort studies that bear witness. Two are "natural" experiments in that a captive workforce was followed through an interval when the psychosocial environment was purposely perturbed: In the early 1990's, the Finnish economy suffered a considerable setback lasting several years. Many workers were dismissed. The effect of impending downsizing on the local-government employees in one small city was monitored.[18] The rate of absenteeism escalated, most markedly for sick leave ascribed to regional musculoskeletal disorders, particularly among employees over the age of 50.

The "Whitehall" studies are cohort studies of British civil servants that long ago documented an inverse relationship between civil service grade and mortality rate, particularly mortality from cardiovascular disease. In recent years it has become

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[6] Linton SJ. A review of psychological risk factors in back and neck pain. Spine 2000;25:1148–56.

[7] Marmot M. Importance of the psychosocial environment in epidemiologic studies. Scand J Work Environ Health 1999;25(suppl 4):49–53.

[8] Heliövaara M. Work load and back pain. Scand J Work Environ Health 1999;25:385–6.

[9] Krause N, Ragland DR, Fisher JM, Syme SL. Psychosocial job factors, physical workload, and incidence of work-related spinal injury: a 5-year prospective study of urban transit operators. Spine 1998;23:2507–16.

[10] Burton AK. Back injury and work loss. Biomechanical and psychosocial influences. Spine 1997;22:2575–80.

[11] Papageorgiou AC, Macfarlane GJ, Thomas E, Croft PR, Jayson MIV, Silman JA. Psychosocial factors in the workplace—do they predict new episodes of low back pain? Spine 1997;22:1117–1142.

[12] Hansson TH, Hansson EK. The effects of common medical interventions on pain, back function, and work resumption in patients with chronic low back pain. Spine 2000;25:3055–64.

[13] Van Tulder MV, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. Spine 1997;22:2128–56.

[14] Davis KG, Heaney CA. The relationship between psychosocial work characteristics and low back pain: underlying methodological issues. Clin Biomechanics 2000;15:389–406.

[15] Israel BA, Baker EA, Goldenhar LM, Heaney CA. Occupational stress, safety and health: conceptual framework and principles for effective prevention interventions. J Occup Health Psychol 1996;1:261–86.

[16] Karasek RA, Theorell T. Healthy Work. New York:Basic Books, 1990.

[17] Guastello SJ, Johnson EA, Rieke ML. Nonlinear dynamics of motivational flow. Nonlinear Dynamics, Psychology, and Life Sciences 1999;3:259–73.

[18] Vahtera J, Kivimäkl M, Pentti J. Effect of organisational downsizing on health of employees. Lancet 1997;350:1124–8.

clear that the association with grade paled next to the association with psychosocial job "stress", particularly job "control", regardless of grade.[19] Similar relationships with job "stress" pertain to sickness absence from disabling regional back pain.[20] The ongoing nature of Whitehall studies made it possible to take scientific advantage of a natural experiment.[21] In 1988, the British government announced a major restructuring. The Property Services Agency was to be "privatized" to which end its function was "outsourced" in 1992. These Orwellian terms fool no one, particularly the thousands of bureaucrats whose jobs were at risk. They realized that many of them would be without jobs, as was the fate of 41 percent in 1992, and that employment in the private sector was predictably insecure. What they couldn't have foretold was that their health would deteriorate during the 3 years anticipating "downsizing" and sick leave would escalate. None of the trends could be ascribed to health-adverse behavior. Impending downsizing wreaks havoc on the psychosocial context of work inflicting "stress" and "strain" on all.[22] Downsizing accelerates that noxious, insalubrious, and lethal process we are denoting as an adverse "psychosocial" work context. And it does so without regard for prior station in life.

Even without the inflammatory influences of downsizing, an adverse psychosocial context works its harm. Slowly it will deprive one of favorable "self-rated health" (SRH). Like socioeconomic status, SRH is a powerful predictor of all-cause mortality, let alone the likelihood that one will seek care for regional musculoskeletal disorders.[23] In a cohort of 5,001 Danish workers, adverse "psychosocial" work context was shown to erode SRH over the 5 years of observation.[24] A similar association has emerged from analysis of the nurses' health study; a perception that psychosocial work conditions were unfavorable predicted declining functional status among some 21,000 nurses followed for 4 years.[25]

There are many lessons from the century of disabling regional backache.[26] [27] Most germane to our discussion today, there is no ergonomic solution. Ergonomics has a role in designing workplaces that are comfortable when we are well and accommodating when we are ill or aging. But ergonomic interventions will not decrease the likelihood that a worker will find his or her next episode of regional musculoskeletal pain disabling. And an ergonomic regulation of the kind recently proposed by OSHA will certainly prove harmful: Such a regulation will medicalize the workforce; no longer will it seem reasonable to cope with back or arm pain without demanding remedies that, for the moment, do not exist. It will perpetuate the sophism that task content is the culprit, and thereby inflame resentment. It will lead to task modifications that have never been shown to be helpful. And most importantly, the regulations enforce a sophistical social construction so that progress in science or policy is impeded.

We know better.

Thank you for your attention.

Senator SPECTER. Thank you, Doctor. Turn now to Ms. Peg Seminario, Director of the Department of Occupational Safety and Health, AFL–CIO.

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[19] Bosma H, Peter R, Siegrist J, Marmot M. Two alternative job stress models and risk of coronary heart disease. Am J Public Health 1998;88:68–74.

[20] Hemingway H, Shipley MJ, Stansfeld S, Marmot M. Sickness absence from back pain, psychosocial work characteristics and employment grade among office workers. Scand J Work Environ Health 1997;23:121–9.

[21] Ferrie JE, Shipley MJ, Marmot MG, Stansfeld SA, Davey Smith G. An uncertain future: the health effects of threats to employment security in white-collar men and women. Am J Public Health 1998;88:1030–6.

[22] Reissman DB, Orris P, Lacey R, Hartman DE. Downsizing, role demands, and job stress. J Occup Environ Med 1999;41:289–93.

[23] Croft P, Schollum J, Silman A. Population study of tender point counts and pain as evidence of fibromyalgia. BMJ 1994;309:696–9.

[24] Borg V, Kristensen TS, Burr H. Work environment and changes in self-rated health: a five year follow-up study. Stress Med 2000;16:37–47.

[25] Cheng Y, Kawachi I, Coakley EH, Schwartz J, Colditz G. Association between psychosocial work characteristics and health functioning in American women: prospective study. BMJ 2000;320:1432–6.

[26] Hadler NM. Laboring for longevity. An annotated poem. J Occup Environ Med. 1999; 41:617–21.

[27] Hadler NM. Occupational Musculoskeletal Disorders. Second Edition. Philadelphia, Lippincott Williams & Wilkins. 1999. Pp. 1–433.

STATEMENT OF PEG SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY AND HEALTH, AFL–CIO

Ms. SEMINARIO. Good morning, Mr. Chairman and Senator Landrieu. Thank you for the invitation to testify today. I am Peg Seminario, Director of Safety and Health for the AFL–CIO.

A couple of points. Work-related musculoskeletal disorders are a huge problem in the workplace today. We have heard the statistics referred to earlier today, one-third of all serious workplace injuries.

The latest Bureau of Labor Statistics' survey showed 582,000 of these cases that were serious enough to result in time off the job. Those come from employer reports. Those are not the AFL–CIO's numbers. Those are not even the Department of Labor's numbers. Those come from employer reports.

And I think if you talk to individual employers, they would confirm that is what they see. I believe a statement was submitted to the record of this hearing by ALCOA by the steelworkers in ALCOA which said that for ALCOA that one third of all of their workplace injuries are musculoskeletal disorders. And in some sectors such as the auto industry and meat packing, it is even greater. And what we have also found is that these numbers really underestimate the problem.

We did a comparison looking at Workers' Compensation data and Bureau of Labor Statistics' data thinking that we would find more cases on the OSHA log. What we found is there were more cases compensable, even though the criteria for compensation are much greater. We found twice as many cases in compensation than even under OSHA.

So this is a huge problem for workers across the United States. It is a huge problem for employers. And I am always struck by coming to a forum such as this and all the work we have done over the last 10 years that what I hear from Mr. Fellner, Dr. Bigos and Dr. Hadler, it does not bear any relationship to the world that we know, the workplaces we know.

There are a number of workers who have come to this hearing today who were with us yesterday as well. These people love their jobs. I mean, they really care about their jobs.

Cindy Wright is a nurse's aid who was with us yesterday, suffered a very, very serious injury, rotator cuff problem, neck problem, from lifting a very heavy patient in a nursing home.

She is crushed that she cannot go back to work. This is not about coping. She is injured. She is in pain. She needs help.

This injury could have been prevented if they had used a mechanical lifting device. But Dr. Hadler would have you believe that, no, she just needs to cope better or she needs to like her job better.

This is not the case. These are very significant serious injuries to workers. Again, they occur throughout all sectors of the economy. They are upper extremity problems, which as you have heard are a particular problem for women workers.

They are problems of the low back, heavy lifting, repetition, awkward postures, vibration. We know the exposures that cause these problems. And what we have seen is that when employers put in place programs that evaluate these hazards, reduce exposure, yes, indeed, we see reductions in injuries. That is what we see. That is the real world.

You can talk about whether there is consensus on this. Clearly as you have heard this morning there is not. But we would agree with Senator Specter that if we had waited for consensus on whether asbestos caused cancer, whether benzine caused leukemia, whether cotton dust caused byssinosis, we would still have workers in this country dying and being exposed today of these very, very serious hazards. And so there may not be consensus but there is evidence.

I think if the committee looks at the reports of the National Academy of Sciences done in 1998, the recent report concluded in 2001, you will see that they are very comprehensive documents that involved a lot of folks, a lot of experts. The experts in the country, over 50 experts involved in the developments of those reports, they came to some very firm conclusions. And we would encourage you to look at those conclusions.

Let me just say that there are approaches to dealing with these problems which we will talk about later today, but just to make the point that these are very real injuries. They are significant injuries. They disable a lot of workers in this country.

PREPARED STATEMENT

This problem really needs a national response. And we are glad that Senator Specter is having this hearing to examine this issue so completely and that both Senator Landrieu and Senator Specter are on legislation directing the Department of Labor to issue a standard. Thank you.

[The statement follows:]

PREPARED STATEMENT OF PEG SEMINARIO

Mr. Chairman, members of the committee, my name is Peg Seminario. I am Director of Safety and Health for the AFL-CIO, a federation of 65 national and international unions representing 13 million working men and women and their families. I appreciate the opportunity to testify at this special hearing on ergonomics and to present our views on why an OSHA ergonomics standard is urgently needed to protect workers in this country.

The AFL–CIO has a long and deep interest and involvement in the ergonomics issue. Musculoskeletal disorders (MSDs) caused by exposure to ergonomic hazards are a major safety and health problem for our members and for all workers. In all economic sectors and in most industries, musculoskeletal disorders are the major source of workplace injury and illness. Workers in meatpacking, poultry, auto assembly, nursing homes, transportation, warehousing, construction, agriculture and data entry are among those at risk.

For more than two decades, unions have been working hard to prevent these injuries through research, joint efforts with employers, union training programs, and by requesting OSHA enforcement actions under the general duty clause.

Since the late 1980's, we have been seeking an OSHA standard to prevent unnecessary musculoskeletal disorders and to control ergonomic hazards. It has been ten years since former Secretary of Labor Elizabeth Dole committed the Department of Labor to "taking the most effective steps necessary to address the problem of ergonomic hazards on an industry-wide basis" and to develop an ergonomics standard. But, due to fierce industry and political opposition to any mandatory ergonomics standard, today workers have no legal protection against these hazards. During the past decade millions of workers have suffered unnecessary injury, illness and disability while an ergonomics standard has been delayed. More than 4,900 workers are injured each day that protections are further delayed. Since the OSHA ergonomics standard was repealed on March 21, 2001, more than 170,000 workers have suffered work-related musculoskeletal disorders.

WORK-RELATED MUSCULOSKELETAL DISORDERS ARE THE NATION'S LEADING JOB SAFETY PROBLEM

Work-related musculoskeletal disorders are the leading type of occupational injury and illness in America today. These disorders include upper extremity disorders such as carpal tunnel syndrome, tendinitis, tenosynovitis, and rotator cuff injuries, and disorders of the low back.

The Bureau of Labor Statistics (BLS) reports that over 582,000 musculoskeletal disorders involving days away from work were reported by private sector employers in1999, accounting for more than one in three of all injuries and illnesses involving recuperation away from work. (Appendix A) The National Academy of Sciences, in its January 2001 report, found that approximately one million people lose time from work each year due to musculoskeletal disorders.

While the total number of lost-time MSDs reported by the Bureau of Labor Statistics has declined since 1992, the problem of workplace MSDs is still great. Despite the downward trend in total numbers of reported cases, MSDs have consistently accounted for more than one-third of total lost worktime cases since 1992. More disturbing, the downward trend seems to be reversing in some areas. According to the most recent BLS survey, the rate of injuries associated with repetitive motion rose from 1998 to 1999 in every industrial sector except finance, and increased over 9 percent nationally. The rate of injuries caused by overexertion increased in construction and mining in 1999, and the rate of illnesses caused by repeated trauma increased from 14.8/10,000 workers to 17.6/10,000 workers in transportation.

These large numbers of injuries reported by the BLS and NAS, however, do not represent the total scope of the problem. These cases represent only those injuries and illnesses which result in more than one day of lost time from work. Based upon the ratio of non-lost work-time injuries to lost work-time injuries which occur in the workplace, (2 to 1), the Department of Labor has estimated that a total of 1.8 million MSDs are reported by employers to the Bureau of Labor Statistics each year.

But even this number understates the magnitude of the problem. The BLS survey only reports injury and illness data for the private sector. The injury experience of the more than 16 million state, county and local public sector workers, and 2.8 million Federal sector workers, including postal workers, is not reflected in the survey (Employment and Wage Annual Averages, 1997, BLS, 1998). While comprehensive and detailed injury data for these groups of workers is not collected, the data that is available shows that MSDs are a major problem for these workers as well. For the 28 states and territories where injury and illness data is collected for state and local public employees, in 1998, the BLS reported 63,374 musculoskeletal disorders that resulted in lost work days.

There is also extensive evidence that the BLS survey understates the extent of the MSD problem for private sector workers. More than 16 studies submitted to the record of OSHA's rulemaking on ergonomics demonstrated significant under recording and under reporting of workplace injuries. Based on this evidence OSHA found that "that for every reported MSD, another MSD goes unreported. Thus, the total number of work-related MSDs estimated by OSHA to occur in the United States annually is 3.6 million." (OSHA, 2000) This estimate does not include MSDs suffered by state, local or Federal employees.

A comparison of data from the BLS survey, workers' compensation data and surveillance data for several states confirms that the BLS data under-represents the extent of work-related MSDs. A review by the AFL-CIO of available BLS data and state workers' compensation data on musculoskeletal disorders for three states—Massachusetts, Oregon and Washington—for a several year period in the 1990's found that the numbers of cases of MSDs reported to BLS were significantly less than the number of MSD cases accepted for workers' compensation—in many instances 50 percent less. These differences are even more significant since the criteria for compensation are much more restrictive than the recording and reporting criteria under the BLS survey (i.e. compensation for MSDs required 4 or 5 days off the job, compared to one day of lost time for reporting to BLS). See Appendix B.

Recent studies have demonstrated that only a small percentage of workers suffering from work-related back injuries, carpal tunnel syndrome and other musculoskeletal disorders are filing workers' compensation claims for these injuries. A study published in the January 2000 "Journal of Occupational and Environmental Medicine" found that only 25 percent of the group of Michigan auto workers studied with diagnosed work-related musculoskeletal disorders filed for workers' compensation (Rosenman et al, 2000). A similar study of Connecticut workers found that only 10 percent of workers with musculoskeletal disorders filed workers' compensation claims (Morse et al, 1999).

Based upon these studies, it appears that the under reporting of MSDs may be far greater than found by OSHA in its ergonomics rulemaking and the true magnitude of work related MSDs far greater than 3.6 million cases a year.

Work-related MSDs are among the most severe injuries facing American workers. The BLS reports that among major disabling injuries and illnesses, median days away from work are highest for carpal tunnel syndrome (27 days). This is significantly higher than the median days away from work for fractures or amputations.

While MSDs occur in every sector and industry across the economy, some sectors have been hit harder than others. Over one quarter of all MSDs involving time away from work occur in the service sector and over one quarter in manufacturing. Nursing aides, orderlies, and attendants, along with registered nurses, accounted for almost 10 percent of all lost time work-related MSDs in the U.S. in 1999. Sixty-five percent of injuries and illnesses involving days away from work for nursing aides, orderlies and attendants are due to sprains and strains, while 60 percent of Registered Nurses' injuries and illnesses are due to sprains and strains.

BLS data show that for many types of MSDs involving the upper extremities, including carpal tunnel syndrome, women workers suffer a disproportionate number of injuries. In 1999, women suffered 67 percent of reported carpal tunnel syndrome cases (18,651) and 61 percent of reported tendinitis cases (10,127) even though women comprise about 46 percent of the workforce and accounted for 33 percent of total workplace injuries (BLS, 1999). As with other musculoskeletal disorders, the number of cases of carpal tunnel syndrome, tendinitis and other repetitive motion injuries reported by BLS understates the extent of the problem found among these workers.

Workers in meat packing plants have a repetitive trauma disorder incidence rate of 912 per 10,000 full time workers. Motor vehicle and car bodies have a rate of 685.5 and numerous textile and apparel sectors have rates exceeding 200.

Ergonomic hazards are also a significant problem for workers in construction, maritime and agriculture. These sectors should be covered by an OSHA ergonomics standard just as they are currently covered by standards in the states of California and Washington. According to the BLS survey, in 1999 there were 52,800 reported cases of lost-time injuries resulting from overexertion and repetitive motion in these sectors. These types of injuries accounted for 23 percent of all reported lost work-time injuries in construction, 21 percent of reported lost time injuries in maritime (SIC Codes 44 and 373), and 18 percent of reported lost work-time injuries in agriculture. A large percentage of construction workers suffer from back injuries, shoulder injuries and other musculoskeletal disorders.

THE TOLL OF MUSCULOSKELETAL DISORDERS ON WORKERS AND THE ECONOMY IS GREAT

Musculoskeletal disorders are painful, disabling, costly injuries. According to the National Academy of Sciences, a conservative estimate of the costs imposed by MSDs on the American economy is between $45 and $54 billion every year (NRC/IOM, 2001). These figures only include the actual monetary losses that result from MSDs, but do not account for the enormous pain, suffering and disability that these preventable disorders cause.

The pain and toll of these injuries was described by dozens of injured workers who testified at OSHA's ergonomic hearings on why a standard was so important—workers like Ron Kline, an auto worker from Maryland, Carol Py, a clerk typist from Pennsylvania and Nancy Foley a newspaper reporter from Massachusetts, all who developed serious work-related MSDs.

"Starting with my right elbow, the illness became so severe, I could not lift the air gun. As this was occurring, my reaction was to start using my left hand to complete my assignment.

"As the pain worsened, even with local treatment from the dispensary, it required surgery.

"The time away from work for my right arm required 13 weeks away from work with less than complete recovery, leaving me with 15 percent permanent loss of full use of my right arm.

"I also endured one year of physical therapy for my right arm.

"Subsequently, I required surgery on my left arm with seven weeks away from work." (Oral testimony of Ron Kline at OSHA Ergonomics Hearings, Tr. 7950)

"I developed cumulative trauma disorder which is like multiple muscular injuries due to repetitive motion, DeQuervains disease in my thumb here, cubital tunnel syndrome which is the ulnar nerve, compression of the ulnar nerve the elbow and trigger finger.

"During the next 12 months, the pain in my hand was so unbearable that I had to have repeat surgery on my right hand. I have trouble turning the pages. I never returned to work as my medical restrictions were so limited that my company could not find me a job.

"Last year, I had surgery on my other hand because my thumb would not move.

"Today, I have difficulty driving, cleaning, cooking, and food shopping. And my husband, he mostly does all my shopping for me. And my grandchildren do a lot of the cleaning for me, too. The yard work is out of the question since I cannot rake or mow the lawn. I had to give up the things that I used to love like sewing and gardening. Before I was injured, I even had a green belt in karate. My arms are so weak now that I can barely take care of my three grandchildren." (Oral testimony of Carol Py at OSHA Ergonomics Hearings, Tr. 6321–6322).

"By the time I left the newspaper I was so severely injured that my recovery has been very slow. I may never fully recover. I live with chronic pain every day. Sitting still triggers pain. I have trouble carrying groceries into my house and doing simple housekeeping tasks. I am trying to retrain to be a school teacher, but my injuries make the retraining difficult. I do my school work by lying in bed and talking into a voice-activated computer.

"I loved my job. I remember thinking how lucky I was to have a job that was so much fun. It was a great disappointment to me to have to give it up...I have suffered from severe depression as a result of losing my career and living with chronic pain. I have lost thousands of dollars in income. I had hoped to have children some day, but I cannot pick up and carry my eight-month old niece." (Oral testimony of Nancy Foley at OSHA Ergonomics Hearings, Tr. 7321–22).

The pain and disability caused by musculoskeletal disorders is widespread. Dr. Robin Herbert of the Mt. Sinai Medical Center, an occupational physician who testified at the OSHA's ergonomics hearings reported that 25 percent of her patients with musculoskeletal disorders have permanent disabilities, and of those 25 percent, ten percent are never able to return to work (Oral testimony at OSHA Ergonomics Hearings, Tr. 1736–37). Preliminary results of one study showed that 15 percent of all patients with MSDs of the upper extremities are characterized as disabled (Oral testimony at OSHA Ergonomics Hearings, Tr. 1738). In New York State, between 1993–1995, 86 percent of workers with carpal tunnel syndrome were deemed to be permanently disabled by workers' compensation judges (Herbert, 1999). A study of workers' compensation claims for ergonomic injuries in North Carolina found that 19.4 percent of the injuries resulted in permanent partial disability; 22 percent of the claimants were unable to return to work (Waldorf and Snow, 1996).

The financial and social consequences of these injuries on workers are significant. Many injured workers receive no workers' compensation. Their injuries and disabilities destroy or severely limit their ability to make a living. Financial burdens created by these injuries result in workers losing their homes, cars and health insurance. Injured workers are often unable to lead a normal life experiencing great difficulty performing routine activities such as writing, cleaning, caring for children, bathing and driving a car. The effects of these injuries on injured workers' well-being is also significant. Workers suffering MSDs report higher levels of depression, anxiety and stress at home.

THE SCIENTIFIC EVIDENCE IN SUPPORT OF AN ERGONOMICS STANDARD IS EXTENSIVE AND STRONG

A broad, extensive, and overwhelming body of scientific evidence firmly establishes that musculoskeletal disorders are caused by exposures to workplace ergonomic risk factors—force, repetition, awkward postures and vibration. This conclusion is strongly supported by evidence obtained from epidemiological studies of worker populations, laboratory findings, and the clinical experience of physicians and health care professionals.

Three recent authoritative and comprehensive reviews of the scientific literature conclude that exposure to ergonomic hazards in the workplace causes musculoskeletal disorders. These are a 1997 report by the National Institute for Occupational Safety and Health, "Musculoskeletal Disorders and Workplace Factors," and two congressionally-mandated reports by the National Academy of Sciences, "Work-Related Musculoskeletal Disorders," completed in 1999, and "Musculoskeletal Disorders and the Workplace," completed in 2001.

In evaluating the extensive body of scientific literature, comprising over 800 research studies and references, the January 2001 NAS report concluded that:

—"The panel's review of the research literature in epidemiology, biomechanics, tissue mechanobiology, and workplace intervention strategies has identified a rich and consistent pattern of evidence that support a relationship between the workplace and the occurrence of MSDs of the lower back and upper extremities."
—"The basic biology and biomechanics literatures provide evidence of plausible mechanisms for the association between musculoskeletal disorders and workplace physical exposures."

The research literature has identified the biomechanical risk factors in the workplace that pose a hazard to workers of developing a musculoskeletal disorder affecting the lower back and upper extremities. Workplace biomechanical risk factors that can cause MSDs include force, repetition, vibration, awkward postures, and heavy lifting. As the 2001 NAS report summarized:

—"The panel concludes that there is a clear relationship between back disorders and physical load; that is, material handling, load movement, frequent bending and twisting, heavy physical work, and whole-body vibration. For disorders of the upper extremities, repetition, force and vibration are particularly important work-related factors."
—"Low back disorder risk has been established through epidemiological studies of work that involves heavy lifting, frequent bending and twisting, and whole body vibration, as well as other risk factors."
—"The pattern of evidence for upper extremity disorders, as for the low back, also supports an important role for physical factors, particularly repetition, force and vibration."

As noted above, the 1998 and 2001 National Academy of Sciences studies on work-related musculoskeletal disorders were the result of Congressional requests for a review of the scientific evidence on work-related musculoskeletal disorders. Both of these reviews concluded that there is a strong body of evidence that musculoskeletal disorders are associated with exposure to workplace ergonomic risk factors and that there are effective interventions to reduce the risk of these disorders. The Congress and the Bush Administration should endorse these findings and support the issuance of a new ergonomics standard to protect workers.

AN OSHA ERGONOMICS STANDARD IS NEEDED TO PROTECT WORKERS FROM MUSCULOSKELETAL DISORDERS

The key finding motivating Congress to enact the Occupational Safety and Health Act in 1970 was the fact that "personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments," 29 U.S.C. § 651(a). The purpose of the Act was to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve the country's human resources.

As the major source of job injury and illness in the nation today costing more than $45–$50 billion a year, work-related musculoskeletal disorders are precisely the type of problem that the Act was intended to address. Just as the Congress acted in 1970 and passed the Occupational Safety and Health Act to address the high toll and cost of workplace injuries and illnesses, it is imperative that OSHA promulgate an ergonomics standard to address the toll and cost of musculoskeletal disorders.

The severity of the problem of MSDs and the need for government action was recognized more than 10 years ago by Secretary of Labor Elizabeth Dole when she committed to taking the most effective steps necessary to address the problem of ergonomic hazards. The need for such action was reaffirmed in 1992 by Secretary of Labor Lynn Martin when she initiated rulemaking on an OSHA ergonomics standard in response to a petition from the United Food and Commercial Workers, AFL–CIO and many unions.

Unfortunately ideological opposition to government action by industry groups and some in Congress has delayed and blocked these needed protections. More than 10 years after government action was promised, workers still lack legal protection against ergonomic hazards.

In the aftermath of the recent action by Congress and the Bush Administration to repeal OSHA's November 2000 ergonomics standard, Secretary of Labor Elaine Chao committed the Department of Labor to developing a comprehensive approach to address musculoskeletal disorders. The AFL-CIO supports and has long advocated a comprehensive approach to addressing MSDs. But any approach to addressing MSDs must have as its core and foundation a mandatory protective OSHA standard. Voluntary compliance assistance, outreach, education and further research can and should complement and supplement regulatory action. But voluntary

approaches alone are insufficient to provide workers the protection they need and deserve.

Indeed, the major advances in protecting workers from MSDs and implementation of workplace ergonomic programs have come as a result of mandatory action required by OSHA enforcement under the general duty clause. Ergonomic programs in auto manufacturing, meatpacking, poultry, and garment industries all have their roots in the settlement agreements that stemmed from OSHA enforcement actions. It is necessary and appropriate to extend these same protections by regulation to all sectors and workplaces where workers face a significant risk of musculoskeletal disorders.

The AFL–CIO has long advocated that an OSHA ergonomics standard be based on the good employer practices that have been demonstrated to be effective at reducing the incidence and severity of work-related MSDs. As the National Academy of Sciences (NRC/IOM, 2001) and General Accounting Office (GAO, 1997) have both reported, these effective practices implement ergonomic principles and follow a programmatic approach which includes employer commitment and employee participation, job analyses and control, training and medical management.

These basic elements form the foundation of OSHA's 1990 Meatpacking Guidelines and settlement agreements that have been implemented successfully in key industries. These basic elements also form the basis of many employer ergonomic programs that have been effective at reducing MSDs. They also form the basis of the voluntary standard on MSDs which is being developed by the Z 365 ANSI standard setting committee. These basic elements were also the backbone of the November 2000 ergonomics standard issued by OSHA.

To be effective at preventing injuries and consistent with the OSHAct, the AFL–CIO believes that an OSHA ergonomics standard should also do the following:

—Cover all sectors and all workers at significant risk of injury. OSHA's November 2000 ergonomic standard was limited to general industry and excluded construction, maritime, agriculture and railroads. MSDs are a major source of injury and illness for workers in all sectors. State ergonomic standards in California and Washington apply to all employers and workers. Any Federal OSHA ergonomics standard should cover workers in all sectors as well.

—Be pro-active and preventive. OSHA's November 2000 standard was triggered only in response to worker reports of MSD injuries or persistent symptoms, when workers also had significant exposure to identified ergonomic risk factors. In the absence of any injury, no action was required, even if the employer had knowledge that serious hazards were present. All other OSHA standards are triggered by worker exposure to hazards, not reports of injuries. To be preventive an ergonomics standard should respond to hazardous exposure, whether or not an injury has occurred.

—Provide for early detection of MSDs and early intervention. MSDs are cumulative progressive injuries that become more serious, disabling and costly with continued exposure. One of the keys to a successful ergonomics program is the early detection of these injuries, so interventions can be made before damage is serious and permanent. Early detection and intervention is also key to reducing the cost of these injuries.

—Encourage reporting of MSDs and hazards and participation by workers and their representatives. The early detection of MSDs is only possible if workers feel free to report MSDs and MSD hazards. Any standard must prohibit discrimination and retaliation against workers who make such reports and prohibit practices or policies that discourage worker reports. Such provisions were appropriately included in OSHA's ergonomics standard. To encourage early reporting and participation in any medical management program, employees should not have to face loss of wages for making these reports. This was the purpose of the work restriction protection provision of OSHA's ergonomics rule. The standard mandated that an employer follow a health care provider's medical determination for job restriction of injured workers. It also provided that on a temporary basis when such restrictions were required, workers should not have to lose wages or benefits.

This work restriction protection was not a workers' compensation system. It's purpose was to encourage early reporting, not after the fact compensation. It, in no way changed or altered workers' compensation laws or benefits. Similar provisions have been included in OSHA standards since 1978 when medical removal protection was included in OSHA's lead standard. Such provisions have been upheld by reviewing courts as permissible and appropriate protective measures under the OSHAct. Such a provision should be included in an OSHA's ergonomics standard.

—Provide for the reduction of exposure to ergonomic hazards to the extent feasible. The reduction of exposure to ergonomic risk factors—force, repetition, awkward posture, and vibration—must be the heart of any ergonomics standard, just as it is the heart of all OSHA standards. An ergonomics standard must require employers to reduce exposures to ergonomic risk factors so they no longer pose a hazard, or if that is not possible, reduce them to the extent feasible.

As stated earlier, some employers have already taken action and implemented measures similar to those outlined above to protect workers. Many countries around the globe have implemented ergonomic standards or manual handling standards. These include British Columbia, Canada, Australia, Sweden and the member states of the European Community which have adopted regulations to implement the European Community directive on manual handling (Council Directive 90/269/EEC, May 29, 1990) and directive on video display terminal use (Council Directive 90/270/EEC, May 29, 1990).

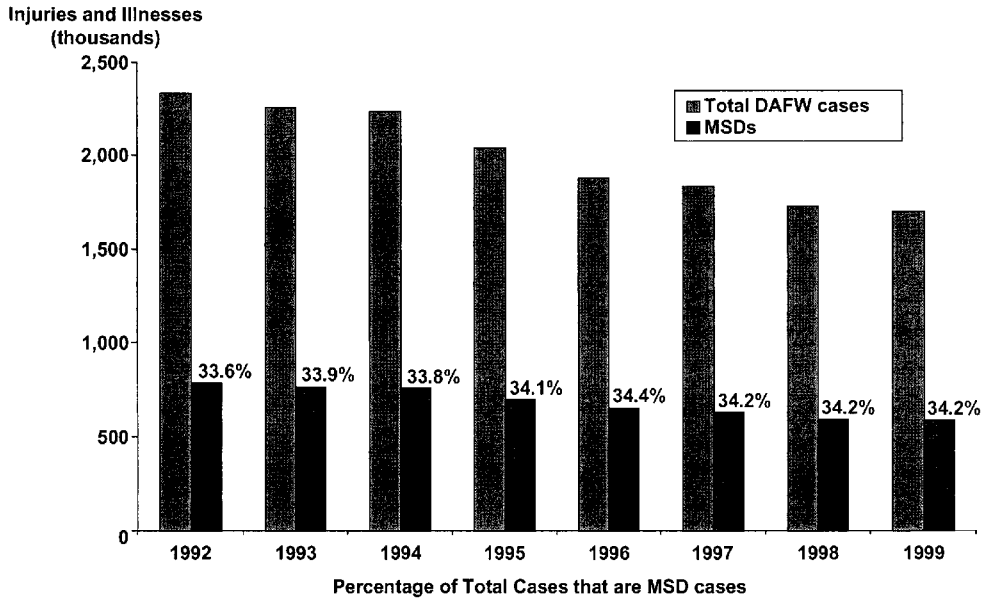
The only reason why a mandatory ergonomics standard is not in place in the United States today is because of the fierce ideological opposition by some business groups, including the U.S. Chamber of Commerce and the National Association of Manufacturers, and others to any government intervention on this issue.

For 10 years these business groups have opposed any and every attempt to regulate ergonomics at the state and Federal level. They opposed state standards in California, North Carolina and Washington. They opposed efforts by states and Federal OSHA to enforce against ergonomic hazards under the general duty clause. They are now challenging longstanding OSHA regulations that require musculoskeletal disorders to be recorded on the OSHA log. They are even trying to block a voluntary ANSI standard on MSDs that is now close to being finalized.

The misrepresentation by these groups of the facts and the science and their fierce opposition to any ergonomic protections is directly responsible for the serious and preventable injury to millions of workers in this country. Unfortunately this past March, a majority in the Congress and President Bush decided to side with these opponents of protections and acted to repeal OSHA's ergonomics standard.

We believe that it is time that Congress, elected to be the people's representatives, and the Bush Administration started doing the people's business. The Department of Labor should act immediately to issue—and the Congress should support—a new ergonomics standard to protect the working men and women of this country.

Comparison of Total Injury and Illness Cases Involving Days Away from Work to MSD Cases Involving Days Away from Work, 1992-1999



The percentage of total cases involving lost worktime that result from musculoskeletal disorders has remained constant since 1992.

SOURCE: Bureau of Labor Statistics, U.S. Department of Labor, Survey of Occupational Injuries and Illnesses.

APPENDIX B—MSD DATA COMPARISON FROM THREE STATES

WORK-RELATED CARPAL TUNNEL SYNDROME IN MASSACHUSETTS

[Massachusetts SENSOR Program vs. Massachusetts BLS, 1993–1996]

Year	Massachusetts SENSOR			CTS cases reported by Massachusetts BLS
	All workers compensation cases	Additional physician reported only cases	Total unique SENSOR cases	
1993	1,076	281	1,357	379
1994	1,156	185	1,341	627
1995	885	86	971	321
1996	915	104	1,019	431

Source: The Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health, January 20, 1999.

MUSCULOSKELETAL DISORDERS IN OREGON

[Number of Injuries by Event that Caused the Injury, 1992–1994]

	1992		1993		1994	
	WC [1]	BLS [2]	WC	BLS	WC	BLS
Repetitive Motion	545	950	1,038	857	1,521	1,156
Overexertion	12,325	7,966	11,786	7,752	11,697	7,315
Total	12,870	8,916	12,824	8,609	13,218	8,471

[1] There are time-loss-claims with 4 or more days away from work. Private insurers accounted for 49 percent of the claims, the SAIF Corporation for 31 percent, and self-insured companies for 20 percent.

[2] Number of private industry nonfatal occupational injuries and illnesses involving three or more days away from work. Days-away-from-work cases include those which result in days away from work with or without restricted work activity.

Source: BLS State data for 1992, 1993, 1994 and ''Oregon Workers' Compensation Characteristics Calendar Year 1995,'' Research & Analysis Section, Oregon Department of Consumer & Business Services, June 1997.

MUSCULOSKELETAL DISORDERS RESULTING FROM OVEREXERTION IN WASHINGTON STATE

[Industrial Insurance Claims vs. BLS Data, 1992–1994]

Year	BLS data [1]		Industrial insurance claims [2]	
	1 or more days away—overexertion	3 or more days away—overexertion	Total # MSD [3] claims—overexertion	Total # time-loss MSD Claims [4]—overexertion
1992	17,107	13,258	48,019	21,575
1993	16,488	12,514	46,970	20,578
1994	14,345	11,046	45,747	19,768

[1] Reflects both State fund and Self Insured employers.

[2] The term claims refers to accepted claims only. Data reflects both State fund and Self Insured employers.

[3] MSDs can include strains/sprains, joint inflammation, lower back pain and nerve compression syndromes. 93 percent of all MSD claims were coded overexertion.

[4] Washington State defines time loss claims as those claims with 4 or more days away from work and includes claims where the employee is kept on salary, has loss of earning power or provisional time loss.

Source: ''Work-Related Musculoskeletal Disorders: Washington State Summary 1992–1994,'' State of Washington Dept. of Labor and Industries, Oct. 1996 and data from the State of Washington Dept. of Labor and Industries, Jan/Feb 1999.

Senator SPECTER. Thank you very much. Dr. Bradley Evanoff of Washington University School of Medicine.

STATEMENT OF DR. BRADLEY EVANOFF, ASSISTANT PROFESSOR OF MEDICINE, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

Dr. EVANOFF. Mr. Chairman, Senator Landrieu, as a general internist and occupational health physician, I diagnose and treat patients with both work-related and nonwork-related illnesses and carry out research on musculoskeletal disorders. Thank you for the

opportunity to address the committee today. I will attempt to answer the specific questions which are posed to our panel.

What types of injuries occur? The term musculoskeletal disease is not a single diagnosis but represents a group of well-recognized injuries and diseases which affect the bones, joints, muscles, tendons, and nerves. Examples of these conditions include hand/wrist tendonitis, epicondylitis, low back pain, and carpal tunnel syndrome.

Specific objective criteria exists for the diagnosis of these musculoskeletal disorders. For example, the American College of Occupational and Environmental Medicine has issued practice guidelines containing specific diagnostic criteria from more than 50 distinct musculoskeletal disorders which may be related to work.

These diagnoses are based on patients' symptoms and on physical examination findings by a treating clinician, and when appropriate, laboratory and radiographic tests. Musculoskeletal disorders are routinely diagnosed by physicians all over the world.

Who suffers these injuries? Musculoskeletal disorders are seen in a variety of patients and have a variety of causes. Factors such as age, gender, and coexisting diseases all influence the probability that a person will suffer from an MSD. However, workplace exposures are among the most important determinants of musculoskeletal disorders in many working populations.

Physicians who evaluate working people with a musculoskeletal disorder routinely evaluate whether their patient's condition is work-related or not by considering both work- and nonwork-related factors. In evaluating work relatedness, physicians can rely on a large body of literature showing that certain musculoskeletal disorders are seen much more frequently in workers whose jobs involved repeated forceful use of the hands and arms, repeated heavy lifting or bending of the back, or exposure to vibration.

When taken as a whole, the medical literature shows that increased exposure to these physical factors is associated with a greater risk of an injury.

Worker groups at increased risk include nurses and nurses' aids, garment workers, construction workers, meat packers and other food processing workers, and workers in manufacturing and agriculture.

How many suffer MSDs and what is their severity? Musculoskeletal disorders are clearly the most common group of occupational diseases and injuries and account for the majority of lost time, lost productivity and workers' compensation costs.

Data from the Bureau of Labor Statistics indicate that there are almost 600,000 lost workday cases due to repetitive trauma and overexertion annually. The National Academy of Sciences estimates that almost 1 million lost workday cases occur annually.

It is important to know that these figures are underestimates. They do not include cases for which no lost workdays occurred. And a number of studies show that employers and workers routinely under report the occurrence of these disorders.

Musculoskeletal disorders represent an enormous burden to our country in terms of lost productivity and personal suffering. Conservative estimates of national costs for musculoskeletal disorders are around $50 billion annually.

The National Academy of Sciences estimated that the cost may exceed 1 percent of our gross domestic product.

The personal cost to workers are much harder to quantify. Many of my patients are unable to perform not only work duties but simple daily activities such as carrying groceries, opening a jar or lifting a child. While many patients recover quickly from these disorders, others have prolonged disabilities.

PREPARED STATEMENT

In summary, musculoskeletal disorders are commonly accepted conditions which can be confidently diagnosed. The personal and economic costs of this disorders are high, and workplace physical exposures are a prominent and preventable risk factor.

In my opinion, an adequate scientific basis exists to support a standard. Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. BRADLEY EVANOFF

My qualifications to testify: I am a physician and researcher with over ten years of experience in treating and studying occupational musculoskeletal disorders (MSDs). I am currently an Assistant Professor of Medicine at Washington University School of Medicine, where I am Chief of the Division of General Medical Sciences and the Richard and Elizabeth Henby Sutter Chair of Occupational, Industrial, and Environmental Medicine. As a medical researcher, I have published more than two dozen peer-reviewed journal articles, dealing primarily with the diagnosis and treatment of musculoskeletal disorders and the prevention of work-related injuries. I have also presented findings of my research at numerous scientific meetings, and have served as the chairperson of sessions at scientific meetings devoted to the prevention of occupational musculoskeletal disorders. I serve as a reviewer for several medical and public health journals. I have been involved in the national debate concerning ergonomics and work-related musculoskeletal disorders through my participation as an invited speaker at the 1998 National Academy of Sciences meeting on "Work-Related Musculoskeletal Disorders: A Review of the Evidence." I have also served as a member of the American National Standards Institute, Accredited Standards Committee on Control of Cumulative Trauma Disorders.

My interests in musculoskeletal disorders were shaped by my clinical experiences in treating injured workers. I was originally interested in occupational cancer research, but as I spent more time in the field of occupational health, I realized that musculoskeletal disorders were by far the largest preventable cause of morbidity and disability among the working populations which I treated. As a treating physician, I diagnose and treat patients every week who have work-related musculoskeletal problems such as back pain, tendonitis, and carpal tunnel syndrome. Over the course of my career, I have treated several thousand workers with musculoskeletal disorders related to their work. Many of these disorders could have been prevented or subsequent disability reduced through better job design and more timely medical treatment which took work factors into account.

I feel that I am fortunate to be involved in many aspects of work-related musculoskeletal problems—I treat individual workers, I advise employers on programs to prevent musculoskeletal problems, and I engage in research on the causes of these disorders and the effectiveness of interventions aimed at reducing their number and severity. There is no question that a great deal of suffering, job displacement, and economic loss is due to musculoskeletal disorders. It is also clear that many of these disorders are preventable, and that appropriate action can reduce this disease burden.

I have based my opinions on my professional background and training, which includes clinical experience treating patients with MSDs, research experience in performing and analyzing studies of work-related MSDs, and work on intervention programs to reduce MSDs in working populations. Based on the existing scientific evidence and my own professional experiences, I conclude that there is strong evidence that certain work exposures are causally related to carpal tunnel syndrome, tendonitis, back pain, and other MSDs among workers. This conclusion takes into account the strengths and limitations of existing studies, including issues of confounding, bias, and research design. The existing research base is also consistent

with my clinical experience, where I have seen thousands of workers with clinically diagnosed musculoskeletal disorders associated with the same physical risk factors described in the scientific literature. Existing research and my own clinical and administrative experiences have demonstrated that ergonomic interventions can prevent injuries in a cost-efficient manner, and that improved medical treatment programs can prevent disability from work-related MSDs.

ADEQUATE SCIENTIFIC AND CLINICAL BASIS EXISTS TO SUPPORT AN ERGONOMICS STANDARD

The workforce of our nation incurs a large number of musculoskeletal illnesses and injuries which are caused by or related to workplace exposures. Many of these disorders are preventable. Both my academic and my clinical experiences indicate that MSDs can be reliably diagnosed using accepted clinical guidelines, that a substantial proportion of MSDs are related to exposure to workplace physical factors, and that a significant part of this burden is preventable.

Acute and chronic work-related musculoskeletal disorders (MSDs) affect an estimated 19 million persons per year in the United States and account for the majority of workers' compensation costs nationwide (Bernard 1997, Webster and Snook 1994). Over the past two decades, there has been considerable evidence presented in the scientific and medical literature which supports a causal relationship between work activities and musculoskeletal disorders, including back pain, carpal tunnel syndrome, and tendonitis. The available literature when taken as a whole strongly supports the presence of a causal association between exposure to certain workplace physical activities and the development of specific MSDs. The actions of health and safety professionals all over the country reflect the knowledge that workplace exposures should be reduced in order to reduce injuries and disability.

The evidence for a causal association between work exposures and musculoskeletal disorders has been well summarized by researchers at the National Institute for Occupational Safety and Health (Bernard 1997) as well as by international scientific panels and by regulatory agencies in other countries. (Kourinka and Forcier 1995) The National Academy of Sciences convened a multidisciplinary international expert panel in 1998 to review available evidence on work-related musculoskeletal disorders. I was one of the invited participants in this process. After thorough review of available scientific evidence, including conflicting points of view, the National Academy of Sciences concluded that musculoskeletal disorders were a major source of disability and economic loss, that workplace physical exposures were an important cause of these disorders, and that interventions to reduce workplace physical exposures could reduce the number of musculoskeletal disorders. Multiple expert panels and individual scientists reviewing the scientific evidence have arrived at these same conclusions, as has a second review completed by the National Academy of Sciences, released earlier this year.

The conclusions of this second panel report by the National Academy of Sciences unambiguously support important arguments in favor of an ergonomics standard. The panel found strong and consistent evidence from both epidemiologic studies and biomechanical studies to support a relationship between workplace physical exposures and the occurrence of MSDs of the low back and upper extremities. The panel found that existing research demonstrated the effectiveness of appropriate ergonomic interventions in reducing the risk of low back pain and upper extremity symptoms. The panel found that work-related musculoskeletal disorders are a major source of costs and morbidity, and that some of this burden to society and to individuals is preventable.

A number of non-governmental groups have taken actions based on the evidence available. After concluding that sufficient evidence existed to promote a standard intended to protect worker health and safety, the American Conference of Governmental Industrial Hygienists (ACGIH) recently announced exposure limits for physical exposures in order to reduce musculoskeletal disorders. The ACGIH is a respected and authoritative non-governmental body which publishes exposure limits for chemical and physical hazards which are widely used in industry. The American College of Occupational and Environmental Medicine has published practice guidelines which clearly link workplace physical exposures to musculoskeletal disorders. The American National Standards Institute has a committee charged with creating a national industrial standard to reduce work-related musculoskeletal disorders. These and other groups have acted because of the scientific evidence showing that MSDs are a serious problem, that workplace exposures are related to many MSDs, and that the risk of harm to employees can be diminished by reduction in physical exposures.

My own reviews of the scientific literature (Evanoff 1999, Evanoff and Rempel 1998) have found that musculoskeletal disorders have been studied in a variety of work settings. Numerous studies have shown that higher rates of these disorders are seen among workers whose jobs demand repetitive or forceful movements, or who are subject to vibration or prolonged awkward postures. Systematic review of the medical and scientific literature shows that there is evidence of a causal relationship between work factors and carpal tunnel syndrome, tendonitis of the hand and wrist, epicondylitis, neck disorders, shoulder disorders, and low back disorders.

Opponents of an ergonomics standard have attacked the scientific basis of the standard by suggesting that MSDs do not represent "objectively" diagnosed entities, and consist only of worker-reported aches and pains. On the contrary, most MSDs fall into well recognized and commonly accepted diagnostic classifications which utilize both symptoms and specific signs detected on physical examination by a health care provider. It must be recognized that "MSD" is not a diagnosis itself, but a term used to group many different diagnoses affecting different body parts. For example, the practice guidelines promulgated by the American College of Occupational and Environmental Medicine list "Diagnostic Criteria" for more than fifty separate musculoskeletal disorders. These conditions include such diagnoses as lateral and medial epicondylitis, ulnar and radial nerve entrapment, shoulder impingement, rotator cuff tear, wrist tendonitis/tenosynovitis, DeQuervain's tenosynovitis, trigger finger, and carpal tunnel syndrome. These diagnostic criteria include mechanism of injury, patient symptoms, physical examination maneuvers, and for some disorders, diagnostic test results. The described mechanisms of injury for over two dozen listed disorders include repetitive use, chronic overuse, or repeated trauma.

Good quality epidemiologic studies have used definitions of MSDs which require combinations of symptoms and physical examination findings which are similar or identical to the information used to diagnose patients in clinical practice. Many of the MSD definitions used in the epidemiologic studies are the same definitions of MSDs described in medical textbooks and in practice guidelines. The work exposures described in the scientific literature are reflected in the work exposures reported by my patients with musculoskeletal disorders, and by the work exposures which I have observed on visits to workplaces with high rates of musculoskeletal disorders. These same work exposures are the ones cited by the American College of Occupational and Environmental Medicine in their practice guidelines and by the ACGIH in their threshold limit values for physical exposures.

THE IMPORTANCE OF EARLY RECOGNITION AND APPROPRIATE TREATMENT OF MSDS

The proposed OSHA ergonomics standard required early access to appropriate medical treatment, evaluation of workers' jobs when there has been a MSD, and the provision of limited or modified work duties when necessary, including when recommended by a health care provider. Each of these individual provisions is supported by current research and clinical practice. In addition, there is good evidence that comprehensive programs which integrate ergonomic changes and medical treatment are effective in reducing the incidence and severity of work-related musculoskeletal disorders.

Early recognition and treatment of musculoskeletal disorders is essential because it allows earlier treatment of affected workers, at a time when treatment can prevent progression to a more severe condition. Workers who are treated in the early stages of a disorder have a better prognosis, and are less likely to have prolonged disability, than workers who receive appropriate medical attention only after prolonged duration of symptoms. The medical literature consistently supports the observation that conservative management is most effective when begun in the early stages of these disorders, and that patients who are treated only after a prolonged symptomatic period are less likely to respond favorably than those treated earlier (Gelberman et al., 1980; Dellon, 1989; Stern, 1990; Rystrom & Eversman, 1991). With some disorders, such as carpal tunnel syndrome, patients can often be treated conservatively in the early stages of disease, while surgery is often necessary when patients present with advanced disease. Early detection is necessary to ensure that signs and symptoms of work-related MSDs are recognized and treated appropriately through medical management, administrative controls, and job evaluation.

Both healthy and injured workers can potentially benefit from evaluation of their workplace for identification of physical stressors that can be eliminated. Simple modifications can often be made to a workplace which enable the work to be done with less effort on the part of the worker. Such modifications, where possible, can prevent injury and can enable injured workers to safely return to their usual jobs more quickly. Clinical experience demonstrates that ergonomic evaluation and intervention is effective in the treatment of workers being treated for a work-related

MSD, since earlier safe return to work is facilitated when clinicians have more information about a patient's job demands and exposures, and when worksite modifications reduce physical exposures. A number of authors have advocated the importance of ergonomic changes in treating workers with work-related musculoskeletal disorders (Melhorn 1996, Higgs and Mackinnon 1995, Norris 1993, Feuerstein et. al. 1993, Halpern 1992, Travers 1992, Herbert 2000).

Comprehensive ergonomic programs which incorporate primary prevention of MSDs through ergonomic changes in jobs, early detection of MSDs through surveillance, and early treatment of MSDs with an emphasis on early return to modified work have been endorsed by many corporations and by medical professionals. The American College of Occupational and Environmental Medicine, the world's largest group of Occupational Health physicians, has recently released "Occupational Medicine Practice Guidelines" which describe what the College recommends as best medical practice in the diagnosis and treatment of work-related disorders. These practice guidelines explicitly recommend many of the elements which are contained in OSHA's proposed regulation as representing best medical practice. These include endorsement of the application of ergonomic principles to job design in order to prevent MSDs, and the use of workstation or tool adjustment to avoid further aggravation of a disorder once it has begun. Return of workers to modified work which has reduced physical exposures is strongly recommended as part of treatment—the guidelines note that the best success with return to work is seen when workers go back to their original job with modifications to reduce physical exposures. The guidelines list "substantive associations" between physical risk factors and a variety of MSDs including shoulder tendonitis, hand/wrist tendonitis, carpal tunnel syndrome, neck muscle tension, and low back pain. Specific job modifications are recommended for these and other disorders. The guidelines also note that delayed presentation (not receiving early recognition and treatment) is a risk factor for delayed functional recovery in patients with a MSD.

My own experiences from over ten years of treating injured workers have shown me the importance of early treatment and the importance of modifying job duties to facilitate return to work. The proposed ergonomics standard addressed these important aspects of disability prevention. While the main focus of prevention efforts should be on primary prevention—the reduction or elimination of workplace risk factors—it is also important to ensure that workers have access to appropriate and timely medical care if they do become injured. The goals of a medical management program should be to reduce or eliminate symptoms, prevent progression of MSDs, reduce the duration and severity of functional impairment, and prevent or reduce the severity of disability. Important elements to such a program include surveillance, timely access to appropriate health care providers, job evaluation of injured workers, and the availability of appropriate job modification. Follow-up of treated workers and coordination with primary prevention efforts are also important.

My clinical experience clearly indicates that effective treatment of work-related musculoskeletal disorders frequently requires a reduction in workplace physical exposures for the affected employee. The vast majority of injured employees are able to return to productive work very quickly, as long as their work is modified to reduce physical exposures to the affected body part. Job modifications which reduce physical exposures are frequently inexpensive and simple, and can help an employee safely return to work sooner, as well as preventing risk of future injury. Examples of job modifications include training or retraining, simple job changes to prevent awkward postures (such as a step stool or tilted work surface), changes in tool design or maintenance, or changes in procedures (such as job rotation). Where there is no simple fix for a physical exposure which is causing or exacerbating a musculoskeletal condition, temporary job transfer or restrictions are important to allow the patient's injury to heal. Examples of temporary restrictions include reduction in pace or quantity of work, restriction of certain tasks, or limitation of hours worked. If an employee is to be transferred to a different job, the new job should be assessed by the employer and the healthcare provider to be sure that the employee will not be exposed to relevant physical risk factors When this cannot be accomplished, temporary removal from work will allow time for healing. In most cases, I feel that keeping an injured employee at work in an appropriate modified position is preferable to time loss. What OSHA is requiring in the standard is common medical practice among occupational health professionals.

In my experiences of treating patients and advising the administration of employee health programs, I have found that choice of a healthcare provider for injured workers is important. Ideally, healthcare providers should have training or experience in ergonomics and the role of work modifications in the treatment of work-related musculoskeletal disorders. Effective diagnosis and treatment requires knowledge of specific job duties. The best way for a healthcare provider to get knowledge

of job duties is through a worksite visit. Since this is impractical in some clinical settings, information about exposures and job duties can also be obtained through a written work description, or a videotape of the job task. Employers should have a contact person with knowledge of job activities and the ability to coordinate appropriate job placement during a recovery period. Working knowledge of the industry and the specific workplace is also needed in order to make appropriate recommendations regarding temporary or permanent job modifications. In my experience, some employers readily provide detailed information about job duties and physical exposures to the treating physician. It is more difficult to provide optimal care for injured workers when this information is not available.

The medical literature has examples of successful programs which have decreased the length or severity of disability resulting from injuries through integrating ergonomic interventions as part of medical treatment of injured workers. One such study evaluated work-related back pain among workers from a variety of industries who had been away from work for more than four weeks due to their back injuries. (Loisel et. al. 1997). Workers were randomly assigned to receive an ergonomics intervention, an intensive clinical and rehabilitation intervention, neither, or both. The ergonomics intervention consisted of a worksite ergonomics evaluation that included labor and employer representatives in determining the need for job modification. After observation of a worker's tasks in conjunction with a trained ergonomist, these parties determined the need for modifications to improve the worksite. Implementation of the recommended solutions remained the employer's responsibility. The clinical and rehabilitation intervention consisted of patient education ("back school"), referral to a back pain specialist, and a multidisciplinary work rehabilitation intervention. Combination of the rehabilitation intervention along with the ergonomics intervention was the most successful in returning injured workers to work. The ergonomics intervention was the most successful element of this program, resulting in more than a two-fold increase in the rate of return to usual work. By facilitating return to usual work, the ergonomics intervention appeared to reduce progression to long term disability. In this study, the intensive clinical and rehabilitation intervention did not significantly reduce the time of absence from regular work when applied separately from the ergonomics intervention.

Another example of an integrated program was reported among sheet metal workers at an aircraft manufacturer. This program combined pre-placement evaluations of workers with ongoing surveillance for symptoms and signs of upper extremity musculoskeletal disorders in order to ensure early medical evaluation of affected workers. Job modification was implemented for those with signs of early disorders, through restriction of work hours and restriction of use of vibrating hand tools. This program reported decreased workers' compensation costs, decreased time loss, and decreased severity of injury following the implementation of this program for screening, surveillance, early medical evaluation, and job modification. (Melhorn JM 1999)

Other authors have described comprehensive initiatives to manage the incidence and cost of occupational injuries that included an ergonomics component directed specifically toward injured workers. One such program has been described among hospital employees at an academic health center (McGrail et. al. 1995). This study showed decreases in musculoskeletal injuries, time loss (change from 10.4 days to 6.6 days average time loss), and total case costs (18 percent reduction) following the implementation of a comprehensive intervention that included case management, treatment by physicians experienced with work injuries, and the use of ergonomic worksite evaluation and modification. A later report from this group described elements of the program aimed at the early diagnosis and treatment of work-related upper extremity MSDs. The program included ergonomic assessment and abatement of the affected employees' work areas, and close coordination between the treating physicians and the ergonomists. The program resulted in pronounced decrease in the number of work-related upper extremity MSDs and a virtual elimination of cases which required surgery. The authors concluded that a coordinated program of medical care, ergonomic assessment, and intervention can be effective in the prevention of MSDs. (Bernacki 1999)

These and other peer-reviewed studies clearly indicate that a multi-element program can reduce the cost and burden of MSDs in different working populations. There are also numerous industry case reports where the introduction of ergonomic or medical management interventions have reduced costs and injury rates. Most major corporations have ergonomics programs, in recognition that such programs are effective in reducing injuries. Successful approaches have most often used a combination of ergonomic principles for prevention, as well as improved recognition and management of those disorders which have occurred.

I have also studied the effects of ergonomic assessments and interventions as part of the care of workers with WRMSD. As the result of a "natural experiment," we

have collected pilot data on cost outcomes of ergonomic intervention in active workers' compensation patients employed by a local educational institution. Prior to September of 1996, ergonomic evaluations requested by the treating physician were not covered by the workers' compensation insurance carrier and requests for this service were denied. This policy changed, and ergonomics evaluation and intervention was then allowed under workers' compensation when ordered by the treating physician. These cases were predominantly neck and upper extremity disorders among office employees; the ergonomic interventions consisted of changes in workstation layout. We compared 11 consecutive cases referred by the treating physician to the ergonomist prior to the administrative change with 20 consecutive cases after coverage was allowed. These cases were all ones in which the treating physician thought that work factors were important in causing disease or retarding healing. Comparison of total workers' compensation costs for these cases showed a median cost of $5,130 among the patients referred for ergonomic evaluation who did not receive it, compared to a median of $4,082 among patients who did receive the physician recommended ergonomic evaluation. Costs included medical treatment, time loss, and permanent disability payments. Cost in the intervention group included the cost of the ergonomic evaluation and intervention, which averaged $280. Although these data do not come from a randomized study, they represent a series of cases from the same workplace referred by the same group of treating physicians, differing only in the fact that the ergonomic intervention was denied to the first group and given to the second. Based in part on this study, we are currently conducting a randomized trial funded by NIOSH to assess the effectiveness of an integrated ergonomics and case management intervention on cost and disability outcomes among injured workers.

THE EFFECTIVENESS OF ERGONOMIC INTERVENTIONS

Review of the scientific literature demonstrates that workplace ergonomic interventions can prevent injuries and reduce days lost due to injuries. This evidence comes from a number of studies published in the peer-reviewed literature which show the effectiveness of ergonomic interventions at various worksites and employers. The 1998 report by the National Research Council stated that "The literature provides evidence that interventions, of various types and complexity, can prevent the development of musculoskeletal disorders in specific industries and occupational groups." The NRC report concluded that "Research clearly demonstrates that specific interventions can reduce the reported rate of musculoskeletal disorders for workers who perform high-risk tasks. No known single intervention is universally effective. Successful interventions require attention to individual, organizational, and job characteristics, tailoring the corrective actions to those characteristics." Examples of published intervention studies familiar to me are given below; the background information provided by OSHA gives over 100 examples of successful ergonomic interventions.

The effectiveness of ergonomic interventions in the prevention of musculoskeletal disorders was shown by a study in a telecommunications equipment manufacturing plant, where workstations were re-designed to reduce postural stress on workers. Following this intervention, time loss was reduced by over 40 percent and employee turn-over was reduced by 75 percent. Cost-benefit analysis showed that the return on investment for the ergonomic interventions was 9 to 1. (Aaras 1994). Another study in telecommunications manufacturing sought to control the incidence and severity of repetitive trauma disorders associated with hand tool operations in a manufacturing facility with 6,600 employees. Repetitive trauma disorders were the leading cause of lost time and workers' compensation expenses at this plant. The incidence rate of OSHA reportable repetitive trauma disorders was 2.2 cases per 100 full-time equivalent workers (FTE) and resulted in 1,001 lost workdays in 1979. In the spring of 1981, the plant safety and health committee undertook a control program that included creation of a task force, a training program, improvements in the design of workstations and tooling, and management of restricted workers. During 1982, the incidence rate of repetitive motion disorders has decreased to 0.53 cases per 100 FTE and resulted in only 129 lost workdays. (McKenzie 1985)

A study at Gold Kist poultry (Jones 1997) reported results of an intervention undertaken due to high rates of upper extremity MSDs—47.7 per 1,000 workers in 1990. This plant instituted a corporate ergonomics program which utilized ergonomic committees at each facility. Key program elements included training, worksite analysis and task design, and the implementation of medical management procedures. This combination of worksite task analysis and medical management is similar to the program elements proposed by OSHA. This program resulted in a 46 percent decrease in upper extremity MSD rates over a five year period.

Another study evaluated a back injury prevention program undertaken in municipal workers in California. The program consisted of a combination of worker education, training in safer work practices, physical fitness activities, and ergonomic interventions including making safety equipment more available and improving the design of work facilities (through such measures as safety flooring, improved furniture, and rearranging storage space to minimize transport distances). Comparison of an intervention group and a control group of employees who did not receive the intervention showed a decline in back pain prevalence and a reduction in injuries among the intervention group. This study evaluated cost savings due to the intervention as well as documenting the reduction in back pain and injuries. Cost-benefit analysis showed a net savings of over $160,000 resulting from decreased workers' compensation and medical claims, and reduction in sick days. Return on investment was estimated at 179 percent. (Shi 1993)

One of my own studies (Evanoff 1999) examined work injuries and other outcomes before and after the implementation of a participatory ergonomics team among hospital orderlies, a group at high risk for injuries of the back, shoulder, and knee. This team designed and implemented changes in training and work practices, which included standardization of lifting procedures, an apprenticeship program for new workers, and use of mechanical lifting and transfer aids. The two year post-intervention period was marked by a 50 percent decrease in OSHA recordable work injury, a 74 percent decrease in lost time injury, and an 81 percent decrease in injuries with three or more days of time loss. Total lost days declined from 136.2 to 23.0 annually per 100 full-time worker equivalents (FTE). Annual workers' compensation costs declined from $237/FTE to $139/FTE. The proportion of workers with musculoskeletal symptoms declined as well. Other researchers using participatory ergonomics teams have demonstrated the abilities of such teams to work effectively to address musculoskeletal hazards (Moore and Garg 1996, Moore and Garg 1997).

I have directed a second study which has been presented as an abstract but not yet published. This was an ergonomics intervention among 117 workers employed in a hospital billing office, who were offered an educational session and individual workstation evaluations, with changes in workstation layout where appropriate. Changes included adjustments in computer keyboard and monitor setup, adjustments in seating, and changes in desk layout. Lost work days and total costs for workers compensation decreased dramatically in the two years following this intervention, compared to the two preceding years. Annual lost work days declined from a rate of 51 days per 100 full-time equivalents (FTE) to a rate of 25 days per 100 FTE. Annual workers' compensation costs declined from a high of $578 per FTE to a low of $120 per FTE. The total cost of the intervention was $255 per FTE; return on investment over 18 months following the intervention was over 2 to 1.

Other studies (Kukkonen 1983, Ohara 1976, Parenmark 1988, Oxenburgh 1985, Lutz 1987) have also demonstrated reductions in symptoms, signs, or lost time following the implementation of interventions to reduce exposure risk factors for musculoskeletal disorders. Ergonomic job design clearly offers great potential for preventing musculoskeletal disorders of the low back and upper extremities. (Garg & Moore 1992).

My personal experience agrees with the literature cited above. I am personally aware of many local worksites where ergonomic analysis and job changes have led to improvements in symptoms or reductions in injury rates among workers. I have seen dozens of case reports of industries where the implementation of ergonomics programs have resulted in reductions in injury rates or lost time. These industry case reports offer important additional information to the peer-reviewed scientific literature, given the daunting logistical and other barriers to performing true "experimental" studies of workplace ergonomic interventions. I have served as the medical director of an ergonomics program aimed at reducing injuries among the 23,000 employees of a large health system. Musculoskeletal injuries and lost days have declined since the implementation three years ago of a system-wide ergonomics program. A NIOSH funded project within five nursing homes in our health system has demonstrated a marked decline in lifting injuries following an ergonomics intervention which consisted of training and the purchase of mechanical patient hoists.

My personal experiences with research studies of ergonomic interventions, as well as my experience with ergonomic programs in industry, have convinced me that appropriately designed ergonomics programs can reduce injuries and disability in many workplace settings.

SUMMARY

Based on my knowledge of the relevant scientific literature, my observations of best practices among employers and physician groups, and my own clinical and ad-

ministrative experiences, I conclude that there is ample evidence to support specific program elements proposed by OSHA. Physical exposures in the workplace are clearly a significant cause of musculoskeletal disorders. Reduction in physical exposures through training, workplace design, or change in practices can reduce disability due to musculoskeletal disorders. Appropriate medical treatment early in the course of work-related musculoskeletal disorders can lead to better functional outcomes and reduced disability. Though future research findings will no doubt refine and better inform our actions, we need not wait to begin action. Effective solutions are available now, and a large burden of disability can be prevented by using what we currently know.

APPENDIX—REFUTATION OF SOME COMMON ARGUMENTS AGAINST AN ERGONOMICS STANDARD

Critics of the conclusion that work activities are causally related to musculoskeletal disorders raise a number of arguments which are not convincing on closer examination. Four common arguments are addressed below.

Argument 1: Epidemiology or observational studies cannot demonstrate causation; only randomized prospective studies can do this.—While experimental studies where humans are randomly assigned to receive or not receive some treatment provide the strongest evidence for a health effect, it is obviously impossible to perform this type of study for exposures we think may cause harm. There are well-established ways to link observational data to a decision about causation of illness which can be valid in the absence of experiemental data. For example, the vast majority of the scientific community concluded that tobacco smoking caused a number of health problems based on observational studies which showed much higher rates of some diseases among smokers. It was not necessary to do an experiment where people were randomly assigned to smoke or not smoke. Data on the health effects of most occupational exposures such as lead or asbestos also rely on observational studies, which can demonstrate causality in a scientifically acceptable fashion.

Argument 2: Work can't be the cause of MSDs since some workers get these disorders and other workers doing the same job don't have any problems.—This argument is specious. People vary in their susceptibility and resistance to disease and injury, and people with identical exposures frequently have different health effects. Exposures clearly interact with personal factors to produce disease in some but not others—this does not change the importance of the exposure in causing the disease. A minority of heavy smokers die from lung cancer, yet we readily accept that smoking causes lung cancer because heavy smokers are much more likely to get this disease than non-smokers. Though genetic makeup and other personal factors are clearly important in determining which smokers die from lung cancer, in the absence of smoking the vast majority of these cancers would never have occurred.

Argument 3: Work can't be a major cause of MSD since there are so many other conditions which contribute to MSD risk.—As with most diseases, MSDs are multifactorial in origin. It is nonetheless possible to study the effects of risk factors in isolation. Consider, for example, heart disease. There are many risk factors for heart disease which cannot be changed, including age, gender, and genetic makeup. There are other risk factors that can be changed, such as high blood pressure, blood lipids, exercise, and smoking. Most individuals have more than one risk factor, yet we can study the amount of heart disease that is caused by smoking, or hypertension, or lack of exercise. We can also direct interventions at reducing heart disease risk by targeting one or more of these risk factors. Changes (positive or negative) in one risk factor can significantly alter the risk of disease, even if other risks do not change. Similarly, in MSDs, personal risk factors such as obesity, age, gender, and other medical conditions account for some fraction of the total disease burden. In many workers, however, workplace exposures are the primary determinant or cause of the disorder. Comparisons of working populations which do not differ substantially in non-work risk factors have shown substantial differences in MSD rates linked to workplace exposures. The intervention studies cited above show that prevention efforts targeted at workplace physical exposures can reduce the risk of MSDs.

Argument 4: Research shows only that work may cause some symptoms of discomfort, but does not show that work causes diagnosable diseases.—High quality studies of work-related MSDs have defined these disorders through the same methods used by clinicians to diagnose MSDs—a combination of history, physical examination findings, and, in some cases, nerve conduction studies. The NIOSH review (Bernard 1997) only considered studies where clinical case definitions included the use of physical examinations as well as symptoms. The case definitions used in much of

the research on musculoskeletal disorders are similar to the diagnostic methods used every day by clinicians.

Senator SPECTER. Thank you very much, Dr. Evanoff. Turn now to Ms. Heidi Eberhardt, international trade specialist.

STATEMENT OF HEIDI EBERHARDT, INTERNATIONAL TRADE SPECIALIST

Ms. EBERHARDT. Good morning. My name is Heidi Eberhardt. I am from Boston, Massachusetts, and I want to thank you for inviting me to testify today.

Two and a half years ago, when I was 30 years old, I was injured at my job from working on the computer. I was working 40 hours a week at a dot com internet publishing company. I was an international trade specialist and my job consisted of using the computer keyboard most 8 hours a day for writing, editing and researching about Latin American countries, surfing the web and e-mailing with foreign officials.

As an undergraduate at Dartmouth College, I majored in Spanish and studied in Latin America. When I started this job 6 years ago, I was thrilled to have found work where I could put my education to use. I was excited to be working in a cutting-edge industry with the advanced computer technology that allowed me to be more productive and perform my job more efficiently.

I had never heard about repetitive strain injuries. I did not know I could be injured from working on the computer. I did not know what workers' compensation was.

I was a healthy and happy individual in all respects and exercised regularly. I had no hobbies that were repetitive in nature.

My company provided no education or training about ergonomics or working safely on a computer. Our computer work stations were not set up properly.

There was another young employee in our department who after only working 3 months with us had already begun to experience symptoms of repetitive strain injury from working at the computer. I was diagnosed with bilateral tendonitis, tenosynivitis, thoracic outlet syndrome and De Quervain's thumb.

At first, my symptoms were merely annoying. My wrists would ache and my hands felt clumsy. Then I started to notice tingling and pain that persisted even at rest, even on the weekends.

My pain and loss of dexterity became so severe that I could no longer type or do anything on the computer, let alone perform any hand-related tasks outside of work.

My doctor sent me out of work for 4 months, and I had to file for workers' compensation. I was returned to light duty for 12 hours a week, but my symptoms had not completely gone away and I was still working in pain.

I since have switched to a job where I do not use a computer, but even writing, looking through files or even holding the phone still hurts my hands. So now at age 32, 2½ years after being injured, I am still on workers' compensation and still working only 12 hours per week. I am greatly hindered in my ability to contribute in a productive way to the workforce and am not paying taxes.

After college, I had spent several years mastering research and writing skills. I was building a career, one that was satisfying, productive and seemed to be full of potential.

I am now sitting before you, a young person faced with having to find a new career that does not require a computer or even much use of my hands. I am faced with reduced income and increased medical expenses. I am faced with chronic pain which affects my work productivity.

I have a restricted personal life and am unable to perform daily chores outside of work without pain. I have had to endure the stigma of being injured and on workers' compensation.

Doctors can tell me what my injury is. My tendons and ligaments are damaged because of repetitive hand use of the computer. No doctor can tell me if I will fully recover.

I am worried about my future and about whether I will ever regain complete use of my hands. I am a single person and do not have anyone to assist me with daily living, nor do I have the financial resources to pay someone to help me.

I would like to get married and have children some day and am worried about not being able to physically raise children.

Here are a few simple things I used to take for granted but I now have difficulty with: Squeezing shampoo bottles, toothpaste tubes, turning on and off faucets, clipping finger and toe nails, driving, shifting gears, holding the steering wheel, carrying groceries, cooking, carrying heavy pots, opening cans, cutting things, putting away dishes, cutting my food, opening milk cartons, making coffee, holding coffee, getting ice cubes out of the ice tray, dressing myself, buttoning my pants and my shirts, pulling things on, hanging up clothes, doing laundry, carrying clothes to the laundromat, pulling clothes in and out of the washer and dryer, folding clothes, cleaning house, writing letters, writing checks for bills, opening mail, opening doors and windows, turning my house key in the lock or my car key in the ignition; in short, almost anything you need your hands to do. And this list does not include anything I might want to do for fun.

In March of last year, I testified at the public hearings that OSHA held on its then proposed ergonomics standard. When the ergonomics standard was issued last November, I was proud of our government for recognizing and acting to prevent what I now know is the Number 1 injury in the workplace, an injury that I know about firsthand and have been trying to recover from for 2½ years, an injury that has profoundly altered my life and left me unable to work on the computer.

So when both houses of Congress voted to repeal the very standard that would have prevented millions of devastating injuries, I was deeply dismayed.

What was most disturbing was the manner in which it was done. The votes were rushed through without any input from the workers it would have protected. This action seemed only to put the interests of corporations above the safety and health of workers in this country. Millions of workers have suffered ergonomic injuries over the past decade while waiting for protections.

Senator SPECTER. Ms. Eberhardt, I have to remind you that the time is up. If you could summarize, we would appreciate it.

PREPARED STATEMENT

Ms. EBERHARDT. I know that companies who have put into place ergonomic programs have been successful. They have reduced costs. And I know that these ergonomics programs which include simple education and training can prevent the kind of injury that I have sustained and I strongly urge you to continue your hard work.

[The statement follows:]

PREPARED STATEMENT OF HEIDI EBERHARDT

My name is Heidi Eberhardt. I am an international trade specialist from Somerville, Massachusetts. I am here today to tell you about an injury that has changed my life.

In the Fall of 1998, when I was 30 years old, I was injured at my job from working on the computer. I was working 40 hours a week at a .com Internet publishing company. There were 8 employees in the company, and I was working in the department responsible for researching and writing about international trade issues.

My job as an international trade specialist consisted of writing, researching, and editing which was performed 8 hours a days, 5 days a week on the computer using a keyboard and a mouse. This included typing, cutting and pasting, formatting, scrolling through 20 page documents, surfing the web and corresponding via email with customers and information providers. We had a heavy workload with weekly, sometimes daily, deadlines. We were always behind. There was so much to do, I stopped only for breaks to go to the restroom and to get my lunch to eat at my desk while I was working.

As an undergraduate at Dartmouth College, I majored in Spanish and studied in Latin America. When I started this job six years ago, I was thrilled to have found work writing about Latin American countries where I could put my education to use. I had never heard about repetitive strain injuries. I did not know I could be injured from working on the computer. I did not know what worker's compensation was. I was a healthy and happy individual in all respects and exercised regularly. I had no hobbies that were repetitive in nature.

In January of the same year I was injured, my company had switched from Windows 3.1, with no internet or e-mail access, to Windows 1995 and a direct connection to the Internet, internal and external email, and websurfing capabilities. I was happy that we could work faster and perform more job tasks on the computer at once. With these new computer programs there is no need to pause between tasks.

My company provided no education or training about ergonomics or working safely on a computer. I've since learned that our computer workstations were not set up properly. There was another young employee in our department who, after working only three months with us, had already begun to experience symptoms of repetitive strain injury from working at the computer. Since being injured, I have received extensive ergonomics education from occupational therapists. This education came too late to prevent my injury, and it is information that most workers will never hear without the types of workplace programs that OSHA tried to put in place.

At first my symptoms were merely annoying. My wrists would ache and my hands felt clumsy. Then I started to notice tingling, and pain that persisted even at rest, even on the weekends. My pain and loss of dexterity became so severe that I could no longer type or do anything on the computer, let alone perform any hand-related tasks outside of work.

At my doctor's and occupational therapists' insistence, I filed for Worker's Compensation. My doctor, who had diagnosed me with bilateral tendonitis, tenosynivitis and DeQuervain's syndrome, prescribed rest and abstaining from work. After being out of work for 4 months, I returned to light duty for 12-hours a week. But, my symptoms had not completely gone away, and I was still working in pain. I since have switched to a job where I do not use the computer, but even writing, looking through files, or even holding the phone, still hurts my hands. Now, at age 32, two and a half years after being injured, I am still on worker's compensation, and still working only 12 hours per week. I am greatly hindered in my ability to contribute in a productive way to the workforce, and I am not paying taxes.

After college, I spent several years mastering research and writing skills. I was building a career, one that was satisfying and productive and seemed to be full of potential. I am now sitting before you, a young person faced with having to find a new career that does not require a computer or even much use of my hands—please imagine that if you can. I am faced with reduced income and increased medical ex-

penses. I am faced with chronic pain which affects my work productivity. I have a restricted personal life and am unable to perform daily chores outside of work without pain. I have had to endure the stigma of being injured and on worker's compensation. And I have suffered depression as a result of dealing with the pain and uncertainties about my future.

Doctors can tell me what my injury is—my tendons and ligaments are damaged because of repetitive hand use at the computer. No doctor, however, can tell me when I will be fully recovered. I am worried about my future and about whether I will ever regain complete use of my hands. I am a single person and do not have anyone to assist me with daily living, nor do I have the financial resources to pay someone to help me. I would like to get married and have children someday and am worried about not being able to physically raise children.

Here are a few simple things that I used to take for granted, but I now have difficulty with:

—squeezing shampoo bottles, dishwashing detergent and toothpaste tubes
—turning on and off faucets
—clipping finger and toe nails
—driving, shifting gears, holding the steering wheel
—carrying groceries
—cooking, carrying heavy pots, opening cans, cutting things, putting away dishes
—cutting my food
—opening milk cartons, bottles, cans
—making coffee, holding coffee
—getting ice cubes out of the ice tray
—moving anything heavy
—dressing myself (buttoning pants and shirts and pulling things on)
—hanging up clothes
—doing laundry (carrying clothes to laundromat, pulling clothes in and out of washer/dryer, folding clothes)
—cleaning house (washing counters, bathrooms, vacuuming)
—writing letters, grocery lists, etc.
—writing checks for bills
—opening mail
—opening doors and windows
—turning my house key in the lock, or my car key in the ignition
—picking up my 2-yr old nephew

In short, almost anything you need your hands to do, and this list does not include anything I might want to do for fun, nor does it include computer or work activities.

In March of last year I testified at the public hearings that OSHA held on its then proposed ergonomics standard. When the ergonomics standard was issued last November, I was proud of our government for recognizing and acting to prevent what I know is the number one injury in the workplace today. An injury that I know about first hand and have been trying to recover from for two and a half years. An injury that has profoundly altered my life and left me unable to work on the computer. So when both houses of Congress voted to repeal the very standard that would have prevented hundreds of thousands of serious injuries, I was appalled. What was most outrageous was the manner in which it was done. The votes were rushed through without any input from the workers it would have protected. The action taken by Congress and the President seemed only to put the interests of corporations above the safety and health of workers in this country.

Millions of workers have suffered ergonomic injuries over the past decade while waiting for protections. How many more workers need to suffer these crippling injuries before this problem is addressed?

When I was first injured, I went to the Massachusetts Coalition on New Office Technology (CNOT) because they offer resources to injured workers. Now I work for CNOT part time, providing training on ergonomics and injury prevention. Part of my work involves evaluating employees' workstations. What I see in my work validates the overwhelming need for a Federal ergonomics standard. More often than not, workers are sitting in improperly set up workstations, with little knowledge of the impact that this can have on their health, and as I know first hand, their entire lives. What is even more frightening is that close to 25 percent of the people I see already have symptoms of injury.

These injuries can be prevented with programs that include appropriate workstations and training for workers. Once an injury sets in it is difficult, if not impossible, to reverse the damage. I implore you to pass legislation that requires OSHA to issue a strong ergonomics standard that covers workers in all industries and emphasizes prevention of repetitive strain injuries. I am only 32, but I know

people who are in their early twenties, working in Internet companies or as software engineers, who are injured.

Workers in this country desperately need an ergonomics standard to prevent even more debilitating injuries from occurring. Too many companies will not act to protect their employees unless required to by law. I sincerely hope that my testimony today gives you a better idea of what can happen to workers, including very young workers, in today's computer-driven workplaces and how these injuries are affecting our lives. Your work to pass this bill can prevent this story from being told over and over again, by injured worker after injured worker. Thank you for this opportunity to tell you my story.

Senator SPECTER. Thank you very much, Miss Eberhardt.

Mr. Fellner, do you think that it is realistic to expect a consensus on the issues that are involved in ergonomics based on the testimony we have heard here in this first panel?

Mr. FELLNER. I think that we will not know the answer to that question until a much more exhaustive analysis of the issues that are touched on this morning has been had at the Department of Labor.

Senator SPECTER. Dr. Bigos, you say there is no scientific basis. You cannot diagnose and you cannot prevent. In the absence of a scientific basis, your testimony is pretty plain that from your professional expertise and in the absence of a scientific basis and the cost of a regulation simply cannot have one. Isn't that right?

Dr. BIGOS. Well, I guess I am not sure I understand the question you are asking me.

Senator SPECTER. Well, let me repeat the question. You testified that there was no scientific basis for an ergonomics regulation, did you not?

Dr. BIGOS. Yes, I did.

Senator SPECTER. So how can you have an ergonomics regulation without a scientific basis as you view this entire issue?

Dr. BIGOS. I do not think you can.

Senator SPECTER. That is my point. You do not think we can.

Dr. BIGOS. No. Without knowing the dose and without knowing how high or how much or some guidance in some way, I do not see any way that we can really do that.

Senator SPECTER. Well, I understand your point. I was just making sure that I understand it. You cannot have an ergonomics regulation. Ms. Seminario?

Ms. SEMINARIO. Seminario.

Senator SPECTER. In the absence of a scientific basis, which Dr. Bigos testifies to, what basis do you have for postulating a regulation besides, if anything, all of these reports of work-related injuries?

Ms. SEMINARIO. A couple of things, Senator. First, we do think there is a scientific basis that is fairly extensive and quite strong and certainly sufficient to regulate. There is also the experience that employers and unions and others have had dealing with these problems in the workplace which again is quite extensive.

And we had encouraged the Labor Department and we would still encourage the Labor Department to look to that experience of employers in addressing these problems as the approach that they should take to regulation.

I would also point out that this issue has been regulated. There are regulations on manual handling, ergonomics, video display terminal use that have been in place in the European community for

more than a decade. Many of the same employers that obviously operate——

Senator SPECTER. Are they in place in Workman's Compensation laws in the State level?

Ms. SEMINARIO. Not the preventative aspects. Obviously these injuries are——

Senator SPECTER. The diagnosed aspects?

Ms. SEMINARIO. Yes. The diagnosed aspects certainly are and the criteria in some of the states are quite similar to the criteria and definitions laid out by OSHA.

Senator SPECTER. When I listened to the testimony of Dr. Evanoff and Dr. Hadler, diametrically opposed, we have quite a number of witnesses to hear, and I will reserve judgment; but from what I have heard on this panel, Mr. Fellner, I do not see a consensus emerging at all.

When you talk about, as Dr. Bigos does about nonphysical factors outweighing physical factors on back pain, we have all had some experience with lifting and pack pain.

My dad had a junk yard in Russell, Kansas. And it did not take me a whole lot of time to figure out that lifting a 30-foot joint of 3-inch tubing that weighed 300 pounds, and I was lifting half of it, and maybe we do not need an ergonomics regulation when my older brother one day told me to throw a rock bed on top of a load of junk which weighed about 80 pounds, and I simply refused, having in mind the sciatica nerve which he had injured and could not lift junk anymore.

He was smart enough to sustain an injury so he could avoid the lifting. But we will wrestle through the problems. I would like to call the second panel now. Dr. Burton, Dr. Punnett and Dr. Mirer. I am sorry. Before the panel leaves, Miss Landrieu.

Senator LANDRIEU. The panel can go. The new panel can come. But I will just make a brief statement, if I could.

Senator SPECTER. Okay. Fine. Pardon me Senator Landrieu, for not noticing you.

You took a seat so far to the right.

There are at least two attributes about your appearance I should have noted, and I will not specify them for the record.

Senator LANDRIEU. And I wore this bright red jacket so it is hard to not notice me today. But I thank you, Mr. Chairman.

Senator SPECTER. It is hard not to notice you in the absence of a red jacket.

Senator LANDRIEU. Thank you, Mr. Chairman. If the new panel would just come forward, I do not want to stop you all from moving forward. I do want to just make a couple of comments though.

Senator SPECTER. Senator Landrieu, while you are making the comments, I am going to excuse myself for a moment. We have Secretary Manetta testifying in Transportation. I am going to be gone for a very brief period of time. Senator Landrieu has the floor and I shall return momentarily.

OPENING STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman. I have a statement I would like to submit to the record. And I would like to ask

unanimous consent. Since I am the only one here, I am going to give myself unanimous consent to submit this to the record.

But I would just want to make a few points, and then unfortunately I am going to have to slip out for another meeting myself, and some responsibilities on the floor.

I want to thank the chairman first of all for calling this very important hearing because we need the chairman and our ranking member to help us stay focused on this very important issue so it does not slip off the radar screen.

I was briefed at some of the comments earlier made about how important it is to develop a consensus. And we try very hard to do that here in Washington on a number of different issues, whether it has to do with health or transportation, environmental issues. It is always desirable I think to build consensus, but it is not necessary. What is necessary is a majority, a majority to vote, to take an action.

We do not need a unanimous vote. We do not need always a consensus. And many of the most important issues that have moved through Congress in the history of this Nation have not necessarily moved by consensus but they have in fact moved by a majority.

And I wanted to just show up this morning to say to the labor and business leaders and to the workers here that I believe there is a majority of Republicans and Democrats today that recognize that this is a serious problem in the United States, that in fact these injuries are real. They are affecting real people in real ways. And we heard some of that testimony.

With all due respect to the scientists and to those academics that would argue otherwise, I think we have passed that point; that this is real and that there are a majority. We do not have everyone. We do not need everyone. But there is a majority of votes in the Senate and in the House to actually produce a rule that will work to prevent, to try to prevent these injuries.

What the challenge is, and I think what the question is which is reflected in the vote that was cast just last week, is that the rule that was presented before us either basically had to be completely adopted or none of it could be adopted. The procedure did not allow for us to sort of reshape that rule.

And so the vote occurred to reject it. But I hope there is no one here in this room or around the country that would interpret that vote as meaning that there are not a large number of Republicans and Democrats, the majority here, to have a rule that will help prevent these injuries and to address it.

There is a majority that agrees that this cannot be voluntary, that while voluntary actions can in fact help, that this needs to be, it is proper rule for government. It needs to be mandatory. Workers have a responsibility themselves in this regard as well as employers.

And so I want to commend the chairman for calling this hearing to say that the challenge is now about how to present to the country a new rule, one that will address some of the concerns that were raised. But we are not going to go backwards. We are going to continue to move forward.

And I hope because of the bill that I have introduced with Senator Breaux and Senator Specter that that time frame could be

short, perhaps coming back with something in about 18 months for the Congress to act on.

And let me say although I missed your testimony and I have the greatest respect for our new Secretary and think that she most certainly can do a wonderful job, I was somewhat disappointed to hear that she was not more enthusiastic about moving forward with a new rule.

And I hope that this bill that we have introduced is going to encourage her in very direct ways to move forward with a new rule within a short period of time, one that many employers could embrace and many workers. We do not need all employers but we need many of them.

And many that came to my office against the old rule said, Senator, we are not opposed to the Government having mandatory rules. We just want to make sure that we can understand it, we can comply with it, that the workers have responsibilities as well as we have responsibilities.

So I am going on their word, all the employers that came into my office to testify to me in that regard. And I am going to do everything I can as a Senator to insist that we move forward way past the discussions about whether this is true or not.

The American people understand these injuries are happening. They are happening to them and their own families. We can hear all the scientific testimony. We are past that point. We are now about how to draft a good rule that works for big employers, for small employers, that prevents these injuries and gives real relief without perhaps overlapping too much with what some states are doing to recognize the specific role of States.

So I am sorry I do not have a whole list of questions. I do, but I do not have the time for them. But I wanted to get that statement into the record. And I thank you all.

If the staff will help me to continue to conduct this meeting while the chairman is going, because I am going to have to slip out in just a moment. But on behalf of Senator Murray who could not be here, she did want me to recognize Dr. Bigos from Washington, from the University of Washington, and to welcome you in her absence because you are a constituent of hers and she wanted me to mention that this morning.

But whoever would like to proceed with their testimony, and then I think if other members show up they will have questions or comments. Who should we begin with?

It has been recommended that we just take a 5-minute recess until the chairman comes back. Thank you.

Senator SPECTER. We'll resume the hearing now with Dr. Kim Burton, director of Spinal Research Unit, University of Hudderfield, United Kingdom. Welcome.

STATEMENT OF DR. KIM BURTON, DIRECTOR, SPINAL RESEARCH UNIT, UNIVERSITY OF HUDDERFIELD, UNITED KINGDOM

Dr. BURTON. Thank you, chairman. It is indeed a pleasure and an honor to address this body on the controversial topic of ergonomics. Recently in the United Kingdom, experts giving evidence in litigation cases need to sign declaration that their duty is

to the Court rather than to the party instructing them. It is in that spirit that I address my views to you.

My background encompasses both clinical science and ergonomics. And as you said, currently I am the director of the Spinal Research Unit at the University of Huddersfield. I am also a registered European Ergonomist, and have prepared reports and guidance for the Health and Safety Executive in the United Kingdom.

It is vitally important to distinguish between the various manifestations of musculoskeletal disorders. That is, they may present as reports of symptoms, the filing of an injury claim, the need for sick leave, the development of chronicity and irreparable damage.

Each of these components is unique. And it is somewhat unhelpful to talk about them as if they are fully interchangeable.

Because low back pain is the area of my expertise and is such a prominent target of OSHA's recent regulation, I will use this as an example. Low back pain is not a discrete disease entity or even a single clinical syndrome. It is a symptom, a symptom experienced by most people during their lifetimes, irrespective of employment.

General adult population surveys find a lifetime prevalence of low back pain of around 60 percent, a 12-month prevalence of over 40 percent, and a point prevalence of approximately 20 percent. The lifetime prevalence in adolescents, at just over 50 percent, is only slightly lower than that for working-age adults. In the face of such figures, attribution of the bulk of the symptoms to work, in my view, is untenable.

Nonspecific low back pain can be occupational in a sense that it is common in adults of working age, frequently affects capacity for work, and often prompts referral for occupational health care. The common assumption that this means that low back pain is necessarily caused by work, however, overlooks the complex and inconsistent relationship between physical and other influences.

The review that I coauthored with Professor Waddell last year concluded that on the balance of the scientific evidence that it showed physical demands of work can precipitate individual attacks of back pain. Certain individuals may be more susceptible and certain jobs may be at higher risk. But viewed overall, physical demands of work only account for a modest proportion of the total impact of back pain.

The development of chronic pain and disability, however, depends more on individual or work-related psychosocial issues than on physical or clinical features. People with physically or psychologically demanding jobs may have more difficulty working when they have low back pain and so lose more time from work. But that can be the effect rather than the cause of their back pain.

It is unrealistic to think that we can expect to prevent all low back pain. What I understand to be OSHA's apparent concept of making all work physically undemanding is not only unsupported but may well have adverse effects. There is strong chance of raising the profile of the attribution concept among workers, their advisors and managers, which in turn could lead to an exacerbation of the overall impact of low back pain on society, rather than a reduction.

The state-of-the-art evidence assessing reductions in physical exposures as a prescription for ergonomic concerns is a comprehensive review from Linton and van Tulder. These authors systemati-

cally searched the literature for studies involving subjects not seeking treatment. One third of the studies considered educational approaches, often including training in lifting techniques, finding strong evidence that they were ineffective. Much of the remaining literature studied lumbar supports and back belts, again, negative findings.

The most telling finding of this review, however, is the lack of control trials that consider job controls modifying so-called risk factors such as force of repetition. We simply do not have the scientific evidence yet that these measures are effective.

I am not convinced that there is reliable evidence supporting blanket ergonomics programs as a remedy for musculoskeletal disorders. In fact, a regulation not dissimilar to the issued proposal was introduced in Europe in the early 1990s.

This has had no discernible influence on disability due to back pain. It may well be better to target our resources towards appropriate management of the symptomatic worker, taking steps to remove obstacles to recovery, both physical and psychosocial, thus facilitating that worker's continued comfortable performance of normal job duties.

PREPARED STATEMENT

Senator SPECTER. Dr. Burton, your time has expired and we have to be very close on that with so many witnesses. Your full statement will be made part of the record. And if you would summarize, we would appreciate it.

Dr. BURTON. That was it. I have finished, sir.

[The statement follows:]

PREPARED STATEMENT OF DR. KIM BURTON

It is a pleasure to address this body on the very controversial topic of ergonomics. Recently in the United Kingdom, experts giving evidence in litigation cases need to sign a declaration that their duty is to the Court rather than to the party instructing them. It is in this spirit that I present my views to you. My background encompasses both biomedical science and ergonomics. Currently, I am Director of the Spinal Research Unit at the University of Huddersfield in the United Kingdom and I serve as Editor-in-Chief of Clinical Biomechanics, a biomedical journal listed in Index Medicus. I am also a registered European Ergonomist, and have prepared reports and guidance for the Health & Safety Executive in the United Kingdom. Last year, in collaboration with Professor Gordon Waddell, I produced what commentators have called the most comprehensive and current review of the evidence related to occupational aspects of low back pain.[1]

The first question posed in this hearing is the nature of the problem, including: "What types of injuries?" and "Who suffers these injuries?" This very articulation, however, oversimplifies the enquiry. It is vitally important to distinguish between reports of symptoms, reports of alleged but medically untested "injuries" such as filing an injury claim, sick leave, chronicity, and irreparable damage—all of which are brought together under the same umbrella. It is also important to recognize that the term "musculoskeletal disorders" or "MSDs," as discussed by OSHA, includes a nearly innumerable body of reported conditions, some of which involve a discrete pathology whilst others are characterized only by their symptoms. Each of these components is unique, and it is somewhat unhelpful to talk about them as if they are fully interchangeable. There is one common thread, however, and that is the compelling evidence of multifactorial influences, including those which are unrelated to work.

[1] Occupational Health Guidelines for the Management of Low Back Pain at Work, Evidence Review and Recommendations (March 2000) (available at www.facoccmed.ac.uk).

Because low back pain is the area of my expertise and is such a prominent target of OSHA's recent regulation, I will use this as an example. Low back pain is not a discrete disease entity or even a single clinical syndrome; it is a symptom. Low back pain, in fact, is a symptom experienced by most people during their lifetimes, irrespective of employment. General adult population surveys find a lifetime prevalence of low back pain of around 60 percent, a 12-month prevalence of over 40 percent and a point prevalence of approximately 20 percent. The lifetime prevalence in adolescents, at just over 50 percent, is only slightly lower than that for working-age adults. In the face of such figures, attribution of the bulk of the symptoms to work is, in my view, untenable. It becomes exceedingly difficult to identify any specific causative agents.

Non-specific low back pain can be occupational in the sense that it is common in adults of working age, frequently affects capacity for work and often prompts referral to occupational health care. The common assumption that this means low back pain is caused by work, however, overlooks the complex and inconsistent relationship of physical and other influences. Workers in heavy manual jobs do report somewhat more low back symptoms and jobs with greater physical demands commonly have a higher rate of reported low back injuries, but most of these "injuries" are associated with normal everyday activities such as bending and lifting and there is usually little if any objective evidence of tissue damage. The review I coauthored with Professor Waddell, which considered 34 existing systematic reviews, 28 narrative reviews, 52 individual scientific studies, 22 additional weaker scientific studies and 17 previous guidelines. We concluded that the balance of the evidence showed that physical demands of work can precipitate individual attacks of back pain, certain individuals may be more susceptible and certain jobs may be higher risk but, viewed overall, physical demands of work only account for a modest proportion of the total impact of back pain occurring in workers.

Whether low back symptoms are attributed to work, are reported as "injuries," or lead to requests for health care or time off of work depends upon a complex combination of individual psychosocial and work organisational factors. The development of chronic pain and disability depends more on individual and work-related psychosocial issues than on physical or clinical features. People with physically or psychologically demanding jobs may have more difficulty working when they have low back pain and so lose more time from work, but that can be the effect rather than the cause of their pain.

It is unrealistic to think, therefore, that we are even close to the point at which we can expect to prevent low back pain. What I understand to be OSHA's apparent concept of making all work physically undemanding is not only unsupported, but may well have adverse effects by exacerbating the psychosocial influences that are now known to be important determinants of MSDs in the workplace. There is a strong chance of raising the profile of the "attribution" concept among workers, their advisors and managers, which in turn would likely lead to an exacerbation of the overall impact of low back pain on society rather than a reduction.

The state-of-the-art evidence assessing reductions in physical exposures as a prescription for ergonomic concerns is a comprehensive review from Steven J. Linton and Maurits van Tulder entitled "Preventive Interventions for Back and Neck Pain Problems: What is the Evidence?"[2] The authors of this review systematically searched the literature for investigations that specifically considered a preventative intervention using randomized or non-randomized controlled trials involving subjects not seeking treatment. Twenty-seven such studies were found, none of which focused on the physical workplace environment. One-third of the studies considered educational approaches (often including training in lifting techniques), finding "strong evidence" that these "back schools" are ineffective. Much of the remaining literature studied lumbar supports such as back belts, yielding consistently negative findings. Exercise programs aimed at improving conditioning showed stable positive evidence of relatively moderate utility, but issues such as compliance and individual need suggest they are not justified for use as a universal remedy. The most telling finding, however, is the lack of any controlled trials—randomized or otherwise—that consider "job controls" modifying so-called "risk factors" such as force or repetition. We simply do not have the scientific evidence yet that these measures are effective.

Such evidence, in my opinion, is essential. Anecdotal evidence of ergonomic "successes" is often cited, but these claims raise more questions than they answer. It is difficult to determine in many cases exactly what the employer has done and how that can be translated into a regulation. Another important issue is that such studies have used different measurements by which "success" is claimed (e.g. absence, injury reports, prevalence rates). Interventions may be said to have some effect on

[2] Institute for Research in Extramural Medicine, Free University, Amsterdam, Netherlands.

absence rates, but in most cases these appear to be the outcome of organisationally-based factors such getting all the players on one side, rather than the product of reductions in physical demands. Without any way to separate out and test these influences, which requires carefully designed controlled trials, it becomes impossible to determine the optimal strategy.

Scientists have likewise been unable to develop any reliable quantified relationships between exposure to "risk factors" and negative health outcomes. We are simply not at the point yet where we can offer a legitimate work-damage model to guide employer conduct, and we are unlikely to reach that point anytime soon. Ergonomics researchers face particularly difficult challenges: measuring exposures in diverse workplaces, accurately diagnosing the response for outcomes such as low back pain that do not manifest objective tissue damage, and selecting interventions that might offer benefit for substantial numbers of workers. Science, after considerable effort, has failed to identify any instances where exposure-response relationships are universally agreed to be positively and accurately quantified. It is difficult to conceive how a workable standard could be applied in the absence of such guidance.

I am not convinced that there is reliable evidence supporting blanket ergonomics programs as a remedy for "MSDs." It may well be proper to target resources toward appropriate management of the symptomatic worker, taking steps to remove obstacles to recovery (both physical and psychosocial) by facilitating that worker's continued comfortable performance of normal job duties. Even then, it is imperative that physical measures be temporary and not a permanent crutch that will impede the worker's return to full function. Helping a worker get back to the job in this fashion, however, is a far cry from using mandatory and potentially permanent job modifications to prevent injuries. The latter alternative, in my opinion, is scientifically unsupported and dangerously counterproductive. Whatever OSHA does as a next step, therefore, I would hope it will not fall into the trap of continued fixation on physical exposures as the key to solving the problem.

Senator SPECTER. Thank you. We should have begun with Dr. Jeremiah Barondess, chairman of the MSD Panel, National Research Council, IOM, and president of the New York Academy of Medicine. Thank you for joining us, Dr. Barondess. And the floor is yours.

STATEMENT OF DR. JEREMIAH A. BARONDESS, CHAIRMAN, PANEL ON MUSCULOSKELATAL DISORDERS AND THE WORKPLACE, AND PRESIDENT OF THE NEW YORK ACADEMY OF MEDICINE

Dr. BARONDESS. Thank you very much, Senator. It is a privilege to be here. On behalf of the panel, my statement is before you and it will be included in the record. And I wish to emphasize a few points in it in the course of this presentation.

This study was conducted by a panel put together by the National Academy of Sciences and it consisted of 19 nationally-recognized experts in the relevant scientific fields. The study took 2 years and was requested. It was requested of us at the outset that it take 2 years. We had then ample opportunity to be comprehensive.

I wish to emphasize that what is presented in this report is not the personal opinion of anyone.

Senator SPECTER. They gave you a deadline?

Dr. BARONDESS. They requested that we not hurry. I would put it that way. Two years was the request.

Senator SPECTER. But they gave you a deadline?

Dr. BARONDESS. Yes, sir. Yes, sir. Once again, this report represents the synthesis of the best thinking of people expert in the relevant fields. We were essentially asked to look only at the science, not policy, and to answer two questions. The first is, does the scientific evidence support the contention that the workplace adds incremental risk of musculoskeletal disorders of the low back

and upper extremities; not is it the entire cause of all such syndromes but is there incremental risk.

The second question was: Is there a scientific basis for the contention that interventions of some sorts and some circumstances are effective. The answer to both questions is yes, in the view of the committee.

I would like to emphasize that this review was rigorous, as it had to be. A lot of the literature in this field is weak. Some of it is easy to dismiss on scientific grounds.

The Commission reviewed more than 3,600 studies and reviews relevant to the fields of mechanobiology, biomechanics and epidemiology as well as some clinical literature, and culled from those papers some 25 percent so that there was a significant filter in the literature that was reviewed.

In addition to the literature reviews, we had numerous informed presentations by representatives of industry, of labor, and various others.

The committee went to two heavy industry plants, kindly given access by the Ford Motor Company, and visited those for a full day. And finally, there were open fora for the expression of opinions by industry, labor and professional bodies.

The conclusions of the 2-year study of the scientific basis that we were asked to review can be very quickly summarized.

The first conclusion is as you have heard this is a very important national health problem. It accounts for some 70 million office visits to physicians annually, not all of it obviously specifically work-related. And it costs something of the order of 1 percent of the gross domestic product of the nation.

Second, the question of whether it is possible to compare the incidents in the workforce to the incidents in the general population cannot be approached. Because more than 80 percent of American adults are in the workforce.

Third, the committee took the position that workplace disorders and individual risk and outcomes are inextricably bound, and therefore these disorders should be approached in the context of the whole person rather than strictly the injured structure. It is the structure that gets injured, it is person who gets disabled.

Additionally, the committee concluded that the weight of the evidence does justify the evidence, the identification of certain work-related risk factors for the occurrence of musculoskeletal disorders. For the low back these include heavy lifting, that is significant physical loads, load moment, which is the distance from the person at which the load to be lifted is positioned, frequent bending, twisting and whole body vibration; and for the upper extremity, repetition, force and vibration.

The committee concluded that psychosocial factors are in fact also very important in addition to the physical factors. I appreciate Mr. Fellner putting up two of our illustrations demonstrating the complexity of human beings. The complexity of humans in these regards does not mean, however, that the problem cannot or should not be approached.

The committee concluded also that the weight of the evidence justifies the introduction of appropriate and selected interventions,

that the scientific basis is there. It is not as robust as we would like but it is sufficient for action.

Some of these interventions should apply ergonomic principles to reduce physical as well as psychosocial stressors. These things have to be applied carefully in a sharply selective manner, should be scientifically based and should be periodically evaluated.

There is no generic solution to these problems. They must be tailored to the specifics of the workplace and the tasks involved in the job.

PREPARED STATEMENT

The committee also concluded that the entire field would benefit from an enhanced information base. There is no science base anywhere that is complete. That includes this one. And additional research would help in the nuancing of responses. I thank you for your attention, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF DR. JEREMIAH A. BARONDESS

Good morning, Mr. Chairman and members of the Committee. My name is Dr. Jeremiah Baroness. I am the President of the New York Academy of Medicine and Chairman of the Panel on Musculoskeletal Disorders and the Workplace. I am accompanied by committee member Dr. David Wegman, Professor and Chair of the Department of Work Environment at the University of Massachusetts at Lowell.

PANEL COMPOSITION

The Panel on Musculoskeletal Disorders and the Workplace was established by the National Research Council (NRC) and the Institute of Medicine (IOM) in January, 1999, to conduct a two-year study of the contribution of workplace physical and psychosocial factors to the occurrence of musculoskeletal disorders of the low back and upper extremities and to examine the effectiveness of various prevention strategies. The panel is composed of 19 experts representing the fields of biomechanics, epidemiology, hand surgery, human factors engineering, internal medicine, nursing, occupational medicine, orthopedics, physical medicine and rehabilitation, physiology, psychology, quantitative analysis, and rheumatology.

IMPETUS

The impetus for the study was a request from Congress (including your subcommittee) to examine the causation, diagnosis, and prevention of musculoskeletal disorders (House Report 105–635). The congressional request was presented in the form of seven questions. The charge to the panel, prepared by the NRC and the IOM, was stated as a series of tasks designed to provide a comprehensive review of the science base and to address the issues outlined in the congressional questions. A complete statement of the panel's charge, approach, conclusions, and recommendations is found in the first attachment: the Executive Summary of the final report. Attachment App. A provides the panel's response to the congressional questions.

APPROACH

The panel approached the complex of factors bearing on the risk of musculoskeletal injury in the work setting from a whole-person perspective, that is, from a point of view that does not isolate disorders of the low back and upper extremities from physical and psychosocial factors in the workplace, from the context of the overall texture of the worker's life, including social support systems at work and in the community and physical and psychosocial stresses outside the workplace, or from personal responses to pain and individual coping mechanisms. The focus of the study was on work-related factors. Individual factors and activities outside of the workplace were considered as context and were accounted for in the literature reviews. Our task was to determine the incremental effect of work-related factors on the occurrence of musculoskeletal disorders.

The panel applied a set of rigorous scientific criteria in selecting the research studies for its review. Because the literature includes both empirical and theoretical approaches and covers a wide variety of research designs, measurement instruments, and methods of analysis, the quality selection criteria varied somewhat among disciplines. At one level, there are highly controlled studies of soft tissue responses to specific exposures using cadavers, animal models, and human subjects. At another level, there are surveys and other observational epidemiologic studies that examine the association among musculoskeletal disorders and work, organizational, social, and individual factors. At yet another level, there are experimental and quasi-experimental studies of human populations designed to examine the effects of workplace interventions. Studies at each level have attendant individual strengths; each also has limitations when considered in isolation. When taken together however, they provide a rich basis for understanding the causes and prevention of musculoskeletal disorders.

DIMENSIONS OF THE PROBLEM

The first conclusion reached by the panel is that musculoskeletal disorders of the low back and upper extremities are an important national health problem, resulting in approximately 1 million people losing time from work each year. These disorders impose a substantial economic burden in compensation costs, lost wages, and productivity. Conservative cost estimates vary, but a reasonable figure is about $50 billion annually in work-related costs—a figure representing approximately 1 percent of GDP.

The panel found that estimates of incidence in the general population, as contrasted with the working population, are unreliable because more than 80 percent of the adult population in the United States is in the workforce. Nevertheless, the magnitude of the problem of work-related musculoskeletal disorders can be gleaned from the Bureau of Labor Statistics data. These data suggest that musculoskeletal disorders are a problem in multiple industrial sectors; they are not limited to the traditional heavy labor environments represented by agriculture, mining, and manufacturing. It was reported, for example, that the service sector is also importantly involved, accounting for 26 percent of sprains/strains, carpal tunnel syndrome, or tendinitis; the manufacturing sector accounted for 22 percent. Another data base, National Center for Health Statistics, using self reports, provided estimates for back pain among those whose pain occurred at work (approximately 11.7 million) and for those who specifically reported that their pain was work-related (5.6 million). In this survey, the highest-risk occupations among men were construction laborers, carpenters, and industrial truck and tractor equipment operators; among women, the highest-risk occupations were nursing aides/orderlies/attendants, licensed practical nurses, maids, and janitor/cleaners. Other high-risk occupations were hairdressers and automobile mechanics.

RELATIONSHIP AMONG WORK FACTORS AND MUSCULOSKELETAL DISORDERS

A second major conclusion is that the weight of the evidence justifies the identification of certain work-related risk factors for the occurrence of musculoskeletal disorders of the low back and upper extremities.

—The panel concludes that there is a clear relationship between back disorders and physical load; that is, manual material handling, load moment, frequent bending and twisting, heavy physical work, and whole-body vibration. For disorders of the upper extremities, repetition, force, and vibration are particularly important work-related factors. That is, physical workplace activities have been shown to be responsible for a significant increment in the occurrence of musculoskeletal disorders of the low back and upper extremities.

—Work-related psychosocial factors recognized by the panel to be associated with low back disorders include rapid work pace, monotonous work, low job satisfaction, low decision latitude, and job stress. High job demands and high job stress are work-related psychosocial factors that are associated with the occurrence of upper extremity disorders.

THE VALUE OF WORKPLACE INTERVENTIONS

A third major conclusion is that the weight of the evidence justifies the introduction of appropriate and selected interventions in the workplace to reduce the risk of musculoskeletal disorders of the low back and upper extremities. These include, but are not confined to, the application of ergonomic principles to reduce physical as well as psychosocial stressors. To be effective, intervention programs should include employee involvement, employer commitment, and the development of inte-

grated programs that address equipment design, work procedures, and organizational characteristics.

There is no generic solution. To be effective interventions must be tailored to the specific work and worker conditions and must be evaluated on a continuing basis to account for changing workplace and worker factors.

Cost and effectiveness of various intervention strategies are a major concern for public and private policy makers, managers, and other leaders facing the practical challenges of allocating limited resources. Despite the availability of cost benefit analysis techniques they have not been systematically applied to the study of workplace interventions designed to relieve or prevent musculoskeletal disorders. Outcome measures generally include relief from pain and loss of function and reductions in worker's compensation claims and time away from work. Although there are individual studies that demonstrate favorable outcomes following the introduction of an intervention, the conditions under which the data are collected make it difficult to determine which of several specific factors are responsible for the outcome. On the other side of the equation are the costs associated with the design and implementation of the interventions. Some interventions require minor changes in procedures or layouts for specific work spaces while others may involve developing large-scale design modifications or instituting new work practices or ways to organize work. Here again, some scattered individual studies exist. What is needed to resolve these issues is careful research to develop a methodology to facilitate both cost and benefit comparisons across alternative interventions in a range of workplaces.

THE NEED FOR DATA COLLECTION AND REPORTING SYSTEMS

To extend the current knowledge base relating both to risk and effective interventions, the Bureau of Labor Statistics should continue to revise its current data collection and reporting system to provide more comprehensive surveillance of work-related musculoskeletal disorders. Specific attention should be given to revising the illness and injury coding system, refining the quantification of risk, and developing denominator data for job-specific demographic features. Reporting should also be enhanced to include details on musculoskeletal disorders that do not involve lost workdays. Enhanced resources are needed to address these recommendations.

The National Center for Health Statistics and the National Institute for Occupational Safety and Health should include measures of work exposures and musculoskeletal disorder outcomes in ongoing Federal surveys (e.g., the National Health Interview Surveys, the National Health and Nutritional Examinations), and NIOSH should repeat, at least decennially, the National Occupational Exposure Survey. NIOSH should develop both a passive surveillance packages for use by a broad range of employees and a model for an active surveillance program for interested employers.

The National Institute for Occupational Safety and Health should take the lead in developing uniform definitions of musculoskeletal disorders for use in clinical diagnosis, epidemiologic research, and data collection for surveillance systems. These definitions should (1) include clear and consistent endpoint measures, (2) agree with consensus codification of clinically relevant classification systems, and (3) have a biological and clinical basis.

A RESEARCH AGENDA

The panel recommends a research agenda that includes developing (1) improved tools for exposure assessment, (2) improved measures of outcomes and case definitions for use in epidemiologic and intervention studies, and (3) further quantification of the relationship between exposures and outcomes. Also included are suggestions for studies in each topic area: tissue mechanobiology, biomechanics, psychosocial stressors, epidemiology, and workplace interventions. In addition, the panel recommends (1) expanding research and research training, (2) promoting collaboration among industry, labor, and academia, and (3) expanding education and training in utilizing workplace interventions to employers. In order to accomplish these objectives, the panel recognized that funding for NIOSH would have to be significantly increased. Broader support for these research programs should also be sought from relevant NIH Institutes.

THE DISSENT

The conclusions and recommendations provided in the panel's report were supported by 18 of the 19 panel members. The dissenting member, a hand surgeon, prepared a statement that was limited to a very narrow concern—the relationship between carpal tunnel syndrome and keyboarding. Unfortunately, he uses this case to question the scientific basis for the panel's review and interpretation of all of the

literature. Essentially, he asserts that because the relationship between low force, high repetition activities and muscusloskeletal disorders is weak, the relationship between any work and the occurrence of a musculoskeletal disorder may not be sound.

Some key points in the dissent assert that the panel used an unscientific approach to the literature review, that it over-reached in interpreting the literature on the relationship between keyboarding and carpal tunnel syndrome, and that it recommends ergonomics as an exclusive remedy for musculoskeletal disorders. All of these assertions are countered in the panel's response to the dissent (see Attachment App. C). It is important to note that many of the research studies cited by the dissenting member in his discussion of the epidemiology of carpal tunnel syndrome and work did not meet the rigorous review criteria established by the panel and were rejected for inclusion in the full report. Furthermore, one of the 18 panel members is a leading and highly regarded hand surgeon and an enthusiastic supporter of the panel's conclusions and recommendations.

Mr. Chairman, I want to thank you for the opportunity to provide testimony on this important topic. I will be happy to answer any questions.

MUSCULOSKELETAL DISORDERS AND THE WORKPLACE—LOW BACK AND UPPER EXTREMITIES

EXECUTIVE SUMMARY

There is no doubt that musculoskeletal disorders of the low back and upper extremities are an important and costly national health problem. Musculoskeletal disorders account for nearly 70 million physician office visits in the United States annually and an estimated 130 million total health care encounters including outpatient, hospital, and emergency room visits. In 1999, nearly 1 million people took time away from work to treat and recover from work-related musculoskeletal pain or impairment of function in the low back or upper extremities. Conservative estimates of the economic burden imposed, as measured by compensation costs, lost wages, and lost productivity, are between $45 and $54 billion annually. There is some variation in estimates of occurrence and cost as a result of inconsistencies within and across existing databases. The ability to better characterize the magnitude of the problem and formulate targeted prevention strategies rests on improved surveillance and more rigorous data collection.

There is also debate concerning sources of risk, mechanisms of injury, and the potential for intervention strategies to reduce these risks. The debate focuses on the causes, nature, severity, and degrees of work-relatedness of musculoskeletal disorders as well as the effectiveness and cost-related benefits of various interventions. None of the common musculoskeletal disorders is uniquely caused by work exposures. They are what the World Health Organization calls "work-related conditions" because they can be caused by work exposures as well as non-work factors. There are a number of factors to be considered: (1) physical, organizational, and social aspects of work and the workplace, (2) physical and social aspects of life outside the workplace, including physical activities (e.g., household work, sports, exercise programs), economic incentives, and cultural values, and (3) the physical and psychological characteristics of the individual. The most important of the latter include age, gender, body mass index, personal habits including smoking, comorbidities, and probably some aspects of genetically determined predispositions. In addition, physical activities away from the workplace may also cause musculoskeletal syndromes; the interaction of such factors with physical and psychosocial stresses in the workplace is a further consideration. The task herein is to evaluate the significance of the risk factors that result from work exposure while taking into account the different types of individual and non-work factors. The complexity of the problem is further increased because all of these factors interact and vary over time and from one situation to another. Research is needed to clarify such relationships, but research is complicated by the fact that estimates of incidence in the general population, as contrasted with the working population, are unreliable because the two overlap: more than 80 percent of the adult population is in the workforce.

The panel approached the complex of factors bearing on the risk of musculoskeletal injury in the work setting from a whole-person perspective, that is, from a point of view that does not isolate disorders of the low back and upper extremities from physical and psychosocial factors in the workplace, from the context of the overall texture of the worker's life, including social support systems and physical and psychosocial stresses outside the workplace, or from personal responses to pain and individual coping mechanisms (see Figure ES.1). The size and complexity of the problem and the diversity of interests and perspectives—including those of medical

and public policy professionals, behavioral researchers, ergonomists, large and small businesses, labor, and government agencies—have led to differing interpretations of the evidence regarding the work-relatedness of musculoskeletal disorders of the low back and upper extremities and the impact of interventions. As a result, Congress requested a study by the National Research Council and the Institute of Medicine covering the scientific literature on the causation and prevention of these disorders. The congressional request was presented in the form of seven questions, which are addressed in Appendix A of this report. The funding for the study was provided by the National Institute for Occupational Safety and Health (NIOSH) and by the National Institutes of Health (NIH).

EXECUTIVE SUMMARY

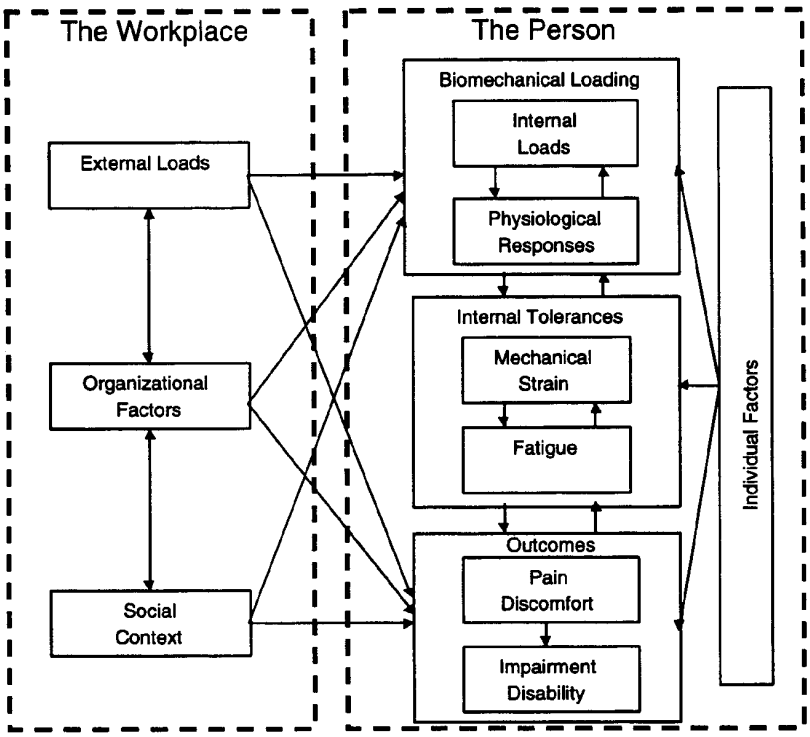


Figure ES.1.—A conceptual model of the possible roles and influences that various factors may play in the development of musculoskeletal disorders. The dotted box outline on the right indicate the possible pathways and processes that could occur within the person, including the biomechanical load-tolerance relationship and the factors that may mediate the load-tolerance relationship, such as individual factors and adaptation. Outcomes may be a result of this relationship and may be influenced by individual factors, such as conditioning or psychological state. The dotted box on the left indicates the possible influences of the workplace on the sequence of events that can lead to musculoskeletal disorders in the person. Arrows between "the workplace" factors and "the person" box indicate the various research disciplines (epidemiology, biomechanics, physiology, etc.) that have attempted to explain the relationship. For example, epidemiology typically searches for associations between external loading characteristics and reported outcomes, whereas the relationship between external loads and biomechanical loading are usually explored via biomechanical studies (adapted from National Research Council, 1999b).

BOX ES.1 The Charge

1. Assess the state of the medical and biomechanical literature describing the models and mechanisms characterizing the load-response relationships and the consequences (adaptation, impairment, disability) for musculoskeletal structures of the neck, the upper extremities, and the low back.

2. Evaluate the state of the medical and behavioral science literature on the character of jobs and job tasks, the conditions surrounding task performance, and the interactions of person, job, and organizational factors and, in addition, examine the research literature on the individual and nonwork-related activities that can contribute to or help prevent or remediate musculoskeletal disorders.

3. Assess the strengths and weaknesses of core datasets that form the basis for examining the incidence and epidemiology of musculoskeletal disorders reported in the workplace.

4. Examine knowledge concerning programs and practices associated with primary, secondary, and tertiary prevention of musculoskeletal injuries, ranging from organization-wide promotion of a safety culture to modified work and a variety of clinical treatment programs.

5. Characterize the future of work, how the workforce and jobs are changing and the potential impact of these changes on the incidence of musculoskeletal disorders.

6. Identify most important gaps in the science base and recommend needed research.

PANEL CHARGE, COMPOSITION, AND APPROACH

The charge to the panel from NIOSH and NIH, which appears in Box ES.1, was to undertake a series of tasks that would lead to a detailed analysis of the complex set of factors contributing to the occurrence in the workplace of musculoskeletal disorders of the low back and upper extremities and that would provide the information necessary to address the questions posed by Congress. The panel viewed this charge as an opportunity to conduct a comprehensive review and interpretation of the scientific literature, with the goal of clarifying the state of existing knowledge concerning the roles of various risk factors and the basis for various efforts bearing on prevention. The focus of the study was on work-related factors. In this context, individual risk factors, such as age, body mass index, gender, smoking, and activities outside the workplace, were considered as sources of confounding and were accounted for in the research reviews.

The panel was composed of 19 experts representing the fields of biomechanics, epidemiology, hand surgery, human factors engineering, internal medicine, nursing, occupational medicine, orthopedics, physical medicine and rehabilitation, physiology, psychology, quantitative analysis, and rheumatology. The panel's work was guided by two underlying principles. The first, noted above, was to approach musculoskeletal disorders in the context of the whole person rather than focusing on body regions in isolation. The second was to draw appropriate scientific inferences from basic tissue biology, biomechanics, epidemiology, and intervention strategies in order to develop patterns of evidence concerning the strength of the relationship between musculoskeletal disorders and the multiplicity of work and individual factors.

The panel applied a set of rigorous scientific criteria in selecting the research studies for its review. Because the literature includes both empirical and theoretical approaches and covers a wide variety of research designs, measurement instruments, and methods of analysis, the quality selection criteria varied somewhat among disciplines (see Chapter 1 for details). At one level, there are highly con-

trolled studies of soft tissue responses to specific exposures using cadavers, animal models, and human subjects. At another level, there are surveys and other observational epidemiologic studies that examine the association among musculoskeletal disorders and work, organizational, social, and individual factors. At yet another level, there are experimental and quasi-experimental studies of human populations designed to examine the effects of workplace interventions. Each level provides a different perspective; together they provide a complementary picture of how various workplace exposures may contribute to the occurrence of musculoskeletal disorders. Although each level has its attendant strengths and limitations when considered alone, together they provide a rich understanding of the causes and prevention of musculoskeletal disorders.

The wide and diverse body of literature addressing the work-relatedness of musculoskeletal disorders suggests various pathways to injury. Figure ES.1 summarizes the analytic framework used by the panel to organize and interpret these various strands of research. This framework is central to the panel's assessment, and it is used to orient and structure the panel's report. The factors are organized into two broad categories: workplace factors and characteristics of the person that may affect the development of musculoskeletal disorders. Workplace factors include the external physical loads associated with job performance, as well as organizational factors and social context variables. A person is the central biological entity, subject to biomechanical loading with various physical, psychological, and social features that may influence the biological, clinical, and disability responses. The rationale underlying the figure is that there may be many pathways to injury, and the presence of one pathway does not negate nor suggest that another pathway does not play an important role. The various pathways simply represent different aspects of the workplace-person system.

PATTERNS OF EVIDENCE

The panel's review of the research literature in epidemiology, biomechanics, tissue mechanobiology, and workplace intervention strategies has identified a rich and consistent pattern of evidence that supports a relationship between the workplace and the occurrence of musculoskeletal disorders of the low back and upper extremities. This evidence suggests a strong role for both the physical and psychosocial aspects of work. There is also evidence that individual factors, such as age, gender, and physical condition, are important in mediating the individual's response to work factors associated with biomechanical loading.

Back disorders and the workplace

Low back disorder risk has been established through epidemiologic studies of work that involves heavy lifting, frequent bending and twisting, and whole body vibration, as well as other risk factors. The relative risks have been derived from a rigorous evaluation of the literature and have been found to be strong and consistent. Strong points in this research include control for confounding, temporal association, and characterization of dose-response relationships; the principal limitation is that a number of the studies are based on self-reports of injury. The epidemiologic literature that specifically quantifies heavy lifting shows the greatest risk for injury when loads are lifted from low heights, when the distance of the load from the body (moment) is great, and when the torso assumes a flexed, asymmetric posture. Biomechanical studies reinforce the epidemiologic findings. Studies in basic biology also describe the mechanisms involved in the translation of spinal loading to tissue injury within the intervertebral disc. In addition, the basic science literature has described pathways for the perception of pain when specific structures in the spine are stressed. Intervention studies have shown how lift tables and lifting hoists are effective in mediating the risk of low back pain in industrial settings. Since risk is lowered when the load is changed from a heavy lift to a light lift, this finding is also consistent with the rigorous epidemiologic findings.

In epidemiologic studies, psychosocial factors in the workplace have also been found to play a role. Specifically, there is evidence for a relationship between low back disorders and job satisfaction, monotonous work, work pace, interpersonal relations in the workplace, work demand stress, and the worker's perceived ability to work. In addition, recent evidence from biomechanics studies points to a mechanism whereby psychosocial stress contributes to increases in spine loading. There is also evidence that exposure to psychosocial stressors may result in greater trunk muscle activity independent of biomechanical load. Some part of the variance in response described in the biological and biomechanical literature appears to be explained by individual host factors, such as age, gender, and body mass index. For example, age and gender appear to play a role in determining the magnitude of load to which a person's spine may be exposed before damage would be expected.

Upper extremity disorders and the workplace

The pattern of evidence for upper extremity disorders, as for the low back, also supports an important role for physical factors, particularly repetition, force, and vibration. The most dramatic physical exposures occur in manufacturing, food processing, lumber, transportation, and other heavy industries, and these industries have the highest rates of upper extremity disorders reported as work related. Psychosocial factors were found to play a role in upper extremity disorders as well, particularly high job stress and high job demands. In addition, several epidemiologic studies of physical exposures (force, repetition) and psychosocial exposure (perceived stress, job demands) have documented an elevated risk of upper extremity disorders among computer users. Nonwork-related anxiety, tension, and psychological distress are also associated with upper extremity symptoms. Biomechanical studies have shown that extraneural pressure in the carpal tunnel is increased with hand loading and nonneutral wrist postures. Basic science studies demonstrate that extraneural pressures may lead to intraneural edema and fibrosis, demyelination, and axon degeneration. These changes in nerve structure may cause impairment of nerve function. The findings in the intervention literature are congruent with those in the basic biology and epidemiology literatures. There is strong support across these bodies of work that high force and repetition are associated with musculoskeletal disorders of the upper extremities; basic biology data provide evidence of alteration in tissue structure. The intervention literature supports the efficacy of tool and workstation design changes, job rotation, and other interventions that directly address these risk factors with regard to upper extremity symptomology.

Although the upper extremity literature is less well developed than the literature on low back pain, an analogous set of themes emerges, lending further support to the conclusion that external loads and psychosocial factors associated with work influence outcomes. These exposure-response associations persist when adjusted for individual factors that may increase vulnerability, such as age, gender, and body mass index. The basic biology and biomechanics studies provide a plausible basis for the exposure-response relationships. The evidence related to the efficacy of ergonomic interventions further supports these relationships.

Interventions

Data from scientific studies of primary and secondary interventions indicate that low back pain can be reduced under certain conditions by engineering controls (e.g., ergonomic workplace redesign), administrative controls (specifically, adjusting organizational culture), programs designed to modify individual factors (specifically, employee exercise), and combinations of these approaches. Multiple interventions that actively involve workers in medical management, physical training, and work technique education can also be effective in controlling risk. Similarly, with respect to interventions for musculoskeletal disorders of the upper extremities, some studies of engineering controls for computer-related work (reducing static postural loads, sustained posture extremes, and rapid motions, and changing the designs of workstations and tools) have resulted in a decrease in upper extremity pain reports. Studies of administrative controls (modifying organizational culture by an emphasis on participatory team involvement) have also reported success. For such interventions, the commitment of management and the involvement of employees have been important to success.

These findings are based on a research and development process that tailors interventions to specific work and worker conditions and evaluates, on a continuing basis, the effectiveness of these interventions in the face of changing workplace and worker factors. It is therefore neither feasible nor desirable to propose a generic solution. The development and application of effective interventions requires an infrastructure that supports (1) gathering data, through surveillance and research, about the engineering, administrative, and worker factors that affect the effectiveness of interventions; (2) using these data to refine, implement, and assess alternative interventions; and (3) translating knowledge from research to practice. These efforts will benefit from cooperation and information exchange among researchers, practitioners, and workers and managers in industry and labor, government, and academia. These practices should be encouraged and extended.

CONCLUSIONS

Based on a comprehensive review and analysis of the evidence, as described above, the panel has reached the following conclusions:

1. Musculoskeletal disorders of the low back and upper extremities are an important national health problem, resulting in approximately 1 million people losing time from work each year. These disorders impose a substantial economic burden

in compensation costs, lost wages, and productivity. Conservative cost estimates vary, but a reasonable figure is about $50 billion annually in work-related costs.

2. Estimates of incidence in the general population, as contrasted with the working population, are unreliable because more than 80 percent of the adult population in the United States is in the workforce.

3. Because workplace disorders and individual risk and outcomes are inextricably bound, musculoskeletal disorders should be approached in the context of the whole person rather than focusing on body regions in isolation.

4. The weight of the evidence justifies the identification of certain work-related risk factors for the occurrence of musculoskeletal disorders of the low back and upper extremities.

—The panel concludes that there is a clear relationship between back disorders and physical load; that is, manual material handling, load moment, frequent bending and twisting, heavy physical work, and whole-body vibration. For disorders of the upper extremities, repetition, force, and vibration are particularly important work-related factors.

—Work-related psychosocial factors recognized by the panel to be associated with low back disorders include rapid work pace, monotonous work, low job satisfaction, low decision latitude, and job stress. High job demands and high job stress are work-related psychosocial factors that are associated with the occurrence of upper extremity disorders.

5. A number of characteristics of the individual appear to affect vulnerability to work-related musculoskeletal disorders, including increasing age, gender, body mass index, and a number of individual psychosocial factors. These factors are important as contributing and modifying influences in the development of pain and disability and in the transition from acute to chronic pain.

6. Modification of the various physical factors and psychosocial factors could reduce substantially the risk of symptoms for low back and upper extremity disorders.

7. The basic biology and biomechanics literatures provide evidence of plausible mechanisms for the association between musculoskeletal disorders and workplace physical exposures.

8. The weight of the evidence justifies the introduction of appropriate and selected interventions to reduce the risk of musculoskeletal disorders of the low back and upper extremities. These include, but are not confined to, the application of ergonomic principles to reduce physical as well as psychosocial stressors. To be effective, intervention programs should include employee involvement, employer commitment, and the development of integrated programs that address equipment design, work procedures, and organizational characteristics.

9. As the nature of work changes in the future, the central thematic alterations will revolve around the diversity of jobs and of workers. Although automation and the introduction of a wide variety of technologies will characterize work in the future, manual labor will remain important. As the workforce ages and as more women enter the workforce, particularly in material handling and computer jobs, evaluation of work tasks, especially lifting, lowering, carrying, prolonged static posture, and repetitive motion, will be required to guide the further design of appropriate interventions.

RECOMMENDATIONS

1. The consequences of musculoskeletal disorders to individuals and society and the evidence that these disorders are to some degree preventable justify a broad, coherent effort to encourage the institution or extension of ergonomic and other preventive strategies. Such strategies should be science based and evaluated in an ongoing manner.

2. To extend the current knowledge base relating both to risk and effective interventions, the Bureau of Labor Statistics should continue to revise its current data collection and reporting system to provide more comprehensive surveillance of work-related musculoskeletal disorders.

—The injury or illness coding system designed by the Bureau of Labor Statistics should be revised to make comparisons possible with health survey data that are based on the widely accepted ICD–9 and ICD–10 coding systems.

—The characterization of exposures associated with musculoskeletal disorders should be refined, including enhanced quantification of risk factors. Currently, exposure is based only on characterization of sources of injury (e.g., tools, instruments, equipment) and type of event (e.g., repetitive use of tools) derived from injury narratives.

—Information collected from each employer should contribute to specificity in denominators for jobs including job-specific demographic features in the workplace, such as age, gender, race, time on the job and occupation.
—Injury and illness information should include, in addition to the foregoing demographic variables, other critical variables, such as event, source, nature, body part involved, time on job, and rotation schedule. Combining these with the foregoing variables would, with appropriate denominator information, allow calculation of rates rather than merely counts or proportions, as is now the case for all lost-workday events.
—Resources should be allocated to include details on non-lost-workday injuries or illnesses (as currently provided on lost-workday injuries) to permit tracking of these events in terms of the variables now collected only for lost-workday injuries (age, gender, race, occupation, event, source, nature, body part, time on job).

3. The National Center for Health Statistics and the National Institute for Occupational Safety and Health should include measures of work exposures and musculoskeletal disorder outcomes in ongoing Federal surveys (e.g., the National Health Interview Surveys, the National Health and Nutritional Examinations), and NIOSH should repeat, at least decennially, the National Occupational Exposure Survey.
—To upgrade and improve passive industry surveillance of musculoskeletal disorders and workplace exposures, the National Institute for Occupational Safety and Health should develop adaptable surveillance packages with associated training and disseminate these to interested industries.
—To provide more active surveillance opportunity, the National Institute for Occupational Safety and Health should develop a model surveillance program that provides ongoing and advanced technical assistance with timely, confidential feedback to participating industries.

4. The National Institute for Occupational Safety and Health should take the lead in developing uniform definitions of musculoskeletal disorders for use in clinical diagnosis, epidemiologic research, and data collection for surveillance systems. These definitions should (1) include clear and consistent endpoint measures, (2) agree with consensus codification of clinically relevant classification systems, and (3) have a biological and clinical basis.

5. In addition to these recommendations, the panel recommends a research agenda that includes developing (1) improved tools for exposure assessment, (2) improved measures of outcomes and case definitions for use in epidemiologic and intervention studies, and (3) further quantification of the relationship between exposures and outcomes. Also included are suggestions for studies in each topic area: tissue mechanobiology, biomechanics, psychosocial stressors, epidemiology, and workplace interventions. The research agenda is presented in Chapter 12.

ADDITIONAL CONSIDERATIONS

Because of the importance of continued data collection and research to further elucidate the causes and prevention of musculoskeletal disorders of the low back and upper extremities, the panel believes it would be useful for relevant government agencies, including the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases to consider the following program initiatives.

1. Expanding research support and mechanisms to study musculoskeletal disorders in terms of risk factors at work, early detection, and effective methods of prevention and their cost effectiveness. Some examples include:
—Developing new mechanisms and linkages among funding agencies (e.g., the National Institute for Occupational Safety and Health, the National Institute of Arthritis and Musculoskeletal and Skin Diseases) to expand ongoing basic research on relevant tissues (e.g., skeletal muscle, tendon, peripheral nerve) to promote study of those parameters that are directly relevant to work-related musculoskeletal disorders.
—Creating mechanisms to stimulate collaboration and cross-training of researchers in the basic and applied sciences directly relevant to work-related musculoskeletal disorders.
—Developing mechanisms to promote research jointly conducted by industry and the relevant academic disciplines on work-related musculoskeletal disorders.

2. Expanding considerably research training relevant to musculoskeletal disorders, particularly with relation to graduate programs in epidemiology, occupational health, occupational psychology, and ergonomics, to produce additional individuals with research training.

3. Expanding education and training programs to assist workers and employers (particularly small employers) in understanding and utilizing the range of possible workplace interventions designed to reduce musculoskeletal disorders. In addition, consideration should be given to expanding continuing education (e.g., NIOSH Education and Research and Training Projects) for a broad range of professionals concerning risk factors that contribute to musculoskeletal disorders inside and outside the workplace.

4. Developing mechanisms for cooperative studies among industry, labor unions, and academia, including:

—Establishing a database of and mechanism for communicating "best practices."

—Providing incentives for industry and union cooperation with due regard for proprietary considerations and administrative barriers.

—Encouraging funding for such studies from industry, labor, academia, and government sources.

5. Revising administrative procedures to promote joint research funding among agencies.

6. Encouraging the exchange of scientific information among researchers interested in intervention research through a variety of mechanisms. Areas that could benefit include the development of (1) research methodologies, especially improved measurement of outcomes and exposures, covariates, and costs and (2) uniform approaches, allowing findings to be compared across studies. In addition, periodic meetings should be considered to bring together individuals with scientific and "best practices" experience.

In order to implement these suggestions, the scope of research and training activities of the National Institute for Occupational Safety and Health would have to be expanded and funding significantly increased. In addition, other Federal agencies (e.g., the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Mental Health) would have to broaden their support of research programs examining musculoskeletal disorders and the workplace. In the panel's view these steps deserve serious consideration.

APPENDIX A.—ANSWERS TO QUESTIONS POSED BY CONGRESS

The questions below provided the impetus for the study. The charge to the panel, prepared by the NRC and the IOM was to conduct a comprehensive review of the science base and to address the issues outlined in the questions. The panel's responses to the questions follow.

Question. What are the conditions affecting humans that are considered to be work-related musculoskeletal disorders?

Answer. The disorders of particular interest to the panel, in light of its charge, focus on the low back and upper extremities. With regard to the upper extremities, these include rotator cuff injuries (lateral and medial) epicondylitis, carpal tunnel syndrome, tendinitis, tenosynovitis of the hand and wrist (including DeQuervains' stenosing tenosynovitis, trigger finger, and others) and a variety of nonspecific wrist complaints, syndromes, and regional discomforts lacking clinical specificity. With regard to the low back, there are many disabling syndromes that occur in the absence of defined radiographic abnormalities or commonly occur in the presence of unrelated radiographic abnormalities. Thus, the most common syndrome is nonspecific backache. Other disorders of interest include back pain and sciatica due to displacement and degeneration of lumbar intervertebral discs with radiculopathy, spondylolysis, and spondylolisthesis, and spinal stenosis (ICD 9 categories 353–357, 722–724, and 726–729).

Question. What is the status of medical science with respect to the diagnosis and classification of such conditions?

Answer. Diagnostic criteria for some of the musculoskeletal disorders considered to be work-related and considered in this report are clear-cut, especially those that can be supported by objective ancillary diagnostic tests, such as carpal tunnel syndrome. Others, such as work-related low back pain, are in some instances supported by objective change, which must be considered in concert with the history and physical findings. In the case of radicular syndromes associated with lumbar intervertebral disc herniation, for example, clinical and X-ray findings tend to support each other. In other instances, in the absence of objective support for a specific clinical entity, diagnostic certainty varies but may nevertheless be substantial. The clinical picture of low back strain, for example, while varying to some degree, is reasonably characteristic.

Epidemiologic definitions for musculoskeletal disorders, as for infectious and other reportable diseases, are based on simple, unambiguous criteria. While these are suitable for data collection and analysis of disease occurrence and patterns, they are

not appropriate for clinical decisions, which must also take into account personal, patient-specific information, which is not routinely available in epidemiologic databases.

Question. What is the state of scientific knowledge, characterized by the degree of certainty or lack thereof, with regard to occupational and nonoccupational activities causing such conditions?

Answer. The panel has considered the contributions of occupational and nonoccupational activities to the development of musculoskeletal disorders via independent literature reviews based in observational epidemiology, biomechanics, and basic science. As noted in the chapter on epidemiology, when studies meeting stringent quality criteria are used, there are significant data to show that both low back and upper extremity musculoskeletal disorders can be attributed to workplace exposures. Across the epidemiologic studies, the review has shown both consistency and strength of association. Concerns about whether the associations might be spurious have been considered and reviewed. Biological plausibility for the work-relatedness of these disorders has been demonstrated in biomechanical and basic science studies, and further evidence to build causal inferences has been demonstrated in intervention studies that show reduction in occurrence of musculoskeletal disorders following implementation of interventions. The findings suggest strongly that there is an occupational component to musculoskeletal disorders. Each set of studies has inherent strengths and limitations that affect confidence in the conclusions; as discussed in Chapter 3 (methodology), when the pattern of evidence is considered across the various types of studies, complementary strengths are demonstrated. These findings were considered collectively through integration of the information across the relevant bodies of scientific evidence. Based on this approach, the panel concludes, with a high degree of confidence, that there is a strong relationship between certain work tasks and the risk of musculoskeletal disorders.

Question. What is the relative contribution of any causal factors identified in the literature to the development of such conditions in (a) the general population, (b) specific industries, and (c) specific occupational groups?

Anwer.

Individual Risk Factors

Because 80 percent of the American adult population works, it is difficult to define a "general population" that is different from the working population as a whole. The known risk factors for musculoskeletal disorders include the following:

Age.—Advancing age is associated with more spinal complaints, hand pain, and other upper extremity pain, e.g., shoulder pain. Beyond the age of 60, these complaints increase more rapidly in women than men. The explanation for spinal pain is probably the greater frequency of osteoporosis in women than in men. The explanation for hand pain is probably the greater prevalence of osteoarthritis affecting women. However, other specific musculoskeletal syndromes do not show this trend. For example, the mean age for symptomatic presentation of lumbar disc herniation is 42 years; thereafter, there is a fairly rapid decline in symptoms of that disorder.

Gender.—As noted above, there are gender differences in some musculoskeletal disorders, most particularly spinal pain due to osteoporosis, which is more commonly found in women than in men, and hand pain due to osteoarthritis, for which there appears to be a genetic determinant with increased incidence in daughters of affected mothers.

Healthy lifestyles.—There is a general belief that the physically fit are at lower risk for musculoskeletal disorders; there are few studies, however, that have shown a scientific basis for that assertion. There is evidence that reduced aerobic capacity is associated with some musculoskeletal disorders, specifically low back pain and, possibly, lumbar disc herniations are more common in cigarette smokers. Obesity, defined as the top fifth quintile of weight, is also associated with a greater risk of back pain. There currently is little evidence that reduction of smoking or weight reduction reduces the risk.

Other exposures.—Whole-body vibration from motor vehicles has been associated with an increase in risk for low back pain and lumbar disc herniation. There is also evidence that suboptimal body posture in the seated position can increase back pain. Some evidence suggests that altering vibrational exposure through seating and improved seating designs to optimize body posture (i.e., reduce intradiscal pressure) can be beneficial.

Other diseases.—There is a variety of specific diseases found in the population that predispose to certain musculoskeletal disorders. Among the more common are diabetes and hypothyroidism, both associated with carpal tunnel syndrome.

Work-Related Risk Factors

Chapter 4 of this report explores the enormous body of peer-reviewed data on epidemiologic studies relevant to this question. Detailed reviews were conducted of those studies judged to be of the highest quality based on the panel's screening criteria (presented in the introduction and in Chapter 4). The vast majority of these studies have been performed on populations of workers in particular industries in which workers exposed to various biomechanical factors were compared with those not exposed for evidence of symptoms, signs, laboratory abnormalities, or clinical diagnoses of musculoskeletal disorders. A small number of studies have been performed in sample groups in the general population, comparing individuals who report various exposures with those who do not.

The principal findings with regard to the roles of work and physical risk factors are:

—Lifting, bending and twisting and whole-body vibration have been consistently associated with excess risk for low back disorders, with relative risks of 1.2 to 9.0 compared with workers in the same industries without these factors.

—Awkward static postures and frequent repetitive movements have been less consistently associated with excess risk. For disorders of the upper extremity, vibration, force, and repetition have been most strongly and consistently associated with relative risks ranging from 2.3 to 84.5.

The principal findings with regard to the roles of work and psychosocial risk factors are:

—High job demand, low job satisfaction, monotony, low social support, and high perceived stress are important predictors of low back musculoskeletal disorders.

—High job demand and low decision latitude are the most consistent of these factors associated with increased risk for musculoskeletal disorders of the upper extremities.

—In addition, in well-studied workforces, there is evidence that individual psychological factors may also predispose to risk, including anxiety and depression, psychological distress, and certain coping styles. Relative risks for these factors have been generally less than 2.0.

Question. What is the incidence of such conditions in (a) the general population, (b) specific industries, and (c) specific occupational groups?

Answer. There are no comprehensive national data sources capturing medically defined musculoskeletal disorders, and data available regarding them are based on individual self-reports in surveys. Explicitly, these reports include work as well as nonwork-related musculoskeletal disorders without distinction; therefore, rates derived from these general population sources cannot be considered in any sense equivalent to rates for background, reference, or unexposed groups, nor conversely, as rates for musculoskeletal disorders associated with any specific work or activity. There are no comprehensive data available on occupationally unexposed groups and, given the proportion of adults now in the active U.S. workforce, any such nonemployed group would be unrepresentative of the general adult population. According the 1997 report from the National Arthritis Data Workgroup (Lawrence, 1998), a working group of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, 37.9 million Americans, or 15 percent of the entire U.S. population, suffered from one or more chronic musculoskeletal disorders in 1990 (these data cover all musculoskeletal disorders). Moreover, given the increase in disease rates and the projected demographic shifts, they estimate a rate of 18.4 percent or 59.4 million by the year 2020. In summary, data from the general population of workers and nonworkers together suggest that the musculoskeletal disorders problem is a major source of short- and long-term disability, with economic losses in the range of 1 percent of gross domestic product. A substantial portion of these are disorders of the low back and upper extremities.

The Bureau of Labor Statistics (BLS) data, while suffering a number of limitations, are sufficient to confirm that the magnitude of work-related musculoskeletal disorders is very large and that rates differ substantially among industries and occupations, consistent with the assumption that work-related risks are important predictors of musculoskeletal disorders. BLS recently estimated 846,000 lost-workday cases of musculoskeletal disorders in private industry. Manufacturing was responsible for 22 percent of sprains/strains, carpal tunnel syndrome, or tendinitis, while the service industry accounted for 26 percent. Examining carpal tunnel syndrome alone, manufacturing, transportation, and finance all exceeded the national average, while for the most common but less specific sprains and strains, the transportation sector was highest, with construction, mining, agriculture, and wholesale trade all higher than average. These data suggest that musculoskeletal disorders are a problem in several industrial sectors, that is, the problems are not limited to

the traditional heavy labor environments represented by agriculture, mining, and manufacturing.

The National Center for Health Statistics (NCHS) survey data provide added information on self-reported health conditions of the back and the hand. This survey presents estimates for back pain among those whose pain occurred at work (approximately 11.7 million) and for those who specifically reported that their pain was work-related back pain (5.6 million).

The highest-risk occupations among men were construction laborers, carpenters, and industrial truck and tractor equipment operators, and among women the highest-risk occupations were nursing aides/orderlies/attendants, licensed practical nurses, maids, and janitor/cleaners. Other high-risk occupations were hairdressers and automobile mechanics, often employed in small businesses or self-employed.

Among men, the highest-risk industries were lumber and building material retailing, crude petroleum and natural gas extraction, and sawmills/planing mills/millwork. Among women, the highest-risk industries were nursing and personal care facilities, beauty shops, and motor vehicle equipment manufacturing.

Questions from the NCHS survey on upper-extremity discomfort elicited information about carpal tunnel syndrome, tendinitis and related syndromes, and arthritis. Carpal tunnel syndrome was reported by 1.87 million people; over one-third of these were diagnosed as carpal tunnel syndrome by a health care provider and half were believed to be work-related. Tendinitis was reported by 588,00 people, and 28 percent of these were determined to be work-related by a health care provider. Over 2 million active or recent workers were estimated to have hand/wrist arthritis. The survey did not report these conditions by either occupation or industry.

Question. Does the literature reveal any specific guidance to prevent the development of such conditions in (a) the general population, (b) specific industries, and (c) specific occupational groups?

Answer.

Development and Prevention in Working Populations

Because the majority of the U.S. population works, the data for the population as a whole apply to the 80 percent who are working. There is substantial evidence that psychosocial factors, in addition to the physical factors cited above (see response to Question 4), are significant contributors to musculoskeletal disorders. Relevant factors are repetitive, boring jobs, a high degree of perceived psychosocial stress, and suboptimal relationships between worker and supervisor.

The weight and pattern of both the scientific evidence and the very practical quality improvement data support the conclusion that primary and secondary prevention interventions to reduce the incidence, severity, and consequences of musculoskeletal injuries in the workplace are effective when properly implemented. The evidence suggests that the most effective strategies involve a combined approach that takes into account the complex interplay between physical stressors and the policies and procedures of industries.

The complexity of musculoskeletal disorders in the workplace requires a variety of strategies that may involve the worker, the workforce, and management. These strategies fall within the categories of engineering controls, administrative controls, and worker-focused modifiers. The literature shows that no single strategy is or will be effective for all types of industry; interventions are best tailored to the individual situation. However, there are some program elements that consistently recur in successful programs:

1. Interventions must mediate physical stressors, largely through the application of ergonomic principles.
2. Employee involvement is essential to successful implementation.
3. Employer commitment, demonstrated by an integrated program and supported by best practices review, is important for success.

Although generic guidelines have been developed and successfully applied in intervention programs, no single specific design, restriction, or practice for universal application is supported by the existing scientific literature. Because of limitations in the scientific literature, a comprehensive and systematic research program is needed to further clarify and distinguish the features that make interventions effective for specific musculoskeletal disorders.

Development and Prevention in Specific Occupations

Occupations that involve repetitive lifting, e.g., warehouse work, construction, and pipe fitting, particularly when that activity involves twisting postures, are associated with an increased risk for the complaint of low back pain and, in a few studies, an increased risk for lumbar disc herniation.

The prevalence of osteoarthritic changes in the lumbar spine (disc space narrowing and spinal osteophytes) is significantly greater in those whose occupations require heavy and repetitive lifting compared with age-matched controls whose occupations are more sedentary. Despite these radiographical differences, most of the studies show little or no difference in the prevalence of low back pain or sciatica between those with radiological changes of osteoarthritis and those with no radiological changes. Based on the current evidence, modification of the lifting can reduce symptoms and complaints. Specific successful strategies, which include ergonomic interventions (such as the use of lift tables and other devices and matching the worker's capacity to the lifting tasks), administrative controls (such as job rotation), and team lifting, appear successful. Despite enthusiasm for their use, there is marginal or conflicting evidence about lifting belts and educational programs in reducing low back pain in the population with heavy lifting requirements. Some examples of positive interventions include:

Truck drivers.—Vibration exposure is thought to be the dominant cause for the increased risk for low back pain and lumbar disc herniation. There are some data to support the efficacy of vibrational dampening seating devices.

Hand-held tool operators.—Occupations that involve the use of hand-held tools, particularly those with vibration, are associated with the general complaints of hand pain, a greater risk of carpal tunnel syndrome, and some tenosynovitis. Redesign of tools is associated with reduced risks.

Food processing.—Food processing, e.g., meat cutting, is associated with a greater risk of shoulder and elbow complaints. Job redesign appears to reduce this risk, but this information is largely based on best practices and case reports.

Question. What scientific questions remain unanswered, and may require further research, to determine which occupational activities in which specific industries cause or contribute to work-related musculoskeletal disorders?

Answer. The panel's recommended research agenda is provided in Chapter 12 of the report.

APPENDIX C.—PANEL RESPONSE TO DISSENT

Dr. Szabo's dissent focuses on whether the panel was consistent in evaluating the literature relevant to this report. His dissent deals almost exclusively with only one of the musculoskeletal disorders considered in the report; specifically he ascribes to the panel overstatements about the research findings relating carpal tunnel syndrome to work exposures of a variety of types.

Dr. Szabo states correctly that criteria for the inclusion of studies in the report differed for the analysis of biomechanical exposures and for the analysis of epidemiologic associations. The four bodies of literature reviewed-tissue mechanobiology, biomechanics, epidemiology, and workplace interventions-have differing study designs, measurement techniques, and outcome variables. The selection criteria used in determining the quality of particular studies necessarily varied among these literatures (see Chapter 1, pp. 22). These criteria were set early in the panel's deliberations. Specifically, the biomechanics papers required detailed measures of biomechanical exposure, while the epidemiologic studies did not require that same kind of detail. Similarly, the epidemiologic papers had to meet criteria for epidemiologic inference that were not required of the biomechanics papers. The panel discussed the distinction carefully before agreeing to adopt it. The distinction would be problematic only if the panel made epidemiologic inferences from studies included in the biomechanics section that failed to meet criteria for epidemiologic studies. We did not do that.

Dr. Szabo contends that the panel concluded that interventions examined in this study prevented carpal tunnel syndrome; this misstates our report, which clearly states otherwise (see Chapter 8, pp. 313). The report states that interventions influenced pain reports and not the occurrence of specifically defined disorders of the upper extremities. The studies are summarized in Table 8.3. The report does not state that interventions prevent carpal tunnel syndrome or, indeed, any other upper-extremity disorder. The emphasis, rather, is on amelioration of symptoms, which is the end point in the relevant literature. Furthermore, the comments on upper extremity interventions carefully state that interventions influence symptoms, not the incidence of specific disorders (Chapter 8, p. 313):

"Studies of engineering interventions for computer-related work that reduce static postural loads, sustained posture extremes, and rapid motions have demonstrated decreases in upper extremity pain reports. Further study of these interventions is needed to determine the amount of pain reduction possible, the duration of salutary effect, and which upper extremity clinical conditions could benefit from these interventions."

Dr. Szabo uses the case of carpal tunnel syndrome with regard to low-force, high-repetition exposures (primarily the use of computer keyboards) as the causal factor to suggest that the relationship of musculoskeletal disorders to work exposure may not be sound. The panel has recognized that the evidence for low-force, high-repetition exposures is weaker than for other relationships among risk factors and musculoskeletal outcomes; however, strong evidence for causal relationships between physical work and musculoskeletal disorders is provided throughout the report.

The epidemiology section as it relates to the upper extremity was carefully written. We discuss the cross-sectional designs of most studies and possible implications for causal inference, including the potential for the "healthy worker" effect. In 9 studies, carpal tunnel syndrome was defined by a combination of a history of symptoms and physical examination or nerve conduction testing. In these studies there were 18 estimates of risk based on various specificities of carpal tunnel syndrome diagnosis and varying degrees of work exposure. Of these, 12 showed significant odds ratios greater than 2.0 (range 2.3 to 39.8), 4 showed nonsignificant odds ratios of greater than 2.0 and 2 showed nonsignificant odds ratios of between 1.7 and 2.0. The epidemiology section, however, does not draw specific conclusions regarding carpal tunnel syndrome. The report points out that just three articles dealt with keyboard work; indeed, keyboard work is not a major consideration or focus in the report.

Dr. Szabo's dissent provides an incomplete view of a study published in the "Journal of the American Medical Association" (Atroshi, 1999). He states: "In the general population the prevalence of Carpal Tunnel Syndrome is the same whether people perform repetitive activities or not." In the panel's view, the nature of the design in that study and its survey instruments were such that the power to demonstrate this association was not high. The study, however, did show a significant risk for carpal tunnel syndrome for blue-collar work, use of excessive force of the hands, working with excessively flexed or extended wrist, or the use of hand-held vibratory tools; these findings are not mentioned by Dr. Szabo.

Dr. Szabo cites the paper of Greenland and Robins (1988) to suggest that without knowledge of cofactors which contribute to carpal tunnel syndrome, "estimates offered by Hagberg as well as the ones used in the NAS report must be interpreted with caution." In fact, the thrust of the Greenland and Robins argument is that such attributable risk calculations may severely underestimate (not overestimate, as implied by Dr. Szabo) the proportion of cases in which the etiologic factor is important because of possible interactions between that factor and the cofactors. Greenland and Robins cite numerous examples in which a small excess risk masks a much larger effect of a primary study factor.

Several articles cited by Dr. Szabo in his discussion of the epidemiology literature on carpal tunnel syndrome did not meet the quality criteria (insufficient participation and inadequate exposure measures were common problems) used by the panel in selecting articles for the epidemiology review and so are not included in the report.

In his dissent, Dr. Szabo states, "More importantly, reliance on ergonomics to the exclusion of medical and health risk factors can have adverse consequences for the patient." Nowhere in its report does the panel suggest the exclusive use of ergonomic interventions.

It is important to reemphasize the fact that we made a major effort to base our conclusions on literature that met accepted scientific criteria and that the report represents consensus of all of the panel members except for Dr. Szabo. At the same time, the report makes plain the panel's view that the literature about musculoskeletal disorders is incomplete, as all clinical and scientific literatures are, and also emphasizes the importance of continuing research on a variety of fronts. There is, however, sufficient basis in the research to date to support our conclusions and recommendations.

Jeremiah A. Barondess, *Chair*
Mark R. Cullen
Barbara de Lateur
Richard A. Deyo
Sue K. Donaldson
Colin G. Drury
Michael Feuerstein
Baruch Fischhoff
John W. Frymoyer
Jeffrey N. Katz
Kurt Kroenke
Jeffrey C. Lotz
Susan E. Mackinnon
William S. Marras
Robert G. Radwin
David Rempel
David Vlahov
David H. Wegman

Senator SPECTER. Thank you very much. Dr. Jane Derebery, occupational physician, Concentra Medical Services.

STATEMENT OF DR. JANE DEREBERY, VICE PRESIDENT OF MEDICAL AFFAIRS, CONCENTRA MEDICAL SERVICES

Dr. DEREBERY. Thank you, Mr. Chairman. I am an occupational medicine physician. I serve as the vice president of Medical Affairs of Concentra Health Services which is the largest occupational health group in the country. We treat over 500,000 injured workers each year.

I am neither an academician nor a researcher, and had not met Drs. Bigos, Hadler and Burton prior to this, but know them very well through their work, which has aided me in my own practice for many, many years. It also aids me in physician training with my company.

In my early training in occupational medicine, of all the courses I took I was most excited by the ergonomic courses. It made logical sense to me that repetitive, awkward and forceful activities of my patients could potentially cause them problems. And it also made sense to apply the principles of ergonomics as a solution.

However, once I got into private practice, I quickly saw that there was no consistency between the amount and type of activities that my patients were performing and whether or not they developed musculoskeletal problems.

Those ailments that are believed to be caused by repetitive motion such as tendonitis and carpal tunnel can and do occur with no provocation, no known cause; are also associated and even caused by many, many medical conditions.

What in actual practice the ergonomics standards simply do not help me with those patients. Instead, I found that dealing with external factors such as underlying medical conditions or health problems and psychosocial stressors coupled with the sports medicine approach seemed to be more effective.

In my concern about the ergonomic standard as it was proposed, was that it is asking me as a physician to treat my patients as if the primary and only cause of their complaint was due to their physical activities at work. To wrongly classify something as work-related not only increases disability likelihood, it misdirects medical care, and it can inappropriately exclude a patient from a job. In addition, it is an unnecessary drain to the workers' comp system.

At my company we have the largest clinical outcome database in the country. And that has facilitated our ability to study and improve our outcomes. In an analysis of work-related, nontraumatic musculoskeletal disorders, we have demonstrated that the treatment strategy when it is focused predominantly on patient issues rather than the physical job factors, that we get substantially improved outcomes.

In one regional analysis, the physicians were given training that promoted demedicalization and early activation in patients that had musculoskeletal problems. And in most of the cases the patients were kept at full duty during treatment.

In the treatment, the extraneous contributing health problems and psychosocial stressors were investigated for, and when appropriate, addressed. A conditioning exercise program as well as stress management principles generally predominated as treatment recommendations. While appropriate job problem-solving and ergo-

nomics suggestions were given, they were very seldom a primary part of our treatment.

And what we found was the clinical outcomes comparing this treatment strategy with other regional providers substantially reduced the lost time, restricted duty, disability and cost with no increase in recurrences and with high patient satisfaction.

We found similar findings with our low back pain change strategy and in which our physicians were encouraged to adhere to the evidence-based treatment guidelines such as those of the Agency for Health Care Policy Research in the United Kingdom.

And once again, we found with those patients the majority were kept at full duty. And with that strategy, we had a substantial improvement over those patients who were treated the traditional way.

The cause of musculoskeletal disorders are multifactorial involving as many psychosocial and medical and health conditions as physical. And my concern as a physician is if we focus on the physical and the ergonomics, it may result in increased morbidity and in disability for my patients and at great cost to industry as well.

PREPARED STATEMENT

Dr. Evanoff in the last panel mentioned the American College of Occupational Medicine Guidelines in his endorsement of the ergonomics standard. I am a fellow of the American College of Occupational Environmental Medicine. And for the record, we did not come out, we did not endorse the ergonomic standards for the same reason that I did not. Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. JANE DEREBERY

I am Dr. Jane Derebery, a board certified occupational medicine physician and the vice president of medical operations for the Southern Region of Concentra Health Services, the largest occupational medicine group in the United States. Each year over five million patients are seen at our clinics, and 500,000 new patients with work-related injuries are treated.

I am neither an academician nor a researcher, but rather a practicing clinician within the private sector. Although I had not met Drs. Bigos, Hadler and Burton previously, I know them through their work and publications, which have aided me in my own practice as well as in physician training. Their work is especially appreciated, as there are widespread misinformation, half-truths, and even myths on the subject in both medical and lay literature.

Since the advent of OSHA in 1970, work places have become safer, material handling reduced, and improved ergonomics implemented in many industries—yet low back disability has continued to escalate, as have complaints of musculoskeletal pain in general. This trend would support what the few high quality studies performed have demonstated: there is not evidence that ergonomic job design will prevent musculoskeletal disorders and pain.

When I first began in occupational medicine in the eighties, I found that the ergonomics courses were the most exciting ones that I took. It made logical sense that the more a worker was exposed to repetitive, awkward or forceful activity, the more likely he was to incur injury. Learning and applying principles of ergonomics seemed like the logical solution for my patients.

Once I was in actual clinical practice, however, I quickly discovered that there appeared to be little consistency regarding amount and type of activity of patients and whether or not they developed musculoskeletal problems. The principles of ergonomics that I had been taught didn't seem to aid me in the real world, particularly with my more difficult patients—instead, identifying external contributors such as underlying medical conditions and psychosocial stressors, and using a sports medicine approach seemed to be more effective.

There are inherent risks in allowing politics and public policy rather than science to decide what causes disease. Musculoskeletal aches and pains are common among all of us regardless of our work and leisure activities. Many ailments attributed to repetitive, forceful or awkward activity can and do occur with no identifiable provoking cause and can also be caused by systemic medical conditions. In the workers compensation arena, physicians are being asked to treat muscloskeletal pain as if the predominant and only cause is the physical aspect of work. Musculoskeletal disorders generally are multifactoral in origin, just as are many other medical maladies such as heart disease or headaches. To wrongly classify a musculoskeletal illness as work-related increases the likelihood of disability developing, misdirects medical care, can inappropriately exclude an individual from his regular job, and places an unnecessary drain on the workers compensation system.

Concentra has the largest clinical outcome database of any medical organization in the country, and having outcome data has greatly facilitated our ability to study and improve clinical outcomes. Analysis of Concentra outcome data has indicated that when dealing with nontraumatic musculoskeletal disorders, a treatment strategy focusing predominantly on patient issues rather than physical job factors results in substantially improved outcomes.

In one Concentra study, seven physicians in Austin were given training that promoted keeping most patients with upper extremity non-traumatic complaints at their regular jobs during treatment, under the presumption that since the job had caused no problems for the worker previously, it was likely that non-work factors were predominant causes of the symptoms.

The physicians are advised to give the patient reassurance that the problem isn't serious, and to prescribe an appropriate program to increase strength, flexibility and endurance. Stress reduction techniques such as regular aerobic exercise, relaxation, etc. are also prescribed. Extraneous contributions such as underlying health problems and psychosocial stressors are investigated and when necessary addressed. While appropriate job problem solving and ergonomic suggestions are made, these are usually not a primary focus of the treatment.

The clinical outcomes of these providers have been followed and compared to 92 other providers in other cities in the southern region. The change in treatment strategy have resulted in substantial, statistically significant improvements in cost of care and disability with no reduction in patient satisfaction. Interestingly, as physicians have experienced good outcomes among their patients, they have gradually become even more assertive in their management of patients, as evidenced by continued improvement from 1997 through 2000.

Between 1997 and 1999, the seven providers had reduced their percentage of patients on restricted duty from 74 percent to 30 percent for an average of 22 days, as compared to the other 92 providers, who placed 82 percent on restricted duty for 26 days. In addition, in 1999, the 367 Austin patients had no lost time, compared to a lost time rate of 3 percent in other cities. Only 6.5 percent of the Austin patients required specialty referral, compared to 21 percent by the other cities' providers. The cost of care in Austin dropped substantially because the patients required fewer physical therapy visits and doctor visits, with the average cost in Austin being $730 per case compared to $959 per case among the other providers.

We have also had similar findings regarding low back pain by encouraging our physicians to adhere to evidence-based low back pain treatment guidelines such as those from the Agency for Health Care Policy and Research and from the United Kingdom. Specifically, the guidelines encourage maintenance or resumption of normal activity, including work, in patients with low back pain. The physicians achieving the best outcomes typically and consistently place only 15–35 percent of their back pain patients on restricted duty during the treatment course, compared to an overall national average approaching 90 percent.

There are strong cultural beliefs and influences that play predominant roles in shaping expectations about the ability of repetitive physical activity to cause musculoskeletal disorders. This has rendered us susceptible to the misinformation and myths being widely published not only in the lay literature but even in the medical literature.

For example, there is no scientific evidence to support that carpal tunnel syndrome can be caused or aggravated by prolonged keyboard use; yet I have repeatedly seen that reported as fact in such widely read periodicals as TIME, Newsweek, and the New York Times. Two years ago, when a hand surgeon from Columbia University testified as an expert witness in a products liability class action suit against a keyboard manufacturer, he rendered his medical opinion that keyboarding caused the claimants' carpal tunnel syndrome. When pressed to cite what scientific article he had read to justify his opinion, he finally stated that he had read it in TIME magazine! In actuality in the almost fifty cases of products liability suits against

keyboard manufacturers not one claimant has ever been awarded a cent, so strong is the scientific evidence that use of a keyboard does not cause carpal tunnel syndrome. Yet, the myth that it does prevails in our society—with profound influence.

The cause of the current spate of CTD disorders is multifactoral, involving as many psychosocial and medical factors as job-related ones. To focus exclusively on the physical and ergonomic aspects of the problem may result in increased morbidity and disability at great cost to the patient and to society. Addressing the problem as it is perceived by the patient or the public, contributes to the problem rather than to its resolution.

Senator SPECTER. Thank you very much, Dr. Derebery. We now turn to Dr. Laura Punnett.

STATEMENT OF DR. LAURA PUNNETT, PROFESSOR, DEPARTMENT OF WORK ENVIRONMENT, UNIVERSITY OF MASSACHUSETTS LOWELL

Dr. PUNNETT. Thank you very much, Senator. I think perhaps there are a few things that almost everyone in this room could agree upon. One is that some musculoskeletal disorders are not work-related. Some I think the rest we may be in disagreement about, but certainly there is an important amount of morbidity which arises in relation to non-occupational factors is really not in dispute by anyone.

Another important point is that some amount of physical activity is essential to maintaining good health. And the key question then for us is how much activity or effort or motion is too much. And I would add what kind and under what conditions.

People who are employed full-time spend——

Senator SPECTER. So where there is agreement is that some ailments are not related to work and some exercise is good?

Dr. PUNNETT. Yes, Senator.

Senator SPECTER. And that is where you stop your testimony on the area of agreement?

Dr. PUNNETT. Correct. I am not sure I am going to be able to offer you much more——

Senator SPECTER. That is not a whole lot of agreement, Dr. Punnett, but it is not inaccurate from what I have heard. Go ahead.

Dr. PUNNETT. I am trying to help you find some consensus.

Senator SPECTER. Trying to help me find what?

Dr. PUNNETT. Some consensus.

Senator SPECTER. I would not call it consensus to say that it is 11:15, which is about what you have said. Go ahead.

Dr. PUNNETT. People who are employed full-time spend more waking hours at our jobs than anywhere else. But I think of equal importance to the hours we spend at work is that while we are at work we do not have the same freedom to choose how we spend our time as we do for example when we are gardening or playing tennis.

A stenographer in a courtroom has to keep up with an expert witness who is giving testimony. A mail carrier has to complete a route and return to the post office within a specified period of time.

A nurse's aid has to move a disabled patient from the wheelchair to the commode when the patient's needs dictate, even if there is no one else nearby to help.

So the way the work is organized, the tasks designated to each individual, the equipment or tools provided determine both the

physical load, how fast you are working, how hard, what body postures are necessary, as well as what we call the psychosocial factors, meaning psychological demands such as time pressure, opportunity to decide what to do when, factors that are generally under the employer's control as well as the physical load factors are.

These psychosocial factors are established to be associated with the subjective experience of stress. They are related to risks of some diseases such as cardiovascular disorders.

The scientific literature on their effect on musculoskeletal disorders is quite more recent and still very limited, while in contrast the literature on physical factors is voluminous.

And we have already heard from the NAS that there are literally hundreds of studies with a variety of study designs and methods, different samples of the population conducted in many different countries all showing risk of musculoskeletal disorders to be proportionate to the level of exposure to physical load.

These kinds of exposure response examples are numerous. Just two very quick examples, a German study showing that new back pain among male construction workers was associated with the amount of handling of concrete blocks and other heavy paving items, and a British study of nurses showing that the incidence of new back pain was proportionate to the number of patients handled per day.

So the literature is voluminous. There have been dozens of reviews of this literature as well. Like both of the NAS reports, virtually all of the reviews, not all but the vast majority, agree that some studies are better than others, that not every question has been answered yet but that there is a very substantial evidence showing the relationship of physical workload to musculoskeletal disorders.

The better studies include a variety of, meet a variety of scientific and methodologic criteria including the fact that they address the role of non-occupational factors. If someone has a history of a wrist injury or goes bowling every Thursday night or has been diagnosed with diabetes, we have statistical methods of removing the influence of these individual factors and making sure that or evaluating whether the association is still there when they are taken out of the picture.

If we limit ourselves to the cream of the crop, the few dozen studies rather than the few hundred which are most rigorous, we still have at least ten times as many studies as OSHA had to rely on in rule making on benzine for example or setting a permissible exposure limit for lead in air or rule making on formaldehyde.

PREPARED STATEMENT

Of course not every question has been answered, but again standards have been passed without every "I" being dotted and every "T" crossed. We had no animal model for asbestos or for benzine effects at the time that those OSHA standards were passed. And I respectfully submit that while we need more research, we also have ample evidence in hand now to begin to prevent the many unnecessary disorders that are occurring.

[The statement follows:]

PREPARED STATEMENT OF DR. LAURA PUNNETT

Qualifications and experience

I am an occupational epidemiologist and ergonomist with a Doctor of Science degree in epidemiology and occupational health and safety from the Harvard School of Public Health and two years of specialized post-doctoral training in occupational ergonomics at the Center for Ergonomics, The University of Michigan (Ann Arbor). I am a founding faculty member of the Department of Work Environment at the University of Massachusetts Lowell (UML), where I now hold the rank of Professor. The Department combines a traditional occupational health and safety approach to the identification of workplace hazards with a more innovative focus on the development and evaluation of engineering control measures for those hazards. I am also Co-Director of the Lorin Kerr Ergonomics Institute for Occupational Injury Prevention at UML. The Institute conducts research and provides technical assistance throughout the region on the health, safety, and productivity consequences of the failure to design jobs to fit human needs. We take a multi-disciplinary approach to the study of work-related musculoskeletal disorders, injuries and psychosocial stress, their impact on employers, workers, and society, and their prevention through changes in work organization and equipment.

My primary research areas are the epidemiology of work-related musculoskeletal disorders; the effect of ergonomic stressors on other health endpoints, such as pregnancy outcomes and acute injury; and methods for workplace measurement of ergonomic exposures, including the validity of worker self-assessments. Since 1981, I have investigated these issues in a wide variety of manufacturing and service occupations, including the automobile industry, garment assembly and other light manufacturing, clerical work, retail food stores, hospitals, small farms, sawmills and wood products processing, and highway construction. I have also studied the factors influencing the effectiveness of ergonomic intervention programs and joint labor-management health and safety committees in industry. I am the author or co-author of about 40 articles in peer-reviewed scientific journals, as well as numerous book chapters, technical reports, and papers and abstracts in peer-reviewed conference proceedings. My research has been funded by the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control Center on Injury Prevention, the UAW-Chrysler Joint National Committee on Health and Safety, the March of Dimes, and the Massachusetts Centers of Excellence Corporation.

Since 1993 I have been a Visiting Lecturer in Occupational Health at the Harvard School of Public Health, in Boston. I am a member of the Research Committee on Musculoskeletal Disorders of the International Commission on Occupational Health. In 1996, I was in residence as a Visiting Scientist in the Division of Ergonomics, National Institute of Working Life, Sweden; since that time I have had continuing collaborations with several researchers at the Institute and have returned for several working visits. I have served by invitation on the NIOSH Mine Health Research Advisory Committee (U.S. DHHS), two NIOSH research review panels, and advisory boards for the Massachusetts Department of Public Health Occupational Disease Surveillance (SENSOR) Project, the Center for VDT and Health Research, Johns Hopkins School of Hygiene and Public Health, the Occupational and Industrial Orthopedics Center (Hospital for Joint Diseases, New York NY), and the Ergonomics Technology Center of the University of Connecticut (Farmington CT). I have consulted on environmental and occupational epidemiology to the World Health Organization. I serve on the Editorial Boards of the peer-reviewed journals, Applied Ergonomics, New Solutions: A Journal of Environmental and Occupational Health Policy, and Salud de los Trabajadores ("Workers' Health," published in Venezuela). I have served as a peer reviewer to 12 scientific journals and several private and public research funding agencies.

Both as an individual consultant and through the Kerr Ergonomics Institute, I have conducted training programs in occupational ergonomics for engineers, supervisors, medical and safety personnel, and labor representatives in a wide variety of workplaces. Consulting clients have included General Motors, Ford Motor Company, Digital Equipment Corporation, General Electric, Millipore, Herman Miller, Jim Walters Paper, CBS/Fox Video, and the U.S. Army Environmental Hygiene Agency. I have lectured internationally on occupational health, ergonomics and epidemiology and presented seminars and professional short courses for professional associations (e.g., American Industrial Hygiene Association, American Society of Safety Engineers, Nordic Institute for Advanced Training in Occupational Health and Safety, International Commission on Occupational Health, Israeli Ergonomics Society) as well as at institutions of higher education in the United States, Canada, The Netherlands, Spain, Chile, and Sweden.

In 1998, I was invited to participate on the panel that reviewed the epidemiologic evidence on work-related musculoskeletal disorders for the National Academy of Sciences (National Research Council), in response to a mandate from the U.S. Congress. In 1999, I was a member of the committee that drafted the new Threshold Limit Values (TLVsR) on Hand Activity Level of the American Conference of Governmental Industrial Hygienists—a set of quantitative exposure limits intended to aid in preventing or reducing the occurrence of upper extremity musculoskeletal disorders.

Issues addressed in this testimony

This testimony primarily addresses the epidemiologic literature on work-related MSDs, including the basis for concluding that there is a causal relationship with occupational physical ergonomic stressors and that reductions in harm to workers can be anticipated by reductions in exposure to these stressors. Exposure-response relationships have repeatedly been demonstrated, and the evidence is at least qualitatively consistent across sectors of the economy and around the world, wherever the problem has come to light. There are unresolved questions regarding the nature and role of psychosocial factors and more research is needed to clarify diagnostic dilemmas and to elucidate pathomechanisms. There is striking evidence that MSDs are greatly under-reported in many workplaces and that therefore, however high the frequency and costs of MSDs may seem, the true magnitude is undoubtedly greater than statistics show. Although formal intervention studies are difficult to conduct successfully, there is substantial experience of the feasibility and benefits of workplace ergonomics interventions (training and engineering controls) implemented by employers.

Scientific evidence regarding physical exposures and the occurrence of MSDs

There is an extensive scientific literature documenting that physical job features can cause musculoskeletal disorders. These hazards can occur in a multitude of forms, depending on the specific nature of the work; the characterization of ergonomics exposures thus often depends on the sector of employment and even the specific occupation. Nevertheless, a common set of occupational exposures has been associated generically with adverse musculoskeletal health effects.

The scientific evidence for the work-related occurrence of musculoskeletal disorders among occupationally exposed individuals includes both epidemiologic studies and basic science (biomechanical and patho-physiological laboratory experiments). The combination of the two is important because together they demonstrate the biological plausibility of the epidemiology and the coherence and complementarity of the findings. For example, tendon strain and cell damage have been shown to occur experimentally as a function of work pace (the frequency and duration of mechanical loading), the level of muscular effort, and recovery time between exertions.

The basic science pertaining to mechanisms by which physical load, in its various forms, can damage soft tissues was reviewed by Rempel et al., Ashton-Miller, and Radwin and Lavender for the National Academy of Sciences (NAS) in 1998 (1), as well as by others (e.g., 2–7). The preamble to the OSHA Ergonomics Standard (Section V., "Health Effects") also summarized the literature, illustrating how repeated or forceful efforts, sustained static loading, anatomically non-neutral postures, accelerated movements, externally applied compressive forces, and vibration are understood to affect musculoskeletal, nerve, and circulatory tissues.

NIOSH REVIEW OF MSD EPIDEMIOLOGY IN 1997

The authoritative review of the epidemiology in this field is that published by the National Institute for Occupational Safety and Health (NIOSH) in 1997 (8). This literature review was conducted according to standard, accepted epidemiologic principles and gave greatest weight to studies in which the results could be shown to be relatively unaffected by selection bias or information bias. Almost all of the studies considered in the review had been published in peer-reviewed scientific journals, meaning that they already had been through the standard quality control process and found to be scientifically valid prior to their publication. The review document itself was evaluated prior to publication by 27 scientists with research, teaching, and consulting expertise in the field of occupational ergonomics.

The NIOSH review concluded that there is "a consistent relationship between MSDs and certain physical factors, especially at higher exposure levels." Although some specific exposure-response relationships have not been demonstrated and more research is needed in several areas, there is evidence that exposure to each of these ergonomic factors causes MSDs in one or more body regions: repetitive upper extremity motion patterns; forceful exertions, whether manual only or whole-body (e.g., heavy lifting); non-neutral body postures; and vibration. The risk is especially

pronounced when a job includes exposure to a combination of two or more of these risk factors.

The odds of finding so many positive studies, using so many variations on study design and methods, in so many countries, would be extremely small if ergonomic exposures were not truly hazardous to the musculoskeletal system. Even were we to restrict ourselves to the 13 investigations that were the most rigorous and convincing, these would represent a larger body of evidence than has been used for OSHA rule-making on many other workplace hazards.

These strongest studies also demonstrate that physical job factors cause MSDs independently of any other factors, such as medical history, age, or psychosocial strain, that might also be associated with MSDs in the general population. In other words, while MSDs have a background rate in the general population that is above zero, there is a marked additional increase among people whose jobs expose them to excessive physical demands.

EPIDEMIOLOGIC EVIDENCE SINCE 1997

In addition to those studies relied upon by NIOSH in the 1997 review, other investigations are continuously being carried out. The studies published since 1997 are too numerous to catalogue them all here; some notable examples have been selected to highlight the ever-expanding knowledge base. These are chosen, in particular, to fill in gaps that NIOSH identified with regard to particular exposure-response combinations, and to illustrate how newer studies, many of them longitudinal, are adding to the evidence confirming earlier conclusions that were based primarily on cross-sectional studies. Longitudinal investigations are particularly important because they are less ambiguous with regard to cause preceding effect than other study designs, so the resulting evidence is inherently stronger. In addition, they can provide evidence regarding the progression ("natural history") of MSDs, the latency period from exposure to effect, and the factors affecting prognosis or outcomes after MSD onset.

For example, the NIOSH review concluded that there was "evidence," but not "strong evidence," that postural stress and repetitive work cause shoulder disorders, and "insufficient evidence" to draw conclusions about the effects of forceful work or vibration on the shoulder. More recently, at least two new studies have provided new evidence regarding the effects of these exposures on the shoulder. Frost and Andersen (9) followed a closed cohort of 1,591 workers from a slaughterhouse and a chemical factory over a seven-year period. The slaughtering and meat processing tasks were videotaped and analyzed in detail and shown to involve pronounced postural stress, with the upper arms elevated to an included angle of 30 degrees or more for about one-half of the work day. Shoulder impingement syndrome, defined as a combination of shoulder symptoms lasting at least 3 months within the past year plus a positive sign of impingement on clinical examination, was more common among slaughterhouse workers than among the chemical workers. The risk increased with number of years of exposure to meat processing work and was particularly high among former slaughterhouse workers. The age-adjusted prevalence ratio showed a steep slope in the first 5 to 6 years of exposure and then another steep increase after about 25 years of cumulative exposure, providing evidence that risk increases with duration of exposure to postural stress and heavy work, even after many years of employment.

My colleagues and I conducted a case-control study of shoulder disorders reported to the in-house medical department of an automobile assembly plant (10). All cases and a random sample of non-case workers from the same production departments were evaluated by interview and physical examination. Shoulder disorders (on combination of medical report and interview) were associated with severe flexion/abduction (above 90 degrees) of the shoulder. The risk of incurring a shoulder MSD increased with the proportion of the work cycle that workers were exposed to severe flexion/abduction. The exposure-response relationships were similar for cases with and without physical findings. Forces exerted through the shoulder did not confound these results; peak torques at the shoulder were rather low for all workers. Use of hand-held tools further increased the risk and also interacted with postural stress.

Relevant evidence regarding the effect of ergonomic exposures on the neck is also found in a report on persistent neck disorders associated with use of a now obsolete grinding machine in a Swedish steelworks (11). Use of this machine had "caused heavy static load to the arms, shoulders, and neck, vigorous impacts and vibrational forces being transmitted upwards via the out-stretched arms." The authors located the last 15 workers who had performed this work, all of whom had left the occupation 11–29 years earlier because of continuous neck-shoulder pain, and 6 of whom were on total disability pension. Even after so many years, all still had persistent

neck pain, stiffness, reduced range of motion, joint degeneration, widespread numbness and tingling and reduced sensation.

A number of new studies have addressed the effects of repetitive manual work on upper extremity disorders (12–15). Nordander et al. (16) examined a set of fish processing jobs that were all highly repetitive, with fast, restricted movements and only light lifting demands. Compared with people with more varied jobs, the fish processing workers had triple the risk of neck/shoulder and elbow/hand diagnoses by physical examination. There were 5 cases each of wrist tendonitis and carpal tunnel syndrome (CTS) among the fish processing workers, compared with 0 and 1, respectively, in the other workers. Work processes changes in another fish processing plant increased the repetitiveness and stereotypy of the physical motion patterns, which led to increased risk of elbow, wrist and finger symptoms (17). In a study of CTS patients and prognosis after medical treatment, the performance of hand-intensive work prior to onset was associated with less complete relief of CTS symptoms after surgery, which in turn predicted failure to return to work due to CTS (18). Thus, NIOSH's findings of "evidence," but not "strong evidence," that repetitive and forceful work cause CTS can also be updated from these more recent findings.

A series of papers by Nathan and colleagues on median nerve neuropathy (MNN), an indicator of CTS, has purported to show that the only "important" causes are individual, non-occupational factors such as age and obesity (e.g., 19–22). This ongoing cohort study suffers from a number of serious methodologic flaws, as noted by NIOSH (see summary in Table 5a–5 of (8)) and others (23). However, it should also be noted that the authors' ranking scheme for physical work demands (repetition and force) was cross-sectionally associated with MNN (19) and predicted the 5-year incidence of slowed nerve function (20). Other reviewers of this paper have concurred in finding these data to show a positive association (24). The question as posed by Nathan and colleagues, whether occupational or non-occupational causes of CTS are "more important," is misleading (and is not appropriately answered by statistical testing such as p-values). Rather, the appropriate policy question is whether, among persons exposed to ergonomic stressors at work, an important proportion of CTS (and other disorders) could be prevented by workplace improvements. The data published by Nathan et al., in fact, support rather than argue against this conclusion.

With regard to back disorders, the NIOSH document also concluded that there was evidence, but not strong evidence, regarding the effect of "heavy physical work" on back disorders. Since then, a German research group published a three-year prospective study of 571 male construction workers, who participated in "comprehensive interview and physical examination surveys" at baseline and again at follow-up (25). The proportion of the population followed up was 86 percent, and only exposure information shown to be reproducible was used in the analyses. After adjustment for age, height, and body mass index, the risk of new low back pain was increased among workers whose work tasks included scaffolding, sawing, erecting roof structures and laying large sandstones. After further adjustment for trade, to account for tasks performed only by carpenters or bricklayers, for example, additional exposure-response relationships were found for two different indices of cumulative exposure to handling heavy stones or concrete blocks.

A prospective investigation of nurses in Great Britain (26) was remarkable for the intensity of its follow-up procedures; the nurses were asked to complete a standardized questionnaire every 3 months for a two-year period. Among those who had been free from low back pain for at least one month at baseline, the risk of new pain was predicted by the frequency of manual transfer of nurses' patients under various conditions. The authors noted, as have others previously, the additional effect of prior back pain, which in itself may be a marker for prior occupational loading on the back. Another recent study of heavy work and back disorders involved a five-year follow-up of a random sample from the general population in Finland (27), in which the outcome was defined as moderate or severe back pain with functional impairment. The study concluded that, "heavy occupational musculoskeletal loading and high general occupational physical demands predicted future back pain." A six-year follow-up of dock workers showed that very heavy work was associated with a higher rate of increase in musculoskeletal disorders on examination of the back, neck, shoulders, hands and feet (28).

Other cohort studies have examined the risk of disorders in the musculoskeletal system overall. A Dutch study reported increased frequency of musculoskeletal symptoms among male employees who performed heavy physically demanding work, especially in the young and middle-aged subjects (29). Long-term disability, especially that due to musculoskeletal disorders, was predicted by the number of years worked in piece-rate garment manufacturing in Canada (30). In a sample of the French population after retirement, the cumulative incidence of disorders of the

back, upper or lower limb joints was higher among those who had performed heavy physical work for longer than ten years (31). Another recent study of my own found a strong cross-sectional relationship between upper extremity disorders and combined ergonomic exposures, with the same exposure index prospectively predicting both the incidence of new disorders after one year and the persistence of upper extremity problems from baseline (32, 33).

OTHER LITERATURE REVIEWS

Other epidemiologic reviews of workplace exposures and MSDs, by experts in various countries, have been published in the peer-reviewed scientific literature. Although they have varied somewhat in their inclusion and exclusion criteria and review procedures, the majority of these reviews have drawn similar conclusions regarding the causal importance of repetitive motion, forceful manual exertions, non-neutral postures, and segmental vibration for upper extremity disorders and of heavy lifting, non-neutral trunk postures and whole-body vibration for disorders of the back and lower limbs (2, 24, 34–60).

NIOSH's review and basis for these conclusions was itself subsequently endorsed, both methodologically and substantively, by the National Academy of Sciences in 1998. The first NAS study was publicly discussed by about 75 scientists and other workshop participants, the overwhelming majority of whom agreed that "There is a higher incidence of . . . injury . . . and disability among individuals who are employed in occupations where there is a high level of exposure to physical loading than for those employed in occupations with lower levels of exposure" (page 23 in (1)). (The second NAS study is not described here because it will be discussed separately at this hearing.)

In 1997, the Swedish National Institute of Working Life (NIWL) commissioned a review of the epidemiologic literature specifically limited to occupational use of video display units (VDU) and upper extremity musculoskeletal disorders. This review covered 72 reports from 56 different epidemiologic studies, primarily peer-reviewed scientific journal articles (61). The NIWL endorsed the conclusion that use of a VDU was a direct causative agent of hand and wrist disorders, mediated primarily through repetitive finger motion and sustained muscle loading across the forearm and wrist. The risk was particularly pronounced for those in more keyboard-intensive jobs, such as data entry, which are more stereotyped and involve more continuous exposure with fewer alternative tasks or rest breaks.

In 1999, Dr. Barbara Silverstein and I re-considered the epidemiologic literature on work-related MSDs, at the request of the American Conference of Governmental Industrial Hygienists (ACGIH), in order to assess the nature of the guidance that could be obtained as a basis for establishing one or more Threshold Limit Values® (TLV) for occupational exposure to physical ergonomic stressors (62). From the most rigorous epidemiologic studies, we extracted data on dose-response relationships and on exposure levels at which there was a significant increase in risk of upper extremity MSDs and which could be operationalized in the form of a TLV; for example, there was quantitative evidence to justify a TLV of 1–2 hours per day of exposure to repetitive wrist bending or twisting, 1 hour per day of highly forceful manual work, and 1 hour per day of shoulder flexion or abduction (work with the arm above shoulder height). Four different studies showed an increased risk of shoulder disorders when such postural stress is experienced for only 1 to 2 hours per day (see Table 6). We also confirmed the findings of Bernard et al. (8) that exposure to multiple ergonomic risk factors in the same job has at least an additive effect, if not much greater, and recommended that a TLV for any one dimension of physical load should take account of whether other forms of exposure are also present in the job. A new report by the European Agency for Safety and Health at Work (63), an office of the European Union, has concluded that, "The scientific reports, using defined criteria for causality, established a strong positive relationship between the occurrence of some WRULDs [work-related neck and upper limb musculoskeletal disorders] and the performance of work, especially where workers were highly exposed to workplace risk factors." The risk factors identified as particularly requiring preventive reductions by the European Agency were a familiar list: non-neutral postures of the shoulder and wrist, force applications at the hand, hand-arm exposure to vibration, direct mechanical pressure on body tissues, cold, and work organization factors.

EXPOSURE-RESPONSE RELATIONSHIPS

A large number of investigations have demonstrated exposure-response relationships between physical ergonomic exposures and the risk of MSDs, and a number of reviewers have cited this evidence in concluding that there were causal relationships (e.g., 2, 8, 41, 43, 58, 64). An exposure-response relationship means, in general

terms, that as the amount (intensity, frequency or duration) of a risk factor increases, so does the probability, or risk, of an adverse health effect. An exposure-response relationship, when present, is considered to strengthen the evidence of a causal relationship because it is believed to be a characteristic of cause-effect situations, in general, absent evidence to the contrary. In addition, it is thought that it would be more difficult for many or most forms of bias or confounding to produce an artifactual exposure-response relationship than to bias a simple association such as an odds ratio.

Some have argued that the lack of comprehensive exposure-response data represents a level of scientific ignorance that prohibits any preventive action. However, it is not a sine qua non, in that an epidemiologic study can provide valuable information even if both exposure and outcome are dichotomous. Furthermore, the lack of an exposure-response relationship is not necessarily evidence against a causal effect, since not all pathomechanisms would produce such trends.

More importantly, there is substantial evidence of interactions among physical exposures, so that (for example) jobs requiring both repetitive and forceful motions have a higher risk than jobs requiring either exposure alone (65–67). The multifactorial nature of these relationships must be taken into account in interpreting research findings. A "low" level of muscular exertion would seem to be safer than a "high" level of force, everything else being equal; but if the low force must be sustained for an excessive period of time, then the prolonged duration of the exertion may render it as hazardous as a brief but more strenuous exertion (6). Thus, the exposure-response curve for each exposure should ideally be described as a function of the level of each other exposure that might also be present in the same job. There are obviously an enormous number of possible exposure combinations, and not all have yet been rigorously studied by epidemiologic methods.

Two misconceptions that have arisen during debate on this literature are that (1) if an exposure-response relationship existed, it would necessarily be linear or monotonic; and (2) that it would necessarily indicate an exposure level that could be used to differentiate between background risk of MSDs and an occupationally elevated risk. First, an exposure-response relationship need not take the form of a straight line through all data points; it may conceivably be better described as a logistic curve, or as a step-function, or as any other of a variety of mathematical functions. As only one example, the analyses described above by Frost et al. (9) clearly showed a non-linear exposure-response trend with cumulative exposure to repetitive and loaded shoulder flexion. A non-linear relationship specifically accommodates the likelihood that some physical activity is beneficial and that only at more extreme levels do adverse health effects occur, another point advanced in supposed disagreement with the evidence summarized here.

Secondly, an exposure-response trend does not necessarily indicate a single exposure level that unambiguously differentiates risk from no risk. On the contrary, a perfectly linear relationship would by definition not provide a clear threshold level. This is especially true if exposure is treated as continuous and the relationship fits a straight line through the origin, in which case each small increment in exposure increases the probability of an adverse health outcome and, extrapolated downward, there may be no discernable point without excess risk above the zero exposure level.

When epidemiologic data indicate a good fit with a continuous exposure-response relationship (rather than a step function, for example), the designation of a permissible exposure level is a policy decision rather than a judgment following inevitably from the scientific data. Several authors have called attention to the complexity of this process of utilizing exposure-response data for quantitative risk assessment in the multi-dimensional domain of physical ergonomics (e.g., 2, 58, 64, 68, 69). It is reasonable to conclude, as these experts have done, that there is a need for continuing study of those relationships and interactions, and at the same time that it is appropriate to implement the scientific knowledge in hand in order to prevent at least part of the work-related morbidity that is presently occurring within the American workforce.

PSYCHOSOCIAL FACTORS AND MSDS

Another type of stressor that has received increasing interest with respect to MSDs is that of psychosocial factors. The term "psychosocial" is used in a variety of ways by different authors, which has led to tremendous confusion both in the scientific literature and in public discussion. It is critical to distinguish between psychological attributes of individuals—such as personality, coping skills, motivation or mood states—and the strain imposed on individuals by features of their work environment resulting from the organization of production activities. Work organization factors—task structure, the division of labor, and skill utilization—are partial deter-

minants of physical load as well as of psychological job content and constraints that may cause workers to experience "stress."

According to one widely used, internationally standardized measurement approach (Job Content Questionnaire), there are three key measures of psychosocial job characteristics: psychological job demands, decision latitude, and social support (70–72). Decision latitude is based on the worker's decision authority and the worker's discretion over skill use, i.e., the worker's ability to control his/her own work process and to decide which skills to utilize to accomplish the job. Psychological job demands reflect both physical pace of work and mental work load, especially time pressure in processing or responding to information. In this model, high psychological job demands in combination with low decision latitude result in residual job strain and, over time, chronic adverse health effects such as cardiovascular disease.

Clearly, these psychosocial features of the work environment are under the control of the employer just as much as are physical factors such as work pace and tool attributes. In fact, there is a recognized overlap between some physical and psychosocial exposures; the experience of performing a repetitive, monotonous task on a machine-paced assembly line can be described equally well in terms of stereotyped, repetitive motion patterns with rigid pacing and few rest breaks, and as "poor" psychological job content, with few opportunities to make decisions, work collaboratively with coworkers, utilize existing skills or learn new ones. The relationship of work organization factors with psychosocial strain has also been demonstrated by intervention studies showing that increasing worker participation in decision-making can resolve physiological strain linked to high levels of demands over which the worker had no control (72).

The occupational psychosocial stressor most consistently associated to date with musculoskeletal disorders is lack of decision latitude or autonomy (73). However, the evidence regarding a causal relationship with MSDs is still quite limited, and several reviews have concluded that the epidemiologic evidence is relatively weak. On the other hand, the known physiological effects of psychosocial strain at work include several plausible mechanisms by which the musculoskeletal system could also be affected: adverse circulatory patterns; high levels of sympathetic nervous symptom arousal with general central nervous system consequences as well as endocrine system impacts on circulating hormones; tonic activation or "psychogenic" muscular tension; and interference with normal muscle and tendon repair processes (e.g., 74–79). These postulated mechanisms deserve further study, but in the meantime the literature on these associations should not be regarded less critically than the literature on physical risk factors.

SUMMARY OF THE EPIDEMIOLOGY

In summary, the epidemiologic evidence linking physical ergonomic exposures at work with risk of MSDs is extensive, biologically plausible, and methodologically adequate to inform primary prevention. Numerous reviewers have concluded that ergonomic exposures such as repetitive work, heavy lifting, forceful manual exertions, vibration, and postural stress are causally related to the occurrence of musculoskeletal disorders affecting neck, shoulder, hand/wrist, and back. New research has strengthened the evidence supporting these conclusions. There is substantial evidence of increasing risk with increasing exposure, and of interactions among physical exposures. These relationships have been found in studies of specific workplaces as well as in samples of the general population. The available longitudinal evidence generally confirms, in general terms, the conclusions previously drawn from cross-sectional studies regarding the etiologic association between working conditions and UE MSDs. The impact of physical exposures at work cannot be explained away by demographics (e.g., age or gender), medical history, or other attributes of individuals.

There is an international near-consensus that effective prevention of these disorders necessarily involves, among other measures, reduction of workplace exposure to ergonomic risk factors, and several eminent scientific reviewers have specifically called for regulatory action, even given imperfect epidemiology and understanding of pathomechanisms to date (e.g., 57, 69). Research agencies of the European Union have endorsed ergonomics standards and presumptive rules for identifying work-related MSD cases (63, 80). Among the U.S. organizations reaching similar conclusions are NIOSH (1997), the National Academy of Sciences (1998, 2001), and ACGIH (1999).

Costs of work-related MSDs

In addition to the human pain and suffering associated with MSDs, other losses are externalized to workers, with adverse financial and psychosocial impacts. There are also costs to employers through workers' compensation claims, scrap and de-

creased production quality, medical insurance premiums, labor turnover, and adverse impacts on labor relations, although many of these are not linked by traditional accounting methods to ergonomic problems per se. The proportion of these injuries and illnesses that are work-related are by definition preventable, as are their costs to employers, to workers, and to society. Several have estimated that the real costs to employers, including "indirect" or "hidden" costs, of workplace injuries and MSDs can range from 2 to 3.5 times the amount paid in workers' compensation cases (81–84).

However, it cannot be assumed that market-driven cost-benefit calculations will be sufficient to motivate worker protection, because firms typically emphasize short-term costs over long-term and because a large proportion of these costs are not identified by traditional accounting methods as due to ergonomic problems in the work process (82). Furthermore, fundamental work organization features are rarely questioned; on the contrary, modifications to increase productivity and profitability, such as just-in-time systems, lean production and total quality management or continuous improvement, appear to have intensified job demands for workers (85).

Workers experience other financial losses—some covered by compensation and others not—including the cost of medical care and lost work time, lost future earnings and fringe benefits, reduced job security and career advancement, lost home production and child care, and home care costs provided by family members (81, 86). Non-monetary losses include pain and suffering, family relations, sense of self-worth and identity, social and community relationships, and recreational activities (84, 87). These costs may accrue for many years, because of the long duration of many MSDs; the 5-year rate of increase in joint pain after retirement was higher among French subjects who had held jobs with heavy physical work load (31). More generally, disability retirement is disproportionately likely when people work in ergonomically stressful jobs such as heavy physical labor or repetitive tasks (30, 88).

Underreporting of MSDs in the workplace

The magnitude of MSD under-reporting through administrative data bases has been noted repeatedly. For example, in one automobile assembly plant, more than one-half of workers selected at random had unreported back or shoulder disorders on interview or examination (10, 89). However, only about 20 percent of workers with a serious episode of musculoskeletal pain appear to have sought in-plant medical attention (83). Less than one percent of medical visits for MSDs were flagged as workers' compensation cases, although 17 percent had work restrictions, almost 8 percent resulted in lost work time, and 5 percent required outside medical treatment. Many workers reported seeking medical care from outside providers.

Others have also shown that the frequency (and therefore the cost) of work-related MSDs is severely underestimated, by as much as 60 percent, when relying on traditional administrative data sources such as workers' compensation records and OSHA logs of recordable injury and illness (90, 91). Even among unionized auto manufacturing employees, who should perceive higher job security than many other workers, only 25 percent of those with work-related MSDs filed a compensation claim or applied for benefits (92). The reasons for under-reporting by employers and by workers likely include failure to recognize work-relatedness; concern about job security; workplace incentives for supervisors to discourage reporting; employee preference to avoid the workers' compensation system and obtain medical care coverage through private insurance, anticipated rejection of the claim, and even denial of the injury itself because of financial need or a sense of self-worth contingent on providing for oneself and one's family (92–98).

Under-estimation of MSD frequency also results from injured workers leaving the workplace, i.e., the "healthy worker effect," also referred to as a survivor or selection bias. Not surprisingly, workers who develop musculoskeletal disorders in ergonomically stressful jobs are disproportionately more likely to transfer to less exposed positions or to leave the workplace altogether (18, 99–103). In the automobile assembly plant studies cited above (10, 89), almost 75 percent of both the back and shoulder cases reported difficulty in doing their current or past jobs, and about one-third had voluntarily transferred out of previous job assignments because of pain and impaired performance.

The significance of this survivor effect is that it artificially reduces the risk measures that can be determined from the population, because the most exposed and affected individuals are missing from the data set. Such a bias masks evidence of exposure-response relationships, meaning that positive associations found in these studies would likely have been even stronger if those subjects could have been included.

Effectiveness of Ergonomics Intervention Programs

The potential to reduce MSD occurrence by reductions in occupational ergonomic exposures is demonstrated in principle by the occurrence of attributable morbidity itself. The proportion of musculo-skeletal injuries and illnesses that are work-related are by definition preventable, as are their costs to employers, to workers, and to society. For example, it has been estimated that at least 50 percent of all work-related musculoskeletal disorders among the working population could be prevented by appropriate ergonomic job design (104, 105). Policy-making on other occupational hazards has not required separate intervention studies; if higher exposures lead to higher prevalence or incidence, then it follows that reductions in exposure would lead to reductions in morbidity.

Some scientific evaluations of ergonomic programs have been undertaken, and these have shown mixed results. A key problem is that any workplace is a highly dynamic institution. Rather large and expensive studies are needed to address all possible risk factors for MSDs in a rigorous manner, and yet the scientific investigator has no control over external or internal events that might occur during the study period. After the study has been initiated, the employer might reverse a decision to implement fully a set of ergonomics recommendations, or a facility might be closed or downsized, or new national legislation on disease reporting might be introduced (106).

Nevertheless, the scientific literature contains numerous examples of intervention studies that document the practical and economic feasibility of workplace ergonomic programs. Effective abatement measures range from well-designed training programs to workstation redesign (107). Reductions in frequency and/or severity of work-related MSDs have been demonstrated in manufacturing as well as in other economic sectors. For example, in motor vehicle manufacturing, ergonomic control measures have been effectively implemented both at the level of the job and in the organization of the production process (e.g., 108–110). Decreases in MSDs among VDU operators can similarly be achieved by provision of adjustable furniture, training sessions to facilitate workers' knowledgeable adjustment of workstations and work schedules, and early reporting systems that aided employers in assisting individual workers before they became too severely injured to benefit from workplace measures (61).

The most effective ergonomics programs appear to be those with multiple, coordinated activities, including workstation improvements, provision of adjustable furniture, training to facilitate workers' knowledgeable adjustment of workstations and work schedules, and enhanced medical surveillance and management systems that aid employers in assisting individual workers before they became too severely injured to benefit (111–120). Shannon et al. found that, in general, lower injury rates are consistently associated with workplace characteristics such as workforce empowerment and top management's active leadership plus delegation of decision-making authority regarding occupational safety (121).

The economic benefits of such improvements should be taken into account when attempting to estimate the cost of ergonomic interventions. It has been reported that tasks identified by workers as having the highest physical demands were far more likely than other tasks to result in quality defects that were not detected until the final inspection stage (122), and that an automobile assembly system designed on the basis of ergonomic principles reduced through-put and idle time, improved car quality, enhanced production flexibility and operator competence in handling a varied mix of vehicle options, and reduced production space requirements (109). Pay-back periods could be substantially less than one year if full-cost accounting methods were used to assess comprehensively both the costs and benefits of ergonomic programs (123).

Conclusions

Many employers voluntarily utilize ergonomic principles to improve working conditions, and they often report economic and other benefits from such programs. Nevertheless, work-related musculoskeletal disorders still occur with high frequency. Thus we must conclude that existing incentives are not sufficient.

Not all MSDs occur in relation to work demands, but individuals with high exposures to ergonomic stresses are at substantially increased risk. The considered opinion of many scientists, internationally, is that the scientific literature on work-related MSDs overwhelmingly demonstrates a causal relationship between occupational physical ergonomic stressors and musculoskeletal disorders.

The fundamental principles of public health practice emphasize the prevention of injury and illness. While there may be debate about the specifics of what an ergonomic standard should contain, there should no longer be any debate that some MSDs can be prevented. Workplace ergonomic programs, including early reporting,

training, and job redesign, are a feasible and effective means for reducing the occurrence and severity of MSDs. Public policy measures are required to ensure prevention of unnecessary injury, illness and disability.

Senator SPECTER. Thank you very much, Dr. Punnett. We turn now to Dr. Franklin Mirer, Director of Health and Safety, United Auto Workers.

STATEMENT OF DR. FRANKLIN E. MIRER, DIRECTOR, HEALTH AND SAFETY, UNITED AUTO WORKERS

Dr. MIRER. Thank you very much, Senator, for the privilege of testifying here. And I can tell you that in the auto industry we do have a consensus. We have a consensus that there are work-related musculoskeletal problems. It is our leading cause of injury and illness.

Senator SPECTER. Employers agree with that?

Dr. MIRER. Yes, they do. And we have consensus on how to measure it using pretty much the same measures across three auto companies. We have consensus on how the program ought to be structured. That is our ergonomics program. And we arrive at that under a deadline which is the end of the auto contract.

Each round of auto bargaining, we improve the ergonomics program. Now, we do not have a consensus that a standard is needed, although I think we would be pretty close to a consensus that the rest of the industry, including our parts suppliers, ought to be doing a better job. And we are continuing in the effort to do that, both the UAW and with some limited support from management. So this is kind of a—some of this argument is alien to us.

Now, yesterday, I was called by one of our several hundred hourly ergonomics reps, local union reps, this one from a parts plant in Flint. She was preparing an invited presentation to a symposium at the American Industrial Hygiene Association in New Orleans.

She is their local expert on the workings of government, having been one of 20 UAW local union witnesses who testified on the standard in Washington, Chicago and Portland. And she had the pleasure of being cross-examined by Mr. Fellner at time to clarify her answers. She told me as recently as——

Senator SPECTER. I'm sorry. I didn't hear that. She had the what?

Dr. MIRER. She had the pleasure of being cross-examined by Mr. Fellner.

Senator SPECTER. I thought that is what you said.

Dr. MIRER. She told me that as recently—never laid a glove on her.

She told me that as recently as this Tuesday, a member approached her on the plant floor to ask if they were going to lose ergonomics because of the vote in Congress. She says that fear has been raised in local union meetings repeatedly on the plant floor the day after the Senate vote.

And I submit that as evidence that the real experts, the hourly people doing ergonomics in the plant, the engineers, the shop floor workers all know what it is about and all think it is needed.

And her answer was, do not worry, we have ergonomics in the contract with UAW. We are never going backwards.

But her problem is, and everyone's problem is it is hard to get upfront money to fix problems in good economic times, in the re-

cent good economic times. Now that it is getting harder, preventive maintenance even to keep production running smoothly is hard to come by.

I am afraid we are going to be doing some sideways stepping. Our major employers foresaw no changes required in their ergonomics programs as a result of the new standard. And we are moving to enhance it.

But we all know that we sought that standard as a safety net against future cutbacks and as a floor for building on in other facilities. So we fear that we might end up with the safety net gone in free-fall or climbing on air.

Now, very quickly in terms of effectiveness of programs, 60 percent of the injuries in the auto sector are musculoskeletal disorders. Practical ergonomics programs became fully effective in 1994 really, and since then we have shown a 35 percent reduction averaged over the whole three sectors in injuries.

But that is an average. Some places are doing better than others. Our methods for relieving ergonomic stresses and procedures for carrying out practical ergonomics are established. We teach that scientific basis using some of these researchers to local union representatives.

We have funded research. A lot of this research has been conducted in the auto industry including some joint funding and NIOSH funding of Dr. Punnett's work. It is pretty straightforward.

So the consensus in manufacturing, on how to go forward, how to design equipment, how to measure stresses, how to retrofit problems, some of this information is on open web sites of the industry.

Where we do not have consensus and where as you have heard here, actually, it might be close to consensus but they are demanding unanimity, we do not have consensus on the need for a standard or some of the fine details of the standard.

PREPARED STATEMENT

But everybody is doing this more or less the same way than are trying to take care of their workers and get a product out the door, a quality product out the door on time. And we need that codified, the practices of the industry leaders codified so we can pull along the followers, the laggards and the outlaws. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. FRANKLIN E. MIRER

This testimony is on behalf of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW and its 1.3 million active and retired members. Equally importantly, this testimony is on behalf of tens of millions of American workers exposed to ergonomic hazards who are not represented by a labor union.

UAW members assemble vehicles and make parts for the Big 3 auto makers, and also produce 18-wheelers, construction equipment, locomotives and the Space Shuttle. Their employers are industrial giants. We also represent nearly 300,000 employees of 1,500 private and public employers in 2,800 bargaining units whose average size is 100. In addition, our units include warehouses, schools, cafeteria workers, health care and social service agencies. These statistics demonstrate the depth and range of the UAW's experience with ergonomics programs in both manufacturing and non-manufacturing sectors.

The UAW's extensive experience with ergonomics programs holds answers to all the questions the members of this Subcommittee pose: Is an OSHA ergonomics standard needed? Is there sound science to support an ergonomics standard? Is an

ergonomics standard consistent with industry practice? Is an ergonomics standard feasible? Is an ergonomics standard applicable and feasible in all sectors of the economy? The answer to each of these questions is a resounding "yes." The actions such a standard would require are not only feasible, they are already commonplace in hundreds of UAW-represented workplaces.

The UAW appreciates that this Subcommittee is interested in hearing the current state of the debate on ergonomics. We would have preferred that this debate had been more fully aired before the Senate voted on, and the President signed, the Resolution of Disapproval of OSHA's ergonomics program standard.

The UAW strongly supported OSHA's ergonomics program standard as a modest, but critical, first step toward abating the largest single cause of injury and disability among American workers generally, and UAW members in particular. The OSHA rulemaking provided an oasis of science amid a desert of lobbying and sound bites. Then, the logic of power overwhelmed the power of logic, and the rule in place was repealed. We are not here to re-debate the disapproval resolution, however. We are here to argue that Congress, having eliminated the protections afforded by the ergonomics standard, should mandate that OSHA issue another enforceable ergonomics standard regulation by a time certain.

The purpose of Federal standards is to codify the practices of industry leaders so that industry followers can adopt those practices while exposing industry laggards and outlaws for what they are. There are literally thousands of consensus safety standards, set by industry to regulate itself. The large majority of OSHA standards are actually outdated, 1970's vintage consensus standards. OSHA standards, adopted through an open, evidence-rich process, may stretch the industry leaders, but they are particularly hated by the laggards because management has to comply, rather than merely being invited to comply.

The UAW testimony today will emphasize the following key points:

1. Ergonomics programs are the only means to prevent the majority of injuries suffered by American workers in the automobile industry, and the manufacturing sector generally. Approximately 60 percent of injuries in the auto sector are muskuloskeletal disorders.
2. Practical ergonomics programs are in place in hundreds of worksites and have set the stage for major progress.
3. The Bureau of Labor Statistics 1998 and 1999 surveys show the effectiveness of UAW-negotiated ergonomics programs.
4. Methods for measuring and relieving ergonomic stresses and procedures for carrying out practical ergonomics programs have been developed and verified over the last decade. The science is well established.
5. The principal need over the next decade is accelerating abatement of exposure to physical stresses.
6. The UAW has developed and implemented an ergonomics model for small manufacturing suppliers and office and professional facilities which demonstrates that ergonomics is necessary and feasible in such facilities. These programs also establish industry recognition of MSD risk factors and the elements of a program needed to protect employees.
7. The OSHA rulemaking process was itself a massive data collection and analysis effort that collected information not previously available to support an ergonomics standard.
8. Both the second National Academy of Sciences 2001 review and the new ACGIH standard for Hand Activity Level limit demonstrate a scientific consensus in support of ergonomics interventions.
9. In conclusion, the ergonomics standard is necessary, feasible and appropriate.

Each of these points is discussed in detail below:

1. Ergonomics programs are the only means to prevent the majority of injuries suffered by American workers in the automobile industry, and the manufacturing sector generally. Approximately 60 percent of injuries in the auto sector are muskuloskeletal disorders.

The need for ergonomics abatement is most clearly shown in the Bureau of Labor Statistics (BLS) Disabling Injury reports.[1] These studies compile employer-supplied data on the types and causes of injuries and illnesses that result in days away from work. The employer data are a sample of OSHA 101 forms for cases with days away from work.

OSHA relied on this same database. We concur with OSHA that these employer-supplied data probably under-report musculoskeletal disorders. However, the data portray the full extent of the problem.

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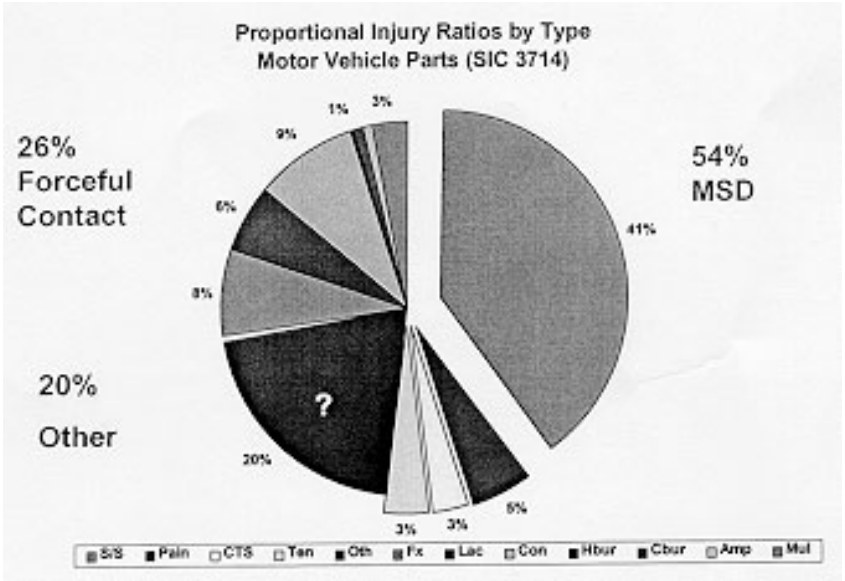
[1] Most recent detailed industry data available are for 1998. These analyses are for the 1997 database, which is not materially different.

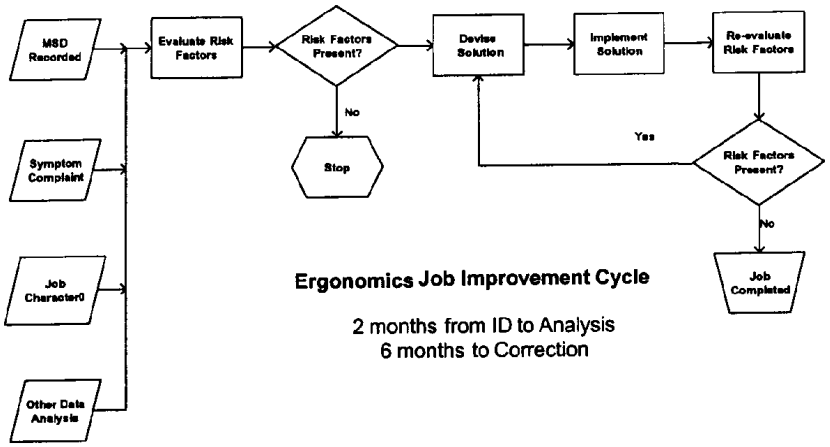
In the motor vehicle parts sector (SIC 3714), the employment category of in the auto industry with processes most common to other manufacturing industry and with the most small establishments, 54 percent of disabling conditions are identified by management as strain or sprain injuries and various cumulative trauma diagnoses which are properly grouped as MSD's. In addition, about 20 percent of disabling injuries were in the "other" category, which includes some MSD's. Therefore, the large majority of disabling conditions are MSD's. For auto parts, 40 percent of injuries were coded as arising from repetitive motion or overexertion, with an additional 11 percent in the "other" category. Back injuries are the largest single diagnosis in this sector, 22 percent, and shoulder injuries are 7 percent. Back and shoulder injuries are almost entirely of ergonomic origin. In short, injuries preventable by ergonomics programs dominate the disabling injuries in the motor vehicle parts sector, and manufacturing in general.



These data demonstrate that the biggest problems now faced by safety specialists and suffered by workers are hazards that can be abated only by ergonomics programs.

2. Practical ergonomics programs are in place in hundreds of worksites and have set the stage for major progress.

Every UAW-represented location in the Big 3 auto companies has a labor-management ergonomics committee in addition to a labor-management health and safety committee. These approximately 300 facilities employ about 350,000 hourly workers and additional salaried personnel, and represent a substantial fraction of the U.S. Gross National Product. The two UAW-represented international transplant assembly plants use the same structure. Labor and management representatives on these committees are trained to analyze injury and illness data to identify high injury jobs; to conduct risk factor analyses; and to identify solutions to reduce ergonomic stresses. Dozens, if not hundreds, of smaller UAW-represented parts suppliers have adopted this model as well. UAW members in the service, clerical and public sectors have been able to implement similar programs. These programs are described in more detail below.

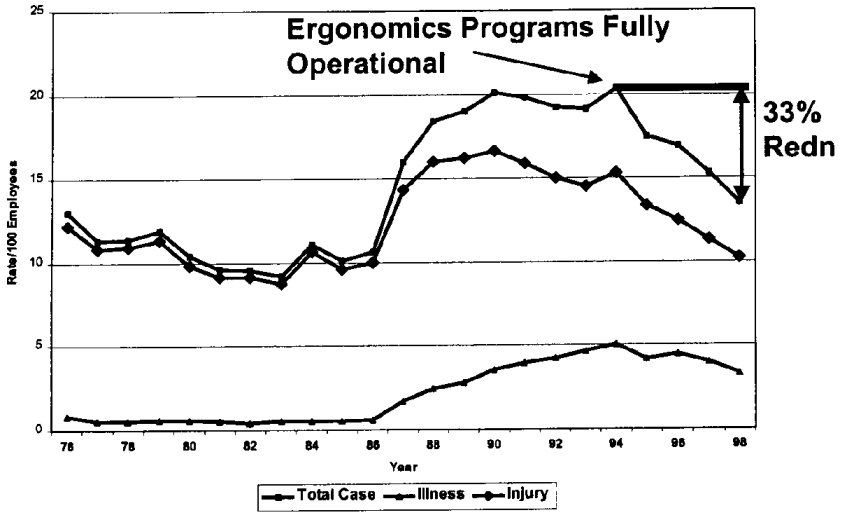


The common ergonomic abatement process used by these committees is shown in the accompanying flowchart. Ergonomics is a continuous improvement process with no clear endpoint. In fact, participants believe that ergonomics improvement is integral to a high performance manufacturing system, just as quality improvement is.

Initially, these UAW ergonomic programs grew from massive penalty OSHA citations for failure to record injuries and illnesses, and from citations under the General Duty Clause. The programs were later codified in labor contracts. Labor and management representatives argue about the best way to do things and whether change is fast enough, but the need for an ergonomics process on this model is no longer in dispute. Our ergonomics programs have been shown to reduce worker injuries and to increase productivity.

Ergonomics program activity goes well beyond the vehicle assembly, stamping, parts manufacturing and parts distribution facilities of the Big 3 auto makers. Similar but less elaborate programs following the same model, including job analysis methods and labor management structure, have been implemented in many smaller UAW represented workplaces. Ergonomics committees at these facilities are often trained by UAW professionals. We have done this in parts plants, bicycle plants, a health maintenance organization, in clerical settings and among public employees.

Injury Rates: Motor Vehicle Parts and Accessories, SIC 3714



3. The Bureau of Labor Statistics 1998 and 1999 surveys show the effectiveness of UAW-negotiated ergonomics programs.

Analysis by the UAW of the most recent government statistics shows that safety and ergonomics programs prevented over 69,000 occupational injuries and illnesses in 1998 in the vehicle assembly and parts sectors. Of these, at least 41,000 were musculoskeletal problems prevented by ergonomics programs.

These data are derived from the Bureau of Labor Statistics' annual injury and illness survey data for 1998, released in December 1999. Reductions in injury rates reported for key UAW workplaces give strong evidence for the effectiveness of UAW safety and health programs generally, and especially for the value of our ergonomics programs.

The UAW believes that the motor vehicle assembly (SIC 3711), motor vehicle parts (SIC 3714) and automotive stamping (SIC 3465) sectors have gone farther than most others in implementing ergonomics programs. My testimony concentrates on the auto parts sector. We selected 1994 as the baseline, because that is when ergonomics programs were first likely to be fully implemented, and also to obtain a five year period. For the auto parts sector, the total case rate dropped 12 percent over one year and 33 percent over five years, while the occupational illness rate fell 17 percent over one year and 34 percent over five years. Cumulative trauma disorders declined 13 percent and 24 percent respectively.

Over this same period the total case rate, injury rate and CTD rate fell slightly for all private employment, while the illness rate increased by a small amount. The vehicle assembly rate however, dropped 5.5 times as fast as the national average over five years, while auto parts dropped 4.5 times as fast. Percentage reductions were 40 percent greater in vehicle assembly and 70 percent greater in parts manufacturing compared to all employers combined.

The 1999 data, which did not become available until December 2000, show an additional 5 percent drop in total rate across the three main auto-related sectors. This evidence of continuing improvement was not included in the record of the OSHA hearings.

These data show that ergonomics programs decrease the number of worker injuries, with attendant savings to employers as well.

4. Methods for measuring and relieving ergonomic stresses and procedures for carrying out practical ergonomics programs have been developed and verified over the last decade. The science is well established.

The important technical developments for effective ergonomics programs emerged two decades ago, and the broad outline is now largely in place. The driving force was combining the engineering and biomechanics disciplines with medical science and epidemiology. The University of Michigan and NIOSH are the key institutions

that have established the United States at the forefront of the science of ergonomics. The technical developments include:

—Development of consistent methods to measure the physical stresses on the human body. Stress is determined by the force exerted on a body part, the frequency of the motion, and the posture of the joint. The Force-Frequency-Posture paradigm is common to both expert and checklist approaches to ergonomic analysis;

—Acceptance of expert ergonomic analysis for measurement of risk factors according to these methods;

—Development of simplified non-expert approaches to measurement of risk factors (checklists);

—Formulation of the NIOSH lifting guide and related biomechanical models which take into account the weight of an object, distance from the body, and motion of the body in lifting;

—Validated semi-quantitative risk factor checklists for hand, arm and shoulder (upper extremity) cumulative trauma disorders;

—Diagnostic criteria for upper extremity CTD's;

—Standardized physical examination protocols for upper extremity CTD's;

—Validation of symptom surveys and discomfort surveys (psychophysical measures) as risk factor identification tools;

—Validation of risk factor checklist and symptom survey by workforce personnel to identify high risk jobs and propose abatement methods;

—Acceptance of the plant ergonomics committee model, especially lay analysis of risk factors using standardized checklists.

These scientific developments rest on an enormous body of published work as well as practical experience. In 1997, NIOSH published a massive compilation of ergonomics studies. The UAW believes that the NIOSH compilation and analysis of virtually all available studies of work-related musculoskeletal disorders settles the question whether there is sufficient science underlying ergonomics. The studies show exposure-response relationships for ergonomic stress factors and musculoskeletal disorders of each body part. NIOSH did an excellent evaluation of hundreds of reports to show the weight and strength of the evidence for cause and effect relationships, and conclusively confirmed that increased stress causes increased injury.

Nonetheless, Congress subsequently funded a review of this issue by the National Academy of Sciences.[2] A steering committee was established in May 1998, under the auspices of the NAS Committee on Human Factors.

NAS studies typically consist of literature reviews and presentations at open meetings, followed by a report drafted by the expert committee and reviewed by the Academy members and other peer reviewers. The ergonomics study involved an open workshop attended by 66 leading technical experts. The UAW participated in this workshop[3], presenting evidence of our experiences with ergonomics programs. The NAS issued a report on the study in 1999. The summary conclusion was: "Scientific research clearly demonstrates that effective work place interventions are available which can reduce ergonomic hazards and prevent musculoskeletal disorders. There is evidence that interventions are cost-beneficial for employers." The report thus validated the scientific conclusions cited by OSHA as the basis for its decision to move forward with an ergonomic standard.

In 1998, Congress commissioned a second NAS study of the same issues.

This section has summarized the state of knowledge when the ergonomics standard was proposed and the hearings began. Below we discuss subsequent scientific developments that further support the need for an ergonomics standard.

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[2] The NAS ergonomics report responds to seven questions posed by Congressman Livingston: 1. What are the conditions affecting humans that are considered to be work-related musculoskeletal disorders? 2. What is the status of medical science with respect to the diagnosis and classification of such conditions? 3. What is the state of scientific knowledge, characterized by the degree of certainty or lack thereof, with regard to occupational and non-occupational activities causing such conditions? 4. What is the relative contribution of any causal factors identified in the literature to the development of such conditions in (a) the general population; (b) specific industries; and (c) specific occupational groups? 5. What is the incidence of such conditions in (a) the general population; (b) specific industries; and (c) specific occupational groups? 6. Does the literature reveal any specific guidance to prevent the development of such conditions in (a) the general population; (b) specific industries; and (c) specific occupational groups? 7. What scientific questions remain unanswered, and may require further research, to determine which occupational activities in which specific industries cause or contribute to work-related musculoskeletal disorders?

[3] Lida Orta-Anes, Ph.D., ergonomist, UAW Health and Safety Department, was invited to present a discussion paper on UAW experiences and her views of the scientific evidence.

5. The principal need over the next decade is accelerating abatement of exposure to physical stresses.

Many case histories show improved health outcomes on jobs where risk factors had been reduced. Many facilities report reduced injury rates after implementing ergonomics programs. Scientific studies show reduced injury rates and symptom complaints after job changes. These case studies were reported in the NIOSH conference and are regularly presented at professional meetings. The data presented above show sector-wide reductions in MSD rates in the sector with the most advanced ergonomics activities. These successes are reasons for government to keep pressure on employers to abate ergonomic hazards.

The principal problem plant ergonomics committees report is not being able to get high-risk jobs fixed in a timely fashion. High-risk jobs are jobs where injuries have already been recorded. Solutions are usually identified directly from the risk factor analysis: the job task must be changed to reduce the force, limit the number of repetitions of the same motion, or allow the worker to do the job in a neutral posture.

Routine solutions include raising loads off the floor with lift tables, adjusting the height of work, reducing the reach to get or place parts, damping vibration, placing the tool or the work in a fixture, reducing or counterbalancing tool weight. Many tricks of the trade are known to engineers and workers alike. People from the workplace know job changes that will allow the work to be done and reduce the stresses. Virtually all these solutions improve quality and efficiency and therefore increase productivity.

Nevertheless, to solve ergonomics problems and to reduce injury rates in the long term, an employer has to invest time and money up front. Unless pressure for job improvement is maintained, employers will resist accepting their responsibility.

The principal improvement in ergonomics programs achieved in the 1999 round of auto contract negotiations was adoption of specific time limits for the job improvement cycle. In all three auto agreements, management committed that a job will be analyzed within two months of the report of a work-related musculoskeletal disorder and modified to abate identified risk factors within six months of completion of the analysis. In addition, design criteria for new equipment are incorporated into the joint new equipment safety reviews. Some of these criteria are available to suppliers over the internet.

6. The UAW has developed and implemented an ergonomics model for small manufacturing suppliers and office and professional facilities that demonstrates that ergonomics is necessary and feasible in such facilities. These programs also establish industry recognition of MSD risk factors and the elements of a program needed to protect employees.

The UAW has implemented ergonomic interventions at approximately 45 smaller UAW-represented worksites over the past five years. The optimal intervention involves all the elements of the OSHA standard, except that MSD management typically falls short of the OSHA proposal.

The essential element of the intervention is training a worksite ergonomics committee to analyze jobs and suggest interventions. In UAW-represented facilities, this training is primarily conducted by peer trainers, called Local Union Discussion Leaders (LUDL's). LUDL's are full-time employees at UAW-represented facilities. They are shop floor employees who move into a trainer position because of their interest and demonstrated training skills. These persons are released from work on union leave at UAW request to conduct training-related activities. LUDLs assigned to ergonomics training are usually ergonomics committee members at their home facility. They have all taken at least a 40-hour course, conducted job analyses, received training technique instruction and been fully evaluated by UAW Staff and University of Michigan training evaluation staff.

Our experience with this training method indicates that because it is based on hands-on activities, it ensures retention of information. The small group discussion and problem-solving allows for direct learning from peers with experience in the topic. The training includes extensive case studies through the use of videos. In addition, it is delivered at the site. It includes a component where participants evaluate real jobs on the shop floor, in real time.

The UAW has implemented successful ergonomics programs using this training at numerous small businesses, including Jaquith Industries (Local Union 1128) in Syracuse, New York. With the completion of a recent 40-hour Practical Ergonomics Training (PET) program, Jaquith workers are now able to evaluate problem jobs and develop solutions. Some jobs in this shop are presently being re-engineered to eliminate job hazards. In a recent letter to the UAW Health and Safety Department from Jaquith's owners, they praised and credited UAW's Health & Safety Department grant staff for a professional job in helping them to assess their ergonomics concerns and offering solutions to the problems they faced.

Other small employers who have worked with the UAW to establish successful ergonomics programs include: Recycle Ann Arbor (Local Union 157) in Ann Arbor, Michigan; Bosch Braking Systems (Local Union 2155) in Johnson City, Tennessee; United Defense Systems (Local Union 683) in Minneapolis, Minnesota; Sidler Corporation (Local Union 417) in Madison Heights, Michigan; and AP Parts (Local Union 12) in Toledo, Ohio.

7. The OSHA rulemaking process was itself a massive data collection and analysis effort that collected information not previously available to support an ergonomics standard.

The Subcommittee should take note of the remarkably open nature of an OSHA standard hearing. Prior to a hearing, OSHA issues the proposal and explanation, and invites written comments. The hearing starts with the OSHA team that wrote the standard appearing on stage taking questions from all comers, industry and labor, explaining and defending the proposal on the record. Then, OSHA presents experts who appear and face questioning by all parties under the same ground rules.

After OSHA has laid out its proposal and its evidence, anyone with an opinion can submit evidence and present oral testimony. However, the price of appearing before the team that will write the standard is taking questions from participants from industry, labor and OSHA, also on the record. For questioning of witnesses during the ergonomics hearings, labor and OSHA relied principally on subject matter experts rather than on lawyers. United Parcel Service, the main opponent of the ergonomics rule, requested two and a half days of testimony, then dropped nearly all its witnesses and took just a couple of hours, thereby crowding out other evidence and limiting the time of other witnesses.

The ergonomics standard had been under consideration for ten years, initiated by then-Secretary of Labor Elizabeth Dole. OSHA invited stakeholders to participate in many meetings to discuss key issues in the rule before a proposed standard was issued. NIOSH held an open invitation national conference to present best practices. OSHA held a series of regional open invitation best practices conferences. There was every opportunity for pre-proposal input to all interested parties. The UAW participated in many of these events. Participation included several joint labor-management presentations of facility experiences.

A working draft of the ergonomics standard was reviewed by small business representatives under the SBREFA process, beginning in February, 1999. OSHA, together with the Office of Management and Budget and the Small Business Administration created a panel to review and comment on a working draft of the standard. The panel sought the advice and recommendations of potentially-affected small entity representatives, consulting with 21 persons. This included a face-to-face meeting on March 24–26, 1999. The UAW notes with concern that small business representatives were given special status and access to rulemakers to ask questions and make comments before workers and the public had an opportunity for similar input. Nevertheless, in accordance with law, the SBREFA panel submitted a report to OSHA on April 30, 1999.

The SEBREFA panel made 36 recommendations to OSHA concerning the ergonomics standard. OSHA responded to each one of them, as detailed in the preamble of the proposed rule. Some comments resulted in modifications to the cost estimates of the standard. Others resulted in clarifications or changes to the explanation of the regulatory text. Finally, several changes in the regulatory text were made in response to recommendations. These changes included: removing a provision that employers must analyze jobs with "known hazards;" providing a step-by-step incremental abatement process; and modifying the medical management program to reduce potential cost to employers.

The UAW notes that some of the changes made in response to small business recommendations—in particular the incremental abatement process—later became the basis for criticism by business representatives.

The OSHA hearings spanned 44 full days of testimony and questioning in Washington, Chicago, Portland, and Atlanta, involved about 900 witnesses, and generated 18,833 pages of transcript. The full transcripts were posted on OSHA's website to be downloaded and reviewed, as well as lists of exhibits. This open access to the complete record had no precedent in previous rulemaking.

The UAW presented testimony at three sites. Presenters included 11 local union representatives from automobile industry facilities; nine local union representatives from other sectors, including parts suppliers, agricultural implement, truck, appliances, joint ventures, private sector clerical and public employees; the UAW co-project manager for ergonomics from each of the three auto collective bargaining departments presenting the joint program at that company; and three Health and Safety Department representatives. The UAW also submitted about 200 pages of

written testimony and commentary as well as training materials and ergonomics manuals developed by the joint UAW-company programs. (The UAW notes that the jointly developed and validated UAW-GM Risk Factor Checklist was recognized by OSHA as a valid means of evaluating ergonomic risk factors.)

The UAW points out that the experiential data presented by local union representatives and staff are rarely available to an agency or to the public through the published literature. Yet, this evidence is crucial to the practical validation and application of biomechanical and epidemiological analyses in the real world. The OSHA process thus created a large and valuable new base of data.

Additionally, OSHA presented several panels of leaders in occupational medicine, ergonomic analysis, engineering and regulatory analysis applied to ergonomics programs. These were all published authorities whose work was available in the open literature. However, the invited testimony made these persons available for questioning on the specific points that management and labor stakeholders thought to be material to a standard. The dialogue in the hearing transcripts provides an additional large new base of data on which to develop ergonomic knowledge.

The OSHA team that had drafted the proposed standard sat through each of these hearings, as did the key labor and management representatives.

8. Both the second National Academy of Sciences 2001 review and the new ACGIH standard for Hand Activity Level limit demonstrate a scientific consensus in support of ergonomics interventions.

On January 18, 2001, the National Academy of Sciences (NAS) and Institute of Medicine (IOM) released their long-awaited report on Musculoskeletal Disorders and the Workplace ("NAS II"). The report, requested by Congress, confirms yet again that there is strong scientific evidence that exposure to ergonomic hazards in the workplace causes musculoskeletal disorders and that these injuries can be prevented by ergonomic interventions.

The study was not an ivory tower effort. The study committee traveled to Detroit, heard a presentation on the state of the art in the auto industry, toured auto plants accompanied by UAW and Ford staff,[4] and heard from local ergonomics committee members, labor and management, who do the work every day.[5]

The NAS II report confirms that the exposures addressed by the OSHA standard—heavy lifting, awkward postures, repetition, force and vibration—cause back injuries and/or upper extremity injuries like carpal tunnel syndrome. It also found that a programmatic approach tailored to individual workplaces, such as that set forth in the OSHA standard, is the most effective means to reduce MSDs. Specific major findings of the study include the following:

"There is no doubt that musculoskeletal disorders of the low back and upper extremities are an important and costly national health problem . . . In 1999, nearly 1 million people took time away from work to treat and recover from work-related musculoskeletal pain or impairment of function in the low back or upper extremities. Conservative estimates of the economic burden imposed, as measured by compensation costs, lost wages, and lost productivity, are between $45 and $54 billion annually." (Page ES–1)

"The panel's review of the research literature in epidemiology, biomechanics, tissue mechanobiology, and workplace intervention strategies has identified a rich and consistent pattern of evidence that support a relationship between the workplace and the occurrence of MSDs of the low back and upper extremities." (Page ES–3)

"The panel concludes that there is a clear relationship between back disorders and physical load; that is, manual material handling, load movement, frequent bending and twisting, heavy physical work, and whole-body vibration. For disorders of the upper extremities, repetition, force and vibration are particularly important work-related factors." (Conclusion 3, Page 11–10)

"The weight of the evidence justifies the introduction of appropriate and selected interventions to reduce the risk of musculoskeletal disorders of the low back and upper extremities." (Page 11–2)

"To be effective, intervention programs should include employee involvement, employer commitment and the development of integrated programs that address equipment design work procedures and organizational characteristics." (Conclusion 8, Page ES–6 and 11–2)

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[4] Dr. Bradley Joseph and Dr. Gordon Reeve, Ford Motor Company, and Dr. Franklin E. Mirer, UAW Health and Safety Department.

[5] Ford Livonia Transmission Plant and UAW Local 182, and Ford Michigan Truck Plant and UAW Local Union 900.

Opponents of an ergonomics regulation promptly issued press releases stating that this report discredited the scientific basis for the OSHA standard. We ask the members of this Subcommittee to judge for yourselves.

Equally compelling was action by the American Conference of Governmental Industrial Hygienists (ACGIH) on December 10, 2000. The ACGIH is the dominant private entity that issues occupational health standards. ACGIH standards are internationally recognized and given deference by many governmental authorities outside of the United States.

The ACGIH preface states:

"ACGIH recognizes work related musculoskeletal disorders (MSDs) as an important occupational health problem that can be managed using an ergonomics health and safety program—Some of these disorders fit established diagnostic criteria such as carpal tunnel syndrome or tendinitis. Other musculoskeletal disorders may be manifested by nonspecific pain. Some transient discomfort is a normal consequence of work and is unavoidable, but discomfort that persists from day to day or interferes with activities of work or daily living should not be considered an acceptable outcome of work."

The ACGIH adopted a Threshold Limit Value (TLV) for hand activity level and issued a notice of intended change to adopt a TLV for lifting.

Hand Activity Level is a numerical function of peak hand force, frequency and duration of exposure. The TLV includes an action level, below the exposure limit. The standard notes that:

"Professional judgment should be used to reduce exposures below the action limits recommended in the HAL TLV's if one or more of the following factors are present:

"—Sustained non-neutral postures such as wrist flexion, wrist extension, wrist deviation, or forearm rotation;

"—Contact stresses;

"—Low temperatures; or

"—Vibration.

"Employ appropriate control measures anytime the TLV's are exceeded or an elevated incidence of work-related musculoskeletal disorders is detected."

9. In conclusion, the ergonomics standard is necessary, feasible and appropriate.

The underlying premise of any OSHA standard is that an employer who knows a job has injured an employee must take feasible steps to make the job safer. Few would disagree with the propriety of this premise. This applies equally to ergonomics. The UAW, our auto industry employers, and many smaller employers have demonstrated that ergonomics programs are a "win-win" for both management and employees. In many of our worksites, ergonomic risk assessment techniques are applied predominantly by hourly workers who, in turn, have been trained by other rank-and-file workers. These methods both measure hazard and validate abatement.

Ergonomics programs works. It is time to get down to the business of applying ergonomics.

Senator SPECTER. Dr. Mirer, from what you have said, then, does the auto industry, UAW and manufacturers need an ergonomics regulation or have you not pretty much solved the problem yourself?

Dr. MIRER. No. The problem is never solved and we bargain over it actually every 3 years. It is a continuous improvement process. And we need the standard as a safety net for when times get hard.

Senator SPECTER. The standard as a safety net. But on an ongoing basis you are pretty well working it out from what I hear in your testimony.

Dr. MIRER. We have been making progress in good times. We are going into bad times now and things——

Senator SPECTER. Well, your experience is obviously not determined in there for all of the industry. You have a very mature industry in automobiles. And you have good bargaining power. And the UAW and the employers, when you say consensus, that is nice to hear, even though it is limited. But you would still like to have an ergonomics regulation from a Federal Government, but as you say from a safety net.

Dr. MIRER. For the three car companies, for the IPS sector, for the supplier sector, the small plants sector, we absolutely need that standard as a floor that we can build on and move forward.

Senator SPECTER. You need a standard forum from some of the suppliers. Well, has the UAW not been successful on your bargaining strength to get a reasonable result from that group?

Dr. MIRER. We are far from where we ought to be in that group.

Senator SPECTER. How do you account for the difference being far from where you ought to be in that group in contrast to where you are in the industry generally?

Dr. MIRER. It is a contrast of combination of collective bargaining, technical resources and the ability of suppliers to turn over their workforce and run away.

Senator SPECTER. Well, I think that the model that you have described though from the most of the industry of the UAW is a good one to be followed. Maybe it needs some sharpening up on it, but it is a lot better to hear that you need a safety standard than you are on each other's throats and cannot agree to anything.

Dr. MIRER. Absolutely.

Senator SPECTER. Dr. Hadler, what do you think of Dr. Punnett's testimony that musculoskeletal pain is proportionate to physical work? I do not have her exact words. They were too complicated and too long and I could not write them all down but that is the thrust of it.

Dr. HADLER. When I was a medical student, epidemiologists observed that the risk for Down's Syndrome, trisomy 21, was not uniform in sibships. The youngest child was more likely to be afflicted with this congenital disorder.

Senator SPECTER. Does this turn out to be responsive to my question?

Dr. HADLER. It is a direct response.

Senator SPECTER. I am not sure about that. I disagree with that already.

But if it is indirect, I will take it.

Dr. HADLER. We are working on consensus. Give me about another two paragraphs.

Senator SPECTER. Okay.

Dr. HADLER. That leads to the hypothesis and research——

Senator SPECTER. Chairman gets very impatient when you have got about 40 witnesses.

Dr. HADLER. I hear you. I will be within my 5 minutes.

Senator SPECTER. I am not necessarily giving you 5 minutes, Dr. Hadler. I want you to respond to my question. You have had 5 minutes.

Dr. HADLER. The answer is, if I need to respond directly, and the analogy would help understand it, is that——

Senator SPECTER. Go ahead with your analogy. It will be shorter than my interruptions.

Dr. HADLER. That lead to hypotheses and research as to what was it about the multiparous uterus that caused the fertilized egg to divide abnormally.

Several years later, epidemiologists returned to this issue to test whether they had missed the real association. The younger the child in the sibship, the older the mother. Could it be that the like-

lihood of bearing a child with Down's Syndrome associated more with the mother's age than the birth rank. The answer proved to be yes. The old hypothesis was superseded and research shifted to the biology of the aging ovary.

Several years later, epidemiologists returned to this issue to test whether they had missed the real association. The older the mother, the older the father. Could it be? The answer was yes and no. The likelihood of bearing a child with Down's Syndrome was associated with both maternal and paternal age. The old hypothesis was superseded and research shifted yet again.

That is the scientific method. We learn from the old hypotheses and the old false starts and we move on. Today no one would consider studies of the microenvironment of the multiparous uterus as relevant to the pathogenesis of Down's. For 60 years, science has sought associations between physical demands of tasks and the likelihood of suffering——

Senator SPECTER. Which paragraph are you on now?

Dr. HADLER. That is the direct answer. The physical demands of task and the likelihood of suffering disabling regional back pain. For 30 years, there have been parallel studies between physical demands of tasks and disabling arm pain.

Associations have been found, but they are inconsistent and weak. There were hints 30 years ago, but science has really risen to the challenge in the past decade, the challenge of asking whether a more important association was being ignored.

A number of cross-sectional and longitudinal studies have attempted to probe for associations between disabling regional back or arm pain and aspects of both, the physical content of tasks and the psychosocial context of work.

The result of these multivariate studies is that the associations with the wide range of physical content of tasks that has been studied are weaker and even more inconsistent. The associations with the psychosocial context of work are also weak but they are more consistent and generally subsume the associations with the physical content of tasks.

I could belabor this new literature. It deserves scrutiny. However, I cannot applaud the insistence on relying on the older literature in the systematic reviews that are promulgated by NIOSH and the NRC and Dr. Punnett in her statement.

Any study that considers only the association between the physical demands of tasks and likelihood of a disabling regional musculoskeletal disorder is out of date, even if it is ongoing or proposed. The state-of-the-science has moved beyond the testing of that hypothesis to newer hypotheses that promise to be more informative.

That is my direct answer, sir. Can I elaborate on it? Because I had planned to.

Senator SPECTER. I do not know whether it is possible to elaborate on it.

I have just been reading the six paragraphs and I would have to study and dissect it to understand it. Dr. Punnett, there are two questions for you. First, did you understand the analogy to Down's Syndrome?

Dr. PUNNETT. Well, Senator, I think what Dr.——

Senator SPECTER. I have not asked the second question yet. But go ahead.

Dr. PUNNETT. I think I guess the very short answer is I think I might have understood it.

Senator SPECTER. Well, when Dr. Hadler disagrees with your conclusion of muscular pain proportionate to physical work, I am going to have to study his statement so that I can understand his reasoning on it.

Dr. HADLER. Can I illustrate with an example?

Senator SPECTER. No. No. You cannot. All right. Go ahead.

Dr. HADLER. Let me tell you briefly about two small area analyses, since they are very easy to follow. There are large companies that have multiple work sites, each with similar facilities and similar demographics of the workforce. The incidence of disabling back or arm pain varies from site to site, sometimes dramatically.

That offers the opportunity to explore whether measurable differences in task content, demographics, or psychosocial context associate best with the variability in the incidence of the disabling regional disorders.

Independently, investigators from NIOSH and myself perform such a small area analysis in U.S. West directory assistance operators. Neither NIOSH nor I could explain the site-to-site variability in the incidence of disabling arm pain by any aspect of the content of the task.

However, multiple aspects of the psychosocial context of the work did associate: Fear of redundancy, work pressure, lack of decision authority, to mention a few.

Dr. MIRER. That will go over real well in Flint.

Senator SPECTER. Well, I have the statement and I am going to have to study it candidly to understand it.

Dr. PUNNETT. Senator Specter, could I just elaborate a little bit on my earlier very quick response?

Senator SPECTER. Just a little bit.

Dr. PUNNETT. I believe that what Dr. Hadler was trying to say was that he thinks that the hypothesis regarding physical load factors is out of date. He just actually cited a rather old study himself.

But I think that the reviewing process which has gone on in the scientific peer-reviewed literature, Dutch reviewers, British reviewers, German reviewers, Japanese investigators really are increasingly coming together very much in line with the NAS conclusions. And the evidence is in fact that even taking account of psychosocial factors, the evidence in favor of physical load factors is consistent and continues to be strong.

Senator SPECTER. Dr. Bigos, have you had an opportunity to examine this report that Dr. Barondess referred to?

Dr. BIGOS. Yes, I have.

Senator SPECTER. And Dr. Barondess articulated the issue better than I had, which would not necessarily take a whole lot, when he said it adds incremental risk. So it is not a causative factor but an incremental factor. Do you disagree with that?

Dr. BIGOS. I think that the data is not strong enough to make that particular association in a way that we can act on it specifically. I think incremental risk is kind of like cardiovascular dis-

ease. It is a U-shaped phenomena that we see all throughout the physical aspects of nature.

That is, people who do not and people who do participate in something seem to do poorer than people who do things in moderation, whether it be exercise or alcohol as we are finding out.

What I would like to talk about a little bit is the science because that is what this session is about. And if I could just have a second, I think that I can make clearer——

Senator SPECTER. Well, if you would be brief. We have two more panels and it is 11:35.

Dr. BIGOS. No problem. I chaired the HCPR guideline panel for back problems. That was under the direction of the U.S. Department of Health and Human Services. Because of the recent Dopper decision at that time, we decided we had to do it not on consensus or opinions but based on the actual data that was available in the literature.

We went through a methodologic process of more than 10,000 abstracts and 4,600 studies putting them on paper so that you could solve for *x*; better, no better, the same, with different aspects.

The long and short of it is we also applied that within the same process to the occupational literature as it relates to back problems. The conclusions are that we found no evidence in the reliable literature, not the literature that gives you a hint that something might be there but the reliable literature that lets you act.

Senator SPECTER. How did you determine what was reliable? A little bit of subjective determination there?

Dr. BIGOS. No, sir. I refer to Holly and Cummings who basically have laid out there are certain studies that provide you with evidence because you have looked at clues. There are certain studies that only provide you with clues.

Retrospective cross-sectional studies provide you with clues that have to be studied to see if the clues are correct. Standing on top of a building and doing a 360 in Kansas would lead you to the determination that the world is flat. But you have to have a better measuring tool and it has to be subjected to some scientific rigor.

Senator SPECTER. Dr. Bigos, do you disagree with what Dr. Barondess said also, that there is, well, I know the answer to this but I will ask it anyway, scientific basis for intervention?

Dr. BIGOS. I thought I saw that there was a call for more research because we didn't have enough information to be able to be specific, especially on the back pain——

Senator SPECTER. Did I quote you incorrectly, Dr. Barondess? You said there was a scientific basis for intervention?

Dr. BARONDESS. I did say that.

Dr. BIGOS. I think that was for the upper extremity. I do not think it was there for the back, was it?

Dr. BARONDESS. Yes, it was. In fact it is stronger for the back.

Senator SPECTER. Dr. Barondess, when you say it is a 1 percent issue on the gross national product, I want to be sure I have got my zeroes in order here, on a $10 trillion gross domestic product, that would be $100 billion in losses?

Dr. BARONDESS. There have been estimates that high, Senator. Actually, I wrestled with the zeroes myself and was operating from

a smaller estimate of the gross domestic product when these figures were put together.

Senator SPECTER. What estimate were you working on?

Dr. BARONDESS. $5 trillion.

Senator SPECTER. $5 trillion. Looks like the tax cut is going to have to be reduced then.

Dr. BARONDESS. That is the difference between a scientist and an economist. We are here to help.

Senator SPECTER. This hearing I think has reached a new milestone in very heavy competition on disagreement. The economists go over the gross national product and the tax cut and the surplus and cannot agree on anything. And notwithstanding Dr. Punnett's testimony, I think witnesses today have agreed on less.

I guess that is impossible but that is the way it seems to me listening. Dr. Barondess, do you have a formula beyond your conclusions on adding incremental risk and a scientific basis for intervention as to what the intervention ought to be and how you ought to tackle these various lines?

Dr. BARONDESS. Yes, sir. This is complex territory and the committee's view is that multiple interventions need to be applied when interventions are applied. They need to include not alone efforts to ameliorate physical load but need to involve also the workforce in their design, need to involve a commitment from management, need to have something to do with administrative alterations as well as mechanical alterations.

When Dr. Hadler says something about physical factors as exclusive causes, that is not at all the conclusion the group came to. And I agree with him that psychosocial factors are extremely important. As I said earlier, humans are complex and reactive on a number of levels.

Senator SPECTER. Thank you all very much. We are going to move to Panel 4, Cost Benefits and Feasibility of Ergonomic Programs. Mr. Dean Sparlin, Dr. Burton, Dr. Derebery, Mr. David Alexander, Mr. Eric Frumin and Mr. Doug Bonacum.

Let me start with you, Mr. Sparlin, if we may. And thank you for joining us and look forward to your testimony.

STATEMENT OF DEAN SPARLIN, ESQ., GIBSON, DUNN & CRUTCHER, LLP

Mr. SPARLIN. Thank you, Mr. Chairman. We are here today to discuss economic issues with six panelists, none of whom is an economist. I am a lawyer having represented clients in safety and health matters during more than 14 years of practice.

The reason we do not have an economist here is that we have not reached the point where one would be useful. So far we have had a battle between big numbers and mind-numbingly huges ones.

OSHA told us last year that its ergonomic standard would cost $4.5 billion per year. Employers countered with cost estimates exceeding $100 billion. Any disagreement of that magnitude has to be more than mathematics.

What we have here is a basic different vision between the two sides. The key to resolving that difference is a clear understanding

of what a standard would entail, educated by OSHA's own history of enforcing similar requirements.

With all due respect, I do not believe that testimonials from ergonomists and safety and health personnel provide the answer. These individuals work on ergonomics programs all the time and they freely offer reports of their success.

The extent to which these claims represent hard facts as opposed to salesmanship from people who make their living promoting ergonomics is open to debate, but that debate is largely academic.

The question is not what employers spend on ergonomics under the status quo, but what they would be forced to spend under a standard that would change the status quo.

My distinguished co-panelist, David Alexander, is an articulate and passionate proponent of the mantra that ergonomic controls are inexpensive. He has written numerous books that promote the cost justification of ergonomics. And he testified at the hearing that ergonomic interventions almost always pay for themselves by ratios approaching 10 to 1.

His views and similar opinions from two other ergonomic consultants were the sole basis for OSHA's cost estimate. OSHA's role, however, is not to tell employers how to improve productivity and save money but to protect safety and health.

If those two goals were as closely aligned as some like to claim, then a standard would be unnecessary because employers would be rushing to get their 10-to-1 pay backs.

But more than a decade of OSHA ergonomics activity pursued on the advice of many of these same ergonomists, paints a very different picture. There is a reason employers are almost universally resisting OSHA regulation. And that reason is not ignorance of economic benefits. It is the reality of what an ergonomic standard would entail.

This stack of paper beside me, which is very high, is just a partial compilation of more than 550 ergonomic citation issued under the so-called General Duty Clause. Each of these citations lists measures that OSHA believed to be necessary abatements of alleged recognized hazards.

Over and over again, OSHA sought burdensome and costly job controls such as the ones you see on the board that was just posted. When employers argued that these citations should be used as a measure to measure a final standards cost, OSHA could not have backpedaled any faster.

OSHA claimed that its new standard would not necessarily be enforced in the same way, even though the standard described what was expected in language that was basically indistinguishable from the citations. All the while, OSHA refused to reveal exactly what its new enforcement policy would be.

The agency also asserted that the abatements were merely recommendations. But the one employer who actually litigated in favor of a less expensive alternative was greeted with a parade of OSHA experts insisting on the listed measures.

The reason OSHA is so afraid of its own history is that the cost of these measures are an entirely different universe. Many employers use these same citations to produce their own cost estimates which added up to more than $179 billion. Taking into account the

employers who were not even represented, the projection of more than $100 billion in total costs is not at all unreasonable.

Now, if OSHA decides to try again, regardless of its chosen approach, it will need to do a far better job of confronting the most fundamental question in any cost analysis.

What does the standard actually require. In the last round, OSHA's entire estimate of cost per job control was developed before the proposed standard was even drafted. And that estimate was never revisited even after major changes in the final standard.

Now, I will not repeat OSHA's mistake of estimating a new standards cost before I have seen the new standard. But I will tell you that any future cost analysis must begin from a very different base line.

PREPARED STATEMENT

OSHA should either use its own enforcement history as a guide or should identify exactly what is different about the new approach. If the agency continues to ignore its own history, it will be doomed to repeat it, once again producing cost estimates that seriously misrepresent reality.

[The statement follows:]

PREPARED STATEMENT OF DEAN SPARLIN

Mr. Chairman and members of the Subcommittee: We are here today to discuss the economics of an ergonomics standard with an engineer, a health and safety director, a spine surgeon, and a lawyer. I am the lawyer, having represented clients in occupational safety and health matters, including ergonomics, during more than 14 years of practice with Gibson, Dunn & Crutcher LLP.

The economic discussion to date has been characterized by a battle between big numbers and mind-numbingly huge ones. OSHA told us last year that its ergonomic standard would cost $4.5 billion per year but would save approximately twice that amount. Employers countered with analyses showing that costs could easily exceed $100 billion. When there is a disagreement of that magnitude, it is safe to say that the discrepancy is more than mathematical. There is a very basic difference in vision between the two sides performing the calculations.

That, more than anything, explains why it is just as well that an economist is not here to address these issues. Before anyone can opine on the economic impact of a standard, there must be a clear understanding as to what the standard would entail. The key to that question lies not in economic theory, but in a practical understanding of burdens that would be imposed in light of OSHA's own history of enforcing similar requirements.

With all due respect, I do not believe that testimonials from ergonomists and safety and health personnel provide an appropriate perspective. It is true that these individuals work together on ergonomics programs all the time, and they freely offer reports of their successes. The extent to which these claims represent hard facts, as opposed to salesmanship from people who make their living promoting ergonomic interventions, is open to debate—but that debate is largely academic. The question before us is not what employers spend on ergonomics under the status quo, but what they would be forced to spend under a standard that presumably would change the status quo.

My distinguished co-panelist, David Alexander, is an articulate and passionate proponent of the mantra that ergonomic controls are inexpensive. He has written numerous books on the subject, including one entitled Selling Ergonomics To Management, which teaches readers how to convince skeptical bosses to sign off on ergonomics programs. He testified at the hearing that ergonomic interventions almost always pay for themselves, by ratios that in his opinion can exceed 10 to 1.[1] He supported that view with descriptions of his experience advising clients and anecdotes he has heard from colleagues in his profession. His views, and similar

[1] Transcript, Mar. 20, 2000, at 2183.

opinions from just two other ergonomic consultants, were the sole basis for OSHA's cost estimate.

It is not OSHA's role, however, to tell employers how to improve productivity and save money. OSHA's role is to protect safety and health. If the agency's safety and health vision were as closely aligned with productivity as some like to claim, then a standard would be unnecessary because employers would voluntarily rush to get their 10-to-1 paybacks. But more than a decade of OSHA ergonomics activity, pursued on the advice of the same ergonomists who testified in favor of a standard, paints a very different picture. There is a reason employers are almost universally resisting OSHA regulation, and that reason is not ignorance of the economic benefits. It is the reality of what an ergonomics standard would entail.

The impressive stack of paper beside me is just a partial compilation of more than 550 ergonomics citations that OSHA has issued under the so-called "general duty clause." Each of these citations lists measures that OSHA believed to be necessary abatements of alleged "recognized hazards." Most of these recommendations never show up on ergonomists' lists of "inexpensive" controls. Over and over again, OSHA compliance officers cited safety and health concerns as a justification for slowing work pace, mandating rest breaks, adding expensive hoists or automated devices, and micro-managing work processes.

When employers argued during the rulemaking that these citations should be used to measure a final standard's cost, OSHA could not have backpedaled any faster. OSHA claimed that a standard would not necessarily be enforced the same way, even though the standard described what was expected of employers in language that was basically indistinguishable from the citations. All the while, OSHA refused to discuss exactly what its new enforcement policy would be. The agency also asserted that the abatements were mere recommendations from which employers could vary. But the one employer who actually litigated in favor of a less expensive alternative approach in response to a general duty clause citation—Pepperidge Farm—was greeted with a parade of OSHA experts insisting that the agency's "recommendations" were gospel.

The reason OSHA is so afraid of these general duty clause citations is not hard to figure out. The costs they entail are in an entirely different universe from OSHA's official estimate. Abatement measures from these citations formed the essence of many employer estimates submitted during the hearings, which added up to more than $179 billion in anticipated costs. There is some overlap in the employer estimates and some differences in their assumptions, but it is also true that a very large portion of affected industry is not represented. It is not at all unreasonable to expect, in light of this evidence, that costs could exceed $100 billion—perhaps by a very wide margin.

Theoretically, OSHA could design a new standard or guideline—assuming appropriate scientific support—that meaningfully departs from past general duty clause excesses. This, however, will require more than hollow assurances that enforcement will concentrate on inexpensive remedies. Unfortunately, it is extraordinarily difficult to draft concrete limitations that would enforceably confine control obligations. Certainly the proposed standard's vague language does not meet this objective. Nor does the final standard, whose "action triggers" and "hazard identification tools" serve primarily to underscore just how far OSHA expected employers to go in retooling their workplaces.

If OSHA does decide to try again, regardless of its chosen approach, it will need to do a far better job of confronting the most fundamental question in any cost analysis: What does the standard actually require? In the last round, OSHA's entire estimate of cost per job control was developed before the proposed standard was drafted—by individuals who afterwards could still not describe the standard's provisions. The estimate was never revisited, even after major changes in the final standard.

I will not repeat the mistake of estimating a new standard's cost before I have seen it. But I will tell you that any future cost analysis must begin from a different baseline. OSHA should either use its own enforcement history as a guide or should identify exactly what is different about the new approach. If the agency continues to ignore its own history, it will be doomed to repeat it, once again producing cost estimates that seriously misrepresent the true picture.

Senator SPECTER. Thank you very much, Mr. Sparlin. Mr. David Alexander, certified professional ergonomist.

STATEMENT OF DAVID C. ALEXANDER, PRESIDENT, AUBURN ENGINEERS, INC.

Mr. ALEXANDER. Thank you very much. Good morning. I welcome the opportunity to join the panel and share my experience on ergonomics. My name is David Alexander. I am president of Auburn Engineers, a leading applied ergonomics consulting company.

My 25 years of private sector ergonomics experience spans a range from small employers to the largest companies in the world. I want to address the feasibility of ergonomic solutions and the cost benefits of their interventions.

It has been widely stated that ergonomic problems are not solvable or that the solutions are simply too expensive. That information is wrong. With 25 years of professional experience, I have yet to see a job that could not be improved with the application of ergonomic principles.

I personally developed thousands of solutions to ergonomic problems and my colleagues have told me of many more. The solutions range from simple workplace changes to complex factory redesigns. For window and door manufacture I was able to reduce ergonomic risk factors by 90 percent while increasing productivity by 300 percent. For chemical manufacture I was able to reduce ergonomic risks by 80 percent while increasing productivity by 50 percent. For an auto components manufacture I reduced loss time by 80 percent while saving a million dollars in operating cost. For a telecommunications company, reduced lost time cases by 80 percent and demonstrated productivity savings as high as 15 percent. These ergonomic projects, while notable, are not uncommon. Similar results have been reported by other practicing ergonomists.

The practice of ergonomics is not limited to experts, however. Many organizations are using employee teams to resolve problems and necessarily this drives the cost down rapidly. Fifty percent of ergonomic problems in my opinion can be solved locally using local resources and local workers and their supervisors.

Many trade associations have developed solution databases for ergonomic problems. They've shared these widely. I've participated and worked with those in textiles, apparel, food distribution, paper chemicals, petroleum, and I know other industries have done the same.

These guidelines get passed from plant to plant. They become more refined, they become more effective and they become cheaper to implement, thus some of the cost from yesteryear do not reflect the cost of tomorrow.

There are thousands and thousands of good examples of interventions out there. OSHA has developed lists of these and shared them, as have insurance companies and many universities. In summary, I find that ergonomic problems are typically easy to identify and rarely require sophisticated techniques to resolve. I have a promotional poster, if I could put that up, that illustrates a simple case of ergonomics. It involves some visiting dignitaries we White House during the last Bush administration as a story. Could you put the—it is a cartoon poster, I am sorry.

As the story unfolds, several shorter dignitaries have difficulty speaking from a podium adjusted for a much taller President Bush. After several near falls, this team of ergonauts uses our simple

problem solving process to develop a cost-effective solution to the problem. As the story illustrates, ergonomics works.

Now, let me turn to the topic the cost benefits. Cost of a dollar spent to implement solutions, benefits were the savings that the organization achieves. The benefits are attained by controlling worker injuries and saving the dollars currently being lost from medical treatment, workers compensation, lost time, replacement workers, overtime, lost production, reduced quality.

All of these have benefits or a number of these have been outlined by OSHA. But that is not the whole story. There are substantial benefits which are not reflected by the OSHA cost calculations. These are the business level improvements that typically result from ergonomic projects. Mr. Sparlin referred to these.

Here gains can be made that increase the operating performance above baseline performance and these are substantial, in some cases approaching ten times the cost. A common problem with cost calculations is under-reporting. People do not do a good job. Common problem with benefits is under-reporting. We do not calculate those well. In one case in the printing industry we were able to document ten times more benefits than what had been initially perceived.

Project costs are frequently inflated. Overdesign is a common problem with an emerging industry and that is what it is with ergonomics. As we gain more experience, cost go down. I also find that some industries have not modernized. They are using out of date processes and unfortunately they lump the cost of modernization along with the cost of ergonomic compliance, thus grossly inflating prices.

PREPARED STATEMENT

When we look at ergonomics, we have to recognize that costs will drop as experience goes on. I've chaired in a flight ergonomics——

Senator SPECTER. Mr. Alexander, your time is up. If you would summarize your full statement, it will be made a part of the record.

Mr. ALEXANDER. Thank you very much. Ergonomics works. Good ergonomics is good business.

[The statement follows:]

PREPARED STATEMENT OF DAVID C. ALEXANDER

CREDENTIALS AND QUALIFICATIONS

Good morning. My name is David Alexander. I have been practicing ergonomics in the private sector for over a quarter of a century. I hold two degrees in engineering, the second a Masters degree with a specialty in ergonomics. I have continued my professional development throughout my career with extensive academic work, short courses, conferences, peer discussions, and professional exchanges.

I am licensed to practice engineering as a registered Professional Engineer in Alabama and Tennessee, and have been for more than two decades. Furthermore, I have authored many questions on ergonomics used to test professional engineering candidates. The exam is required for registration as a Professional Engineer.

I am a Certified Professional Ergonomist, and have been for many years. For the past 4 years, I have served as an officer on and member of the Board of Certification in Professional Ergonomics (BCPE). I assist with the CPE test development process, and have worked to increase the number of Certified Professional Ergonomists in the United States and the world. I am currently Vice-President of BCPE.

My peers in the field of industrial ergonomics have recognized me as one of their outstanding practitioners. I received the Ergonomics Award from the IIE in 1986. I was awarded Fellow status in the Institute of Industrial Engineers in 1990. I re-

ceived the Industrial Ergonomics Award from the Industrial Ergonomics Technical Group of the Human Factors and Ergonomics Society in 1993. I am the only ergonomics professional to be recognized by both of these two leading professional societies.

I hold two patents for the design of ergonomics inventions. The first is a revolutionary new tool handle design, and the second is for an ergonomically designed piece of equipment used for decorating cakes and other baked goods.

I speak routinely on ergonomics and its application in industry. I have been invited to speak for groups in engineering, health care, safety, health, legal and all other professions related to ergonomics. My presentations have included invited keynote speeches as well of papers, workshops and tutorials. I have taught thousands of people my techniques and practices.

Currently, I am President of Auburn Engineers, Inc., an ergonomics consulting company. I have many Fortune 100 companies as clients. My staff and I provide a wide range of ergonomics services and have since 1988. During my tenure in ergonomics, I have worked with many organizations, both large and small, representing many different industries. I have worked with labor unions and with management, with safety and health professionals, with engineers and health care practitioners, with production workers and their supervision.

Prior to my work with Auburn Engineers, Inc., I was an engineer, an ergonomist, and an ergonomics program manager for Eastman Kodak Company, and performed hundreds of ergonomics projects in all facets of their operations.

During my quarter century of professional ergonomics practice, I have worked in many different industries. A listing of recent clients includes: Chemicals, Forest Products, Petroleum, Food Production, Health Care, Medical Equipment, Hospitality, Government, Food Service, Electronics, Plastics, Aerospace, Paper and Pulp, Metals Refining, Distribution and Delivery, Printing, Auto Assembly, Metal Processing, Consumer Products, Telecommunications, Missiles and Space, Textiles, Apparel, Appliances, Auto Parts, and Mining. Over the years, I have worked with more industries, provided training for their staffs, visited and toured others, and have spoken with ergonomists and engineers from yet even more.

DOES ERGONOMICS WORK?

During my years of experience with ergonomics, I have yet to find a job that cannot be improved with the application of ergonomics principles. I would like to share some examples of the outcomes of ergonomics when it is applied in business:

—This company builds automotive equipment for a major auto assembly manufacturer. It must provide components in a just-in-time environment to an assembly plant a few miles away. We were initially identified as a source of assistance by a state agency whose mission it is to help state manufacturers that are in distress or are having significant problems with productivity, environment, safety or other major issues. This company employs approximately 300 people at this site. When we were first introduced to this company, they told us that their injury rate was overwhelming, that their costs from these injuries were approaching $1,000,000 annually, and that they felt an OSHA citation was possible since OSHA was investigating other issues at the plant. We worked collaboratively with them to plan, then implement, an effective ergonomics program. The work included identification of jobs with risks, development and implementation of engineering and administrative controls, training, and the use of job hazard analysis for all jobs. Within a 6-month period, there was an 83-percent reduction in workers compensation costs, and a drop in the OSHA recordable rate from over 50 to less than 4. There was also a 100-percent placement of workers with restrictions into normal production jobs with no "make work" jobs being performed. This company was recently awarded the PACE award in the automotive industry for innovation management practice. So not only have they made substantial gains in business performance, they have been recognized by their peers for this accomplishment and the way in which it was made.

—This company produces wood products in the mid-West, and had a significant ergonomics problem. We helped reduce their compensation costs from over $720,000 per year to $25,000 per year, and dropped their injury rate from 180 per year to less than 5 per year. We did this with a combination of engineering and administrative controls, training, management support, and other ergonomics program measures.

—This company produces pre-hung doors and windows. It was experiencing excessive back injuries from manually handling the doors and from poor work positions. We reviewed their jobs, and developed a number of job enhancements in-

cluding supported tools, better work tables, guides and fixtures, and a new conveyor line. When we were done, the result was a 300 percent increase in productivity and a 90-percent reduction in ergonomics risk. The plant was now able to produce 900 doors rather than 300 doors per shift with no additional personnel.

—On a chemical bag filling operation, we were asked to provide improvements for a bag filling and sealing operation. We did a careful analysis and made recommendations that permitted a 50-percent increase in productivity along with an 82-percent reduction in ergonomics risk. The number of bags that could be filled went from 960 per shift to 1,400. The changes included an alternate method of moving bags on a conveyor, changing work heights, and altering the methods of feeding bags into a heat sealer.

I share these with you because they make the point I wish to leave with you—Ergonomics works!

There are hundreds and thousands of successful ergonomics interventions out there. Ergonomics works, and works well. These successes range from simple changes to work methods to complete reorganizations of factories and workplaces. Many of these successes can be found by talking with practitioners in industry and business, or by reviewing the many case studies found in the scientific and trade press publications.

WHAT ARE THE TANGIBLE BENEFITS TO THE APPLICATION OF ERGONOMICS?

To answer this question, it is helpful to understand the types of benefits one can expect from ergonomics applications. They fall into several categories: avoided costs, and performance improvements.

Avoided costs begin with the avoidance of direct injury/illness costs by controlling or eliminating the injury/illness. As this occurs, then one also avoids the indirect costs of injury/illness such as replacement workers, the manufacture of off-quality products, time for the investigation of incidents, implementation of necessary corrective actions, and so on. Essentially these are unplanned losses, or costs, or expenses, which take profits away from the bottom line of the organization.

Besides avoiding losses, there is a great opportunity to achieve performance improvements. Performance improvements occur when ergonomics improvements permit one to achieve breakthrough performance that exceeds the current baseline. These improvements are most often reflected as traditional business measurements such as enhanced productivity, less downtime, product quality, delivery, fewer bottlenecks, and so on. They may also include lower costs for workers' training or employment as jobs become less stressful. The best way to think of these items is that they improve upon your expected level of operation and permit you to operate better than planned. The result is increased profits to the business.

Ergonomics benefits are measured in at least 17 different ways, according to my research, but one of the most common is benefit/cost ratios. These calculate a ratio of the benefits associated with an ergonomics project relative to the costs required for implementing the project. The benefit/cost ratio should be greater than 1.0 for an economical, value added project. The benefit/cost ratio can be impacted in two ways: one, increase the level of benefits for the project, or, two, decreases the costs associated with the project.

The benefits can be increased by identifying and reporting more benefits (a common problem with cost justification is that economic benefits are chronically underreported). The costs can be reduced by lowering the cost of the project, perhaps by using administrative controls or with less sophisticated engineering controls.

The cost of ergonomics projects is highly variable. Solutions range from low cost administrative controls (work methods, job redesign) to very expensive mechanical equipment. Often, for a single set of risk factors, as many as 5–10 different solutions can be developed and implemented. The choice of the solution has a great impact on the overall cost of the project. For many projects that report high costs, the problem is that an overly expensive solution has been chosen, when in fact, a lower cost solution would work just as well.

In my work, I found that about half of the ergonomics projects cost less than $500, and can be done on a standard work order without the need for detailed justification. And only a third of the projects cost more than $1,000. In other words, an ergonomics project is likely (two times out of three) to cost less than $1,000, and usually can fit within most operating budgets. Hugh budgets for the implementation of widely expensive ergonomics program simply do not occur.

At the request of one of our clients, we examined these benefits with the goal of developing "multipliers" which could be used to determine the value of the benefits relative to workers compensation costs. For ergonomics, the benefits multiplier was

found to be from 0.5 to 2.0 for the ratio of direct to indirect costs. We also looked at the benefits attained from improved performance, and found them to be very large. This multiplier was found to range from 2 to 10 times the cost of workers compensation.

One real opportunity, and one that is commonly overlooked, is the savings that can occur from better design practices. We have measured the costs associated with design for ergonomics, and find them to be a highly attractive investment. In fact, this is how we characterize these costs. They are an investment in the design, which should provide a payback later on. The cost of design goes up substantially as the project progresses. The difference between "doing it right the first time" at the initial design stage and waiting until injuries occur during normal operations, is tenfold. The costs will be ten times higher when retrofits are utilized rather than having ergonomics designed in from the start. Similar figures have been reported by others practitioners, especially those in the auto industry. What this means is that costs for ergonomics interventions for current operations cannot and should not be extrapolated into the future. When workplaces, tools, equipment, vehicles, assembly lines, and factories are designed properly from the start, the ergonomics costs should be one-tenth of the current estimates.

TRENDS IN APPLIED ERGONOMICS

I founded the Applied Ergonomics Conference Series and last month we held our 4th Annual Conference, with almost 800 people in attendance. They represented industry and business from virtually every employment sector, as well as organized labor, trade and professional groups, and government. We heard 100 presentations on ergonomics programs and interventions.

There is widespread use of ergonomics in the private sector for both injury/illness control and business performance improvements. During the four conferences I have chaired since 1998, we have had some 300 presentations on successful applications of ergonomics, dozens of workshops and seminars, and keynote speakers from industry, labor and government. Many of these presentations are documented in our printed volumes of ergonomics case studies, and more recently in electronic form on the internet.

And we have had 2,500 attendees representing virtually every state in the union, our NAFTA partners Mexico and Canada, and a number of European countries. The attendees represent 500 companies, universities and Federal and State governments.

The Applied Ergonomics Conferences have been sponsored by a diverse list of professional organizations and agencies including:

—Institute of Industrial Engineers
—Department of Labor Occupational Health & Safety Administration
—National Institute for Occupational Safety and Health
—American Association of Occupational Health Nurses
—American Industrial Hygiene Association
—American Society of Safety Engineers
—Association of Canadian Ergonomists/L'Association Canadienne d'Ergonomie (ACE)
—Board of Certified Safety Professionals
—Board of Certification in Professional Ergonomics
—Ergonomic Assist Systems and Equipment—a product council of Material Handling Industry of America
—International Labour Organization
—Risk and Insurance Management Society
—Society for Risk Analysis
—Society for Work Science
—Voluntary Protection Programs Participants' Association

At these conferences, I have been able to listen to many presentations and to talk with dozens of participants about their on-going work on ergonomics. I found the following trends:

—Ergonomics is being applied in increasingly diverse settings. We have examples of ergonomics in food distribution, health care, government, petroleum, meatpacking, retail, construction, agriculture, distribution, and other industries.
—More and more people are involved with the application of ergonomics. We have many examples of shop-floor teams, most including supervision or staff, but some with just production workers. There is normally involvement with nurses and health care providers for root cause determination, and with maintenance and engineering for equipment alteration.

—There are many examples of shop floor improvements leading to injury/illness reduction and to productivity and quality improvements. Most teams will report benefits for both safety and health, and for productivity or quality.
—Training is becoming more commonplace and less burdensome. Some teams develop skills with a few hours of training, and then are ready to develop and implement successful ergonomics improvements.
—There is extensive sharing of solution ideas. This sharing is occurring within companies, within industries, and even across industry sectors.
—There is a clear trend toward the use of design to prevent problems rather than just to fix problems. Several major auto manufacturer touted their successful work in the design of manufacturing cells, production lines, and even in vehicle design in order to prevent ergonomics injuries and illnesses before they occur. A couple of important points about this:
  —They use risk factors as their guide, not injuries. This indicates a high level of maturity with the surveillance and ergonomics problem identification part of their programs.
  —They do this design work for business reasons. Ergonomics is good business, and it is economical to spend millions of dollars in this way. For a new model change-over, the costs may run into the millions of dollars, yet create savings equal to 10 times that number.
  —They report that the majority of these changes result in other positive business improvements like productivity (77 percent of the time), quality (50 percent of the time) and reduced vehicle weight (10–15 percent of the time).
—Many who originally opposed ergonomics now support it! There are many examples of companies who came to learn about ergonomics from an OSHA citation, but who now tout its benefits. Originally, they bemoaned ergonomics as a burden to their business and unnecessary for the protection of their workers. How time and experience can dramatically alter one's viewpoint.

IF YOU GO FORWARD

I have worked with industry for many years, and I find that ergonomics programs are more effective when they include the following:
—Involve employees in solving ergonomics problems. Ergonomics solutions are not usually difficult to identify. In my experience, 50 percent can be handled at the worker/supervisor level, and most of the others are resolved with an in-plant team.
—Use trade groups, sister plants and other organizations to both identify and resolve ergonomics problems.
—Have a sound health care program and treat injuries both quickly and with respect.
—Have management leadership on ergonomics, just like it provides leadership on safety, health, production and quality issues.
—Provide training where necessary to ensure effective performance. JHAs are necessary in modern industry.
—Prevent ergonomics problems by reviewing new jobs, tools, and equipment.
—Review the ergonomics program to ensure its effectiveness.

There are clear differences between effective programs and ineffective ones. Effective programs contain certain elements and work in certain ways.

IN CLOSING

Finally, in closing, let me say that ergonomics is tool that is already used in industry. It is not a new tool, it is not difficult to use, and it is not burdensome. It is part of continuous improvement programs used in many organizations to improve safety and health, quality, productivity, and cost.

Thank you for your attention. I look forward to providing additional clarification with your questions and on-going deliberation on ergonomics.

Senator SPECTER. Thank you. We turn now to Mr. Eric Frumin, director of Safety and Health, Union of Needle Trades, Industrial and Textile Employees Mr. Frumin.

STATEMENT OF ERIC FRUMIN, DIRECTOR, SAFETY AND HEALTH, UNION OF NEEDLE TRADES INDUSTRIAL AND TEXTILE EMPLOYEES

Mr. FRUMIN. Good morning, Senator. First I just want to submit for the record a slightly corrected version of the written testimony I submitted.

Senator SPECTER. It will be made a part of the record in full.

My name is Eric Frumin. I am the health and safety director of UNITE. On behalf of our members in Pennsylvania and Philadelphia and throughout the Nation, we very much appreciate the opportunity to testify here today.

The arguments about costs and benefits have generated much sound and fury and from some quarters like Mr. Alexander, actual enlightenment. From other quarters, however, there's been nothing but fury and active disinformation. Today UNITE is confident in stating the following. First, the cost of these injuries are huge to employers, workers and taxpayers alike.

Second, the requirements of the OSHA ergonomic standard are eminently feasible. The potential cost of those requirements are sensible in business investments, and the benefits of ergonomic programs to workers, employers and society are substantial.

The arguments you have heard today and before about the feasibility, costs and benefits have degenerated into a virtual warfare and as the saying goes, the first casualty of war is the truth. It is been obstructed, the argument, has by what we would call a big lie campaign orchestrated by the most rabid opponents of reasonable worker safety rules who misled and frightened employers large and small.

The Stanley company, as you know, is one of the nations largest makers of tools. Their sales of ergonomically designed tools depend heavily on employer confidence that ergonomics works. But as one of their senior managers told Business Week magazine, we're competing against ignorance. How much do these injuries cost? As Dr. Barondess pointed out, between $45 and $54 billion annually, about 1 percent of the gross domestic product.

The cost of these injuries is the very reason why this Congress passed the Occupational Safety and Health Act. But actual industrial experience shows that ergonomics programs are technically feasible and are cost-effective and I want to take you, Senator, to Lewistown, Pennsylvania to the Leer Corporation.

Repeatedly before both the Senate Labor Committee and the OSHA rulemaking record local union officers have testified about the OSHA citation at that plant, about the benefits of the ergonomics program which the management implemented as a result of that citation. That citation and the program the employer implemented did exactly the same things that Mr. Sparlin is listing on his chart here this morning and I am curious why Mr. Sparlin hasn't pointed to the Leer Corporation. That company came out strongly in support of OSHA enforcement of the general duty clause and we know that that ergonomic injuries in that plant have been seriously reduced to virtually no disabling injuries anymore in that plant. And Senator, we would invite you to come and visit that plant.

The auto parts industry is highly competitive. Good jobs like this in central Pennsylvania are not easy to find. But the management and these workers have nothing to fear from ergonomics and everything to gain.

The OSHA rulemaking record is replete with examples like this from large and small employers alike. The Xerox Corporation submitted, Mr. Senator, a formal cost benefit analysis to the OSHA rulemaking record. They spent $3.4 million on the ergonomics program in 1999. They said the resulting savings was $7 million in that year for avoided workers compensation claims. These kinds of benefits are achievable throughout the economy and OSHA reviewed hundreds of studies and scientific evaluations and case studies which came to the same conclusion.

Senator SPECTER. What company was the last one you referred to?

Mr. FRUMIN. Xerox Corporation and that is in my prepared statement.

Unfortunately, Senator, with rare exception it appears that these and other well-meaning companies were not present at the OSHA hearing. They did not show up to testify. You've heard about the auto companies. Where were the Big Three companies at the OSHA hearings. Where were the individual grocery chains, where were the nursing homes? Seems like they were all in hiding to avoid admitting the truth about their actual investments in ergonomics and the returns that they enjoyed.

What OSHA did here instead largely with speculation about possible compliance problems but the testimony of one participant was most revealing, the United Parcel Service, the single most active employer never showed up at the hearing to testify. None of their managers came. Only later did OSHA receive a corporate memo from UPS, UPS corporate memo, March 10th, the year 2000, from the corporate industrial engineering department entitled Ergonomic Endeavors clearly identifies the capital investments and operating investments they've made to improve the ergonomics in their work force.

Never once did any of their representatives at that hearing provide this kind of information to OSHA or identify the cost that—the investments that UPS was making or the savings that UPS was enjoying. Why? We cannot answer for them. Maybe they can answer for themselves. But the real question to UPS and to the other employers who have opposed this in the way that they have, what are you now spending on it? Why don't you tell us what the truth is, how much are you saving and why are you making these investments.

PREPARED STATEMENT

Senator SPECTER. Mr. Frumin, your time has expired, your full statement will be made a part of the record so if you would now summarize, please.

Mr. FRUMIN. We have heard, and as Congress unfortunately has heard, a figure of $120 billion as the cost of this standard. We reject that as a total fabrication. We call upon the Congress to look at the findings of previous OSHA rulemaking such as the OTA, the Congressional Office of Technology Assessment has shown OSHA's

rulemakings to be feasible, to be economically achievable and we urge the Congress to immediately compel the Secretary to issue a new standard forthwith. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF ERIC FRUMIN

Good morning. Mr. Chairman, members of the Committee, my name is Eric Frumin. I am Health and Safety Director of the UNITE. I am also the chairman of the Advisory Committee on Occupational Safety and Health Statistics to the U.S. Bureau of Labor Statistics, and a member of the Board of Scientific Counselors to NIOSH.

I am here to address several key questions regarding the OSHA standard on ergonomics:

—the actual feasibility of the standard's requirements
—potential costs of those requirements, and
—likely benefits to employers, workers and society.

THE FIRST CASUALTY OF WAR IS THE TRUTH

I want to state initially, however, that as with the so-called debate about the underlying science of ergonomics, the discussion of feasibility, costs and benefits has been obstructed by a Big Lie campaign. This campaign was orchestrated by the most rabid opponents of reasonable worker safety rules, who misled and frightened employers large and small with their fabrications. This of course contributed to the misinformation feeding the Congressional debate earlier this year, and adds another unfortunate chapter at today's hearing.

This campaign of lies and distortion is truly shameful. Not only has it irreparably harmed OSHA's ability to issue cost-effective standards to prevent the biggest job-safety problem in the American economy. It has also sowed confusion and fear of essential preventive activities in the minds of America's managers and workers—the very people who must understand clearly that ergonomics works, that ergonomics both protects workers and saves money for employers and workers alike.

ACTUAL INDUSTRIAL EXPERIENCE SHOWS THAT ERGONOMICS PROGRAMS ARE TECHNICALLY FEASIBLE AND ARE COST-EFFECTIVE

On June 21, 1995, President Rick Treaster of UNITE Local Union 2400 from Lewistown, PA, testified before the Senate Committee on Labor and Human Resources. About OSHA's intervention at his plant—the Masland Co. auto carpet plant in (now owned by the Lear Corp.), which employs 200 workers. Mr. Treaster described in detail how OSHA's strict enforcement of the general duty clause for ergonomic hazards accomplished two things: first, it helped both the management and the workers focus on real solutions to a serious safety problem. And second, it prompted the company and the union to work together on new joint efforts to improve wages, quality and productivity. At that hearing, the management wrote to Chairman Kassebaum stressing its strong support for strict enforcement of OSHA rules.

Attached to my testimony are the actual numbers of worker injuries at the Lewistown, PA plant as of 1995.

During the OSHA rulemaking hearing on the proposed standard, Rick's successor Greg Wakefield testified again about the continuing success of the ergonomics program in the plant. Wakefield reported, as was confirmed by the management, that serious ergonomically-related injuries had been virtually eliminated in the plant due to an aggressive comprehensive program which virtually mirrored the core elements of the OSHA standard: worker education, early reporting, job interventions and when needed intensive job and equipment redesign. This resulted in substantially lower costs to the company, which accompanied substantial boosts in productivity and quality. The auto parts supply industry is highly competitive, and good jobs like these in central Pennsylvania are not easy to find. But this management, and these workers, have nothing to fear from ergonomics, and everything to gain.

Mr. Chairman, as is revealed in both OSHA's final standard and the testimony today of Dr. David Alexander, the OSHA rulemaking record is replete with similar examples from large and small companies alike.

One company—Xerox Corp.—actually submitted a formal cost-benefit analyses regarding its ergonomics program (Exh.#30–1963). According to Xerox, their total 1999 ergonomics program investment of $3.4 million yielded a

". . . resulting benefit . . . of more than a $7 million reduction in the annual cost of ergonomic-related workers compensation claims from the 1992 peak."

In other words, it shows that a corporate ergonomics program is a net cost-savings measure when accounting even if one relies solely on workers compensation costs. Moreover, such an analysis does not begin to take into account the many other ergo-related cost types (such as other disability and Human Resource costs, reduced productivity from poor job design, limited quality due to bad job engineering, etc.).

A few other industry groups, such as the textile and apparel industry associations, acknowledged that ergonomics programs were cost-effective and a necessary part of a competitive business strategy in today's economy.

Indeed, whenever anyone has looked seriously at actual industrial experience with ergonomic principles and interventions, for those few cases of failure or frustration there are many more cases of clear and cost-effective success.

This includes the hundreds of detailed case studies reported previously by corporate personnel, OSHA, NIOSH, labor unions and ergonomics consultants. Others were performed directly by OSHA's expert witnesses, including Dr. Alexander and others. These reports and studies were done at the most recognizable names in American industry: General Motors, Ford and Chrysler; Compaq Computer Co.; Allied Signal, Coca-Cola, Kellogg Foods, Nabisco, Proctor and Gamble, Scott Paper, and literally hundreds of other companies large and small.

Not surprisingly, in its Final Economic Analysis, OSHA specifically cited 7 examples from the rulemaking record of well-documented, cost-effective comprehensive ergonomics programs, including, Dow Chemical, Consolidated Edison, US Defense Department, and Levi Strauss, in addition to the company-specific programs in both large and small businesses provided by three labor unions in the auto, food and apparel sectors.

OSHA also cited in its Final Economic Analysis the large number of both scientifically-designed evaluations of ergonomic interventions and individual "case studies" on specific workplaces or occupations, some of which clearly identified the employers in question.

Some of the same hundreds of companies which were also undoubtedly included in the last-minute, biased survey by the Employment Policy Foundation (EPF). This so-called claimed to indicate that the annual costs to employers would approach $120 billion. Notwithstanding the fact that this ridiculous estimate was submitted too late to be subject to serious critical evaluation by OSHA or anyone else, it is instructive how vastly different are the EPF estimates from those of the real-world experiences of America's employers and workers.

Indeed, what surprised many observers at OSHA's hearing last year was the utter absence of significant reports of actual "bad" employer experience with ergonomics program, especially from the multiple companies which had implemented ergonomics programs in the past.

Unfortunately, with rare exception, it appeared that these otherwise well-meaning employers—companies which knew that ergonomics works and saves money—were avoiding the OSHA hearing like the plague.

Where were the representatives from the Big Three auto companies who had invested millions of dollars in ergonomics program far beyond anything OSHA had required in its ergonomic citations?

Where were the individual grocery chains who had already spent millions on improved checkstands?

Where were the nursing homes chains which are grappling with unsupportable workers compensation costs and turnover rates because of the epidemic of disabling back injuries among nurses aides?

They were all in hiding. We can only assume that they were avoiding the prospect of embarrassing or frankly undermining their customers or the know-nothing companies in the same industries. It seems they had to avoid admitting the truth about their actual investments in ergonomics activities, and about the returns they enjoyed on those investments through the reduced costs for workers compensation or the improved productivity of their operations.

Those skeptical or pessimistic estimates which OSHA did hear, instead, was almost exclusively speculation about possible compliance problems. Much of this speculation came from companies which had not made serious efforts to prevent ergonomic injuries among their employees. And given the campaign of fear which emanated from the National Association of Manufacturers and Chamber of Commerce, it is not surprising that the uninformed would attack ergonomics programs in this way.

But the testimony of one participant was most revealing. Judging by the number of lawyers present at any moment, the United Parcel Service was the single most

active participant in the entire rulemaking. They initially requested an opportunity for over 20 witnesses to appear. Most were supposedly independent medical personnel, but several UPS managers were included. However, when UPS' turn came, almost all their witnesses disappeared, including all participation by their corporate managers.

Only later did OSHA receive—from the Teamsters union—the actual evidence of UPS' views on the feasibility of ergonomics programs. Attached to my testimony is the March 10, 2000 internal UPS memorandum from the Corporate Industrial Engineering Department entitled "Ergonomic Endeavors". This memo clearly identifies substantial capital and operating investments which UPS has made to implement an ergonomics program throughout the company. It reveals that UPS has invested significantly in new trucks, ergonomic tools for drivers, new warehouse equipment, new computer software and hardware, new office equipment and extensive training of management personnel.

This is the company which claims there is no science underlying ergonomics, but that under the heading "Comprehensive Self Evaluation" apparently has "trained over 500 UPS people (including some hourly) in ergonomic principles . . ."

This is the company that claims that ergonomics interventions do not prevent lifting-related injuries, but that under the heading "Ergonomics Awareness" had run "over 20 workshops . . . at districts, regions across the country to convey importance of ergonomic principles, job set-up and methods, and workplace design. . . ."

Mr. Chairman, UPS' lawyers attended the OSHA hearing virtually day, and never once did they give OSHA any inkling of the extensive nature of UPS' activities on ergonomics. Never once did they admit to UPS having spent significant corporate resources to established an ergonomics program. Never did they offer an actual UPS manager with the authority to speak or answer questions about the company's engineering investments in labor-saving equipment or the savings which UPS enjoyed from that investment.

It is easy to understand why: because if UPS managers had revealed officially the company's activities comparable to the very same measures included in the proposed standard, OSHA or someone else might have challenged them to say how UPS ever justified that investment. What were the costs of the injuries that these investments were designed to prevent? How large was the company's savings by the avoidance of these costs? And how much more did the company save in productivity improvements as a result of these investments?

$120 BILLION: A FIGURE VIRTUALLY FROM THIN AIR

Mr. Chairman, those questions linger today even as the Employment Policy Foundation's phony $120 billion cost figure continues to reverberate around the Congress and throughout the media.

We completely reject this absurd, trumped-up fabrication. Notwithstanding their complaints about OSHA's rush to judgment, EPF and their presumptive allies at the NAM and UPS waited until March 2000 to begin to collect data about employers' costs of compliance. They did not make any of their data available until June 26, well after their witnesses appeared at OSHA's actual hearing to answer questions. They then reported the summary version of their actual economic estimates on August 9, including their reference to their computer modeling which generated the infamous $129.5 billion first-year cost figure.

This estimate purportedly relies on survey data from an unspecific number of Fortune 500 companies with about 1.7 million workers in nearly 20,000 separate establishments (averaging over 500 establishments per company).

However, despite that extensive direct line of communication with the largest corporate entities in the entire world, the EPF survey did not identify the actual compliance costs for a single specific high-risk job or operation. Not for a single truck driver, or grocery warehouse or retail checkstand, or nursing home, or paint booth, or parts assembler.

Furthermore, their survey itself was not submitted for the record, only portions of it dealing with the employers' estimates of time allotments. And the actual methodology for the conduct of the survey was never revealed—only the summary results.

(At the same time, they acknowledged that the benefits would be significant—albeit less than OSHA estimated in the proposed rule. But they failed utterly to provide any accounting of the derivation of the benefits, nor to report the experiences of individual employers regarding the returns on ergonomic investments which such employers have enjoyed.)

We may contrast this with the extensive and detailed examination which OSHA gave to specific industry sectors in both the proposed and final standards, as re-

quired by the OSH Act and the Regulatory Flexibility Act. OSHA made multiple analyses to confirm the legitimacy of its approach. OSHA ultimately derived a cost-estimate which began with job-specific estimates covering nearly half the reported MSD's in the entire economy. In addition, OSHA dealt specifically in the final standard with the criticisms of its opponents, including UPS and EPF, regarding OSHA's cost estimates for individual jobs or operations.

All of this analysis would be reviewable by the Court of Appeals. As in the past, OSHA's opponents would have detailed opportunities to challenge OSHA's methods and conclusions, and request a stay of the proceedings if needed.

But OSHA's opponents had no sincere interest in legitimate analysis or discussion. Their only interest, it is now evident, was to quash any real evaluation of the facts about workplace injury or effective job safety investments, and destroy OSHA's ability to ever regulate these hazards.

HISTORY OF INDUSTRY MISREPRESENTATIONS ABOUT COSTS

But this is by no means the first time that an industry coalition or trade association has sought to undermine the basic functioning of the Occupational Safety and Health Act by vastly overestimating the potential technological or economic problems of compliance with a proposed OSHA standard. Virtually every time that OSHA has proposed to substantially improve worker, the affected industries have cried wolf about the supposed costs, and threatened to close up shop. And time after time, the actual costs have been within OSHA's estimate—or indeed far less.

In 1995, the Congressional Office of Technology Assessment reviewed this sordid history of industry obstructionism, and tried to identify the actual costs. OTA, no captive of the labor unions or environmental activists, concluded, among other things:

1. The agency's findings and estimates on hazard control options and regulatory impacts are often the subject of vigorous review and challenge by stakeholders and various experts on all sides of rulemaking issues. But this reaction does not generally indicate underlying agency analytical neglect. The agency's rulemakings are often lightning rods for controversy and are conducted in a politically polarized setting.

2. The agency's findings and estimates on hazard has generally performed this task with workable accuracy—that is, standards determined by OSHA to be "feasible" in the course of its analytical deliberations have usually proved to be so when industries took the necessary steps to comply. Nonetheless, the agency's demonstrations of feasibility are often based on conservative assumptions about what compliance responses will predominate across affected industries. As a result, there are often sizable disparities between OSHA's rulemaking projections of control technology adoption patterns, compliance spending, and other economic impacts, and what actually happens when affected industries respond to an enacted standard. In a good number of the cases that OTA examined, the actual compliance response that was observed included advanced or innovative control measures that had not been emphasized in the rulemaking analyses, and the actual cost burden proved to be considerably less than what OSHA had estimated.

3. . . . OSHA's rulemakings are not generally imposing unworkable compliance burden on industry. In six of the eight cases considered industry stakeholders and their representatives argued in the course of the rulemaking (modestly to vigorously, depending on the case) that compliance would pose unworkable problems. . . .

For the most part, the post-promulgation reality observed in this project's case study standards proved much the opposite of these representations. [footnote omitted] In almost all these cases . . ., the industries that were most affected achieved compliance straightforwardly, and largely avoided the destructive economic effects invoked by their rulemaking arguments. Very few companies left the industry chiefly because of the new compliance requirements. And, in a good many of the cases, the actual cost burden of compliance proved considerably less than OSHA's final estimate—about one-quarter the estimate in Vinyl Chloride, one-third in Cotton Dust, and one-half in Formaldehyde (metal foundries). Furthermore, in half of the eight cases examined, the standard stimulated changes in the production technology of affected industries that yielded benefits beyond a means for health and safety hazard compliance.

In Vinyl Chloride, several of the principal industry members capitalized on the altered business and regulatory setting to commercialize innovative processes for polyvinyl chloride polymerization, which enhanced manufacturing productivity, better rationalization of material inputs, largely eliminated the need for manual reac-

tor cleaning (a prime source of high exposures for the workforce), and provided a new source of income to the technology's developers through licensing arrangements.

In Cotton Dust, OSHA's mandate for greater dust control, combined with a strong need for more competitive production capacity, drove much of the textile industry to accelerate investments in modern production equipment—this modernization yielded improvements in manufacturing productivity and product quality while providing a more cost-effective means to bring dust levels within the terms of compliance.

Other aspects of this persistent problem are described in the attached analysis of the OTA report from the New York Times.

We have witnessed this year probably the most catastrophic example of this unscrupulous behavior. It remains up to the Congress heed the conclusions of the Office of Technology Assessment, and to set the record straight: OSHA's work has benefited the American people, and deserves our support even in the face of an hysterical political juggernaut like that opposed to the ergonomics standard. To do otherwise is to tell America's workers that they are simply expendable.

COST OF INJURIES

American workers are currently paying the price for these injuries, and the costs to them, their employers and society are immense. The recent review by the National Academy of Sciences concluded that the total bill to the U.S. economy for Workers Compensation and other medical/disability costs, and for lost productivity, amounts to between $45 and $54 billion annually, or about 1 percent of our Gross Domestic Product. This is an immense sum.

The Liberty Mutual company, the nation's largest workers compensation insurance carrier, has repeatedly called attention to the high costs of back injuries and other disabilities related to ergonomic hazards. Their data on disability costs figured prominently in OSHA's estimate that each disabling injury prevented by a reasonable ergonomics program would yield injury-related cost savings averaging $22,000.

Who is paying these costs now? Billions of dollars of these costs are now paid by employers. Many of these employers should know better—and invest in the simple equipment to prevent injuries. But they unfortunately are not willing to make even these small investments for worker safety and require an OSHA standard to simply get their attention.

Other costs—often great than employers pay—are paid by workers and their families. The daily pain and agony of back pain or carpal tunnel syndrome. The inability to pick up a child or a frying pan. The depression from severe disability and the fear of family economic survival.

Other costs are paid by the taxpayer, as workers tossed overboard are washed ashore as recipients of Social Security Disability benefits and Medicaid.

In addition there are substantial benefits to employer from ergonomic investments that improve productivity. Whether it is a simple shelf or conveyor in a warehouse, or redesigning an entire assembly line to reduce lifting of parts and tools, the improvements in productivity which OSHA identified during the rulemaking hearing are common, sensible and often quite impressive.

CONCLUSION

These costs—and benefits—are immense. They are the very reasons that the Congress passed the OSHAct in the first place.

The benefits are achievable, and are exactly what's needed to preserve real jobs for working families in a period when so many working families are left behind.

We urge the Congress to immediately restore OSHA's authority to adopt an Ergonomics Program Standard, and to compel OSHA to issue such a standard with all deliberate speed.

UNION OF NEEDLE TRADES INDUSTRIAL AND TEXTILE EMPLOYEES, DISABLING WORKER INJURIES AND ILLNESSES, 1987–1994, LEAR CORP. (FORMERLY MASLAND INDUSTRIES INC.), LEWISTOWN, PA

	Injuries		Repetitive motion cases	
	Number	Lost days	Number	Lost days
Pre-OSHA inspection:				
1987	76	460	37	462
1988	110	955	31	608
1989	49	887	35	527

UNION OF NEEDLE TRADES INDUSTRIAL AND TEXTILE EMPLOYEES, DISABLING WORKER INJURIES AND ILLNESSES, 1987–1994, LEAR CORP. (FORMERLY MASLAND INDUSTRIES INC.), LEWISTOWN, PA—Continued

	Injuries		Repetitive motion cases	
	Number	Lost days	Number	Lost days
Post-OSHA:				
1990	48	473	17	324
1991	21	33	15	206
1992	20	202	9	1
1993	29	209	9	188
1994	29	64	19	75

Senator SPECTER. Thank you. Mr. Doug Bonacum, director of Patient Safety, Kaiser Permanente.

STATEMENT OF DOUG BONACUM, DIRECTOR, PATIENT SAFETY, KAISER PERMANENTE

Mr. BONACUM. Thank you for the opportunity to testify here today. I am the director of Patient Safety and Environmental Safety for Kaiser Permanente, the largest private nonprofit provider of health care services in the United States, with approximately 8.2 million members in 9 States and the District of Columbia.

Our mission is to provide high quality health care services to improve the health status of our members in the communities we serve. In support of this mission, the organization strives to provide a safe, healthy and supportive work environment for our employees, our physicians and our members. We believe an important component of this objective is to identify, evaluate and mitigate ergonomic risk factors that challenge our work force.

I am here today to discuss strategies for minimizing and preventing work injuries and illnesses related to risks associated with musculoskeletal disorder and will highlight one particular ergonomics-based application of this approach at Kaiser Permanente. Kaiser Permanente's occupational injure and illness reduction strategy is based upon a multifaceted approach that begins far upstream of worker injury illness and ends with the safe and efficient return to work program.

Our focus is on engineering controls, safe work practices and injury response and recovery in that order while our current OSHA recordable case rate is about average for our industry, we are confident that the program elements we have put in place will measurably improve our safety record.

We are initially focusing our energies in two primary areas, housekeeping and patient handling. For injuries occurring during 2000 alone this constituted approximately 30 percent of our workers compensation cases and costs. The majority of injuries in both areas result from overexertion.

As our nursing work force is aging with the demand for new nurses exceeding the current supply, our inpatient population is becoming sicker and often heavier. As a result, we are particularly concerned about the back safety of our nursing staff. For this reason we have begun implementing an aggressive back safety program, targeted patient handling, that is now in its second year of a 2 year project to demonstrate the efficacy of patient handling

equipment, training and monitoring in significantly reducing back injuries to our patient care staff.

There are, of course, numerous reasons for lifting and transferring patients in the course of care. For example, ambulating a patient after surgery may be a significant part of the healing and recovery process or lifting a wheelchair dependent patient to an exam table provides the caregiver with an appropriate opportunity to facilitate a more through and complete physical examination. Without the right equipment, training and patient—without the right equipment and training, patient repositioning, lifting and transfer tasks that seem to go without hitch on TV can result in musculoskeletal strains resulting in painful, life-changing injuries to our precious work force.

With 27 of our 29 owned and operated hospitals located in the State of California, we are currently focusing our patient handling ergonomic interventions there first. At the core of this program is patient handling equipment.

The patient handling equipment we have selected includes vertical lifts, pivot transfer aids, special patient chairs and lateral transfer devices. The selection process was performed with input and hands on evaluation from employee user groups, expert advice from consultants and discussions with other health care organizations using similar equipment.

There are three primary methods for utilizing the patient handling equipment with the most preferred option being full time staff dedicated to the use of the equipment and associated tasks. The dedicated patient handling lift team is recruited, trained and assigned accountability for identified high-risk tasks. On average, there may be two patient lift teams per 250 hospital beds. They generally conduct lifts in pairs and depending upon the hospital's accident experience and resources, may be staffed during one shift or around the clock.

Prior to joining Kaiser Permanente the individual leading our program implemented a patient handling lift team in another health system in California and achieved a reduction of back injuries of over 80 percent during a 3 year period. We are looking to do the same.

Employee participation has taken place on all back safety interventions and many are sponsored by local management partnership committees that typically include employee representation. Kaiser Permanente's labor management partnership is about engaging our work force from problem solving through strategic planning in order to attain our mission of providing high quality care to our members. In short, worker safety is part and parcel to our partnership.

While the primary focus of our early efforts on back safety have been on the worker, we recognize there are linkages to and synergies with other critical performance areas including patient safety, facilitating adequate path for our members with disabilities and compliance with state OSHA requirements.

PREPARED STATEMENT

In other words, we feel the appropriate application of ergonomic interventions at Kaiser Permanente will have far-reaching, positive

impact well beyond our primary goal of ensuring worker safety. For Kaiser Permanente, a healthy work force operating in a safe workplace is part of our commitment to providing high quality affordable care. Thank you.

[The statement follows:]

PREPARED STATEMENT OF DOUG BONACUM

Chairman Specter and Committee Members: Thank you for the opportunity to testify here today on the very important issue of ergonomics. I am Doug Bonacum, the National Director of Patient Safety and Environmental Health and Safety for Kaiser Permanente in Oakland, California. I would like to take a few minutes to discuss some of the efforts Kaiser Permanente is undertaking to improve ergonomics in our workplaces.

KAISER PERMANENTE

The Kaiser Permanente Medical Care Program is a predominantly prepaid, group practice health maintenance organization that is committed to providing excellence in both quality of care and quality of service. In each region in which it operates, Kaiser Permanente is composed of three closely cooperating organizations: Kaiser Foundation Health Plan, Inc., a California nonprofit corporation that is a federally qualified HMO; or one of its regional health plan subsidiaries; Kaiser Foundation Hospitals, a California public benefit corporation, which provides or arranges for hospital services to our members; and the Permanente Medical Groups, which are multi-specialty physician group practices organized as partnerships or professional corporations and which provide or arrange for all medical services our members require.

Founded in 1945, Kaiser Permanente is the largest private, non-profit provider of health care services in the United States, with approximately 8.2 million members in 9 states and the District of Columbia. We operate 29 acute care medical centers and 423 medical offices in which we employ approximately 90,000 people. More than 11,000 physicians practice within the Permanente Medical Groups.

The mission of Kaiser Permanente is to provide affordable, high quality health care services to improve the health status of our members and the communities we serve. In support of this mission, the organization strives to provide a safe, healthy, and supportive work environment for our employees, physicians, and members. We believe an important component of this objective is to identify, evaluate, and mitigate ergonomic risk factors that challenge our workforce.

ADDRESSING ERGONOMIC ISSUES IN THE HEALTH CARE WORKPLACE

While significant media attention has more recently been focused on patient safety, the healthcare industry is not without its fair share of worker health and safety risks as well. These include potential exposures to bloodborne pathogens and infectious diseases, high-level disinfectants, sterilants, anesthetic gases, and laboratory chemicals, and occupational injury and illness from such activities as patient lifting and transport. I am here today to discuss strategies for minimizing and preventing worker injuries and illnesses related to risks associated with musculoskeletal disorders, and will highlight one particular ergonomics-based application of this approach at Kaiser Permanente.

For the purposes of this discussion, ergonomics means the practice of adapting the physical environment and implementing safe work practices consistent with a human being's capabilities and limitations, resulting in optimal individual health and productivity. While the overall goal of an ergonomics program should be to ultimately eliminate occupational injuries and illnesses caused by ergonomic stressors, our guiding principles include trying to put the least amount of stress on the body's framework, requiring the least amount of physical work by tissues and joints to maintain safe postures and positions while providing high quality care. We look to minimize or prevent the cumulative application of biomechanical stress to tissues and joints by identifying and controlling the following risks: (a) The frequency of specific physical motion or exertion known or believed to potentially cause harm, (b) The force or physical exertion /pressure applied to vulnerable parts of the body during specific motions, and (c) The duration or length of period in which an activity occurs that leads to the risk of an ergonomic injury.

Kaiser Permanente's occupational injury and illness reduction strategy is based upon a multi-faceted approach that begins far upstream of worker injury or illness, and ends, in the event of an injury or illness despite best efforts to avoid it, with

a safe and efficient return-to-work program. It is based on a safety hierarchy that addresses risk in the following fashion: (1) Eliminate, (2) Mitigate, (3) Administrate, (4) Educate, and when necessary, (5) Remediate. In other words, the focus is on engineering controls, safe work practices, and injury response and recovery, in that order. While our current OSHA Recordable Case Rate is about average for our industry, we are confident that the program elements we have put in place will measurably improve our safety record. These elements include:

(1) Mandatory design and construction standards for casework, furnishings, and the work environment, as well as mandatory purchasing requirements for ergonomic accessories. Multi-functional teams develop these standards with representatives for our physicians, nursing staff, other caregivers, and administrators. Because Kaiser Permanente is an Integrated Delivery System, we can ensure that each of our newly constructed or renovated facilities is designed with adherence to our internal standards, and products and materials are purchased from contracts that include ergonomically correct equipment.

(2) Training and education efforts that include new employee orientation, an online refresher course addressing basic ergonomic principles and procedures, and task or job specific training for high risk areas (e.g., patient handling).

(3) The application of on-the-job hazard recognition and control principles principally applied to patient handling and housekeeping operations, as well as repetitive laboratory and back-office procedures.

(4) An active medical management program that has been instrumental in getting injured employees back to the workforce in a safe and efficient manner.

(5) Performance monitoring and internal reporting systems based upon workers' compensation case rates, as well as program evaluation to assess and report compliance with internal standards, best management practices, and various State regulations.

We are initially focusing our energies in two primary areas: Housekeeping and Patient Handling. For injuries occurring during 2000, these two areas alone constituted approximately 30 percent of our workers' compensation cases and costs. The majority of injuries in both areas result from overexertion. As our nursing workforce is aging, with the demand for new nurses exceeding the current supply, our in-patient population is becoming sicker and often heavier. As a result, we are particularly concerned about the back safety of our nursing staff. For this reason, we have begun implementing an aggressive back safety program targeted at patient handling.

We are currently in the second year of a two-year project to demonstrate the efficacy of patient handling equipment, training, and monitoring in significantly reducing back injuries to our patient care staff. We have benchmarked with other healthcare organizations and partnered with a recognized industry expert in formulating our approach and expect to achieve significant reductions of back injuries in targeted areas well in excess of 50 percent.

Anyone who watches one or more of the popular television hospital dramas will often see a team of people manually, and seemingly, comfortably transferring a patient from gurney to bed or bed to wheelchair, for example. These types of lifts or transfers occur repeatedly in the course of diagnosis, treatment, and recovery, both in the hospital environment, and across the continuum of care. Unfortunately, patient handling is seldom comfortable and often done without the aid of a large team of people. This has resulted in significant back issues for nursing workforces.

There are numerous reasons for lifting and transferring patients in the course of care. For example, ambulating a patient after surgery may be a significant part of the healing and recovery process; transferring a patient from gurney to procedure, exam or radiology table may be required to ensure the patient receives the appropriate examination or follow-up care; and aiding patients in unexpected situations such as assisting a patient who has fallen to the floor. Lifting a temporarily disabled or disabled wheelchair-dependent patient from a wheelchair to an exam table provides the caregiver with an opportunity to facilitate a more thorough and complete physical examination. Without appropriate equipment, training, and feedback, these patient repositioning, lifting and transfer tasks that go without hitch on TV, can result in musculoskeletal strains, resulting in painful, life changing injuries to the workforce.

With 27 of our 29 owned and operated hospitals located in the State of California, we are focusing our patient handling ergonomic interventions here first. We are piloting an approach which provides flexibility in individual hospital implementation, but, at its core, consists of the following four main elements:

—The identification, selection, and implementation of lift equipment to take strain off the backs and shoulders of our workforce and place it instead on the mechanical arms of engineering controls.

—Development of expected practices and protocols for utilizing the equipment and lifting patients.
—Training and education for the affected work force on basic ergonomic principles, the mechanics of safe lifting, utilization of the equipment, and the application of safe work-practices.
—Program monitoring, modification, and back-injury reduction tracking and reporting.

The patient handling equipment we have selected includes vertical lifts, pivot transfer aids, special patient chairs, and lateral transfer devices. The selection process was performed with input and hands-on evaluation from employee user groups, expert advice from consultants, and discussions with other healthcare organizations using similar equipment. The patient care team develops consensus on the application and utilization of the lift equipment including who will use the equipment, how to use it, and when it will be used.

There are three primary methods for utilizing the patient handling equipment, including: (1) Training current staff how and when to use the equipment, (2) Designating select staff members to use the equipment as patient handling specialists, or (3) Hiring full time staff dedicated to the use of the patient handling equipment and associated tasks (preferred strategy). The dedicated staff patient handling "lift-team" is recruited, trained, and assigned accountability for identified high-risk tasks. On average, there may be 2 patient lift team members per 250 hospital beds for any eight hours of hospital coverage. They generally conduct lifts in pairs, and, depending upon the hospital's accident experience and resources, may be staffed during one shift or around-the-clock. Prior to joining Kaiser Permanente, the individual leading our program implemented a patient handling lift-team in another health system in California and achieved a reduction of back injuries of over 80 percent during a 3 year period. We are looking to do the same at Kaiser Permanente. The initial estimated cost for purchasing the lift equipment averages approximately $100,000 per center. At an estimated average cost of $20,000 per back injury, even the strictly financial return on investment from the appropriate selection and implementation of lift equipment can be as short as one year.

To date, we have fully implemented patient handling projects in 9 medical centers, three of which are piloting the lift team intervention, and we are on track to have full implementation in the remaining medical centers by year-end. We will monitor the Program's success through quarterly workers' compensation case rate reports, as well as using an internal audit program to ensure compliance with relevant Kaiser Permanente Standards and Federal and State regulatory requirements.

Employee participation has taken place on all back-safety interventions and many are sponsored by local Labor-Management Partnership committees or Local Safety Committees that typically include employee representation. Kaiser Permanente's Labor Management Partnership is about engaging our workforce, from problem solving through strategic planning, in order to attain our mission of providing high quality care to our members. The objective of the Partnership is to create a culture of consultation within the organization, in which labor and management routinely collaborate to address issues of operations, the quality of patient care, and the quality of work life at Kaiser Permanente. In short, worker safety is part and parcel to our Partnership.

While the primary focus of our early efforts on back safety have been on the worker, we recognize there are linkages to and synergies with other critical performance areas including Patient Safety, facilitating adequate care for our members with disabilities, and complying with California OSHA requirements for reducing occupational injuries and illnesses. An example of the Patient Safety connection is recognition that a member who is routinely and safely ambulated after surgery has potentially less chance of falling, acquiring bed sores, contracting a respiratory illness, or suffering an increased hospital length of stay due to slower than expected recovery. The linkage to providing appropriate care for our disabled community is as simple as ensuring that a wheel chair bound patient can be safely transferred from their wheel chair to an exam table for a complete and thorough examination. In other words, we feel the appropriate application of ergonomic interventions at Kaiser Permanente will have far reaching, positive impact well beyond our primary goal of ensuring worker safety. In short, a healthy workforce, operating in a safe workplace is part of our commitment to provide easier access and delivering high quality, affordable care.

Thank you for your time. I would be happy to answer any questions you may have.

Senator SPECTER. Thank you, Mr. Bonacum. I had hoped that Secretary Chao will stay for the entire hearing. She was unable to do that. I know she has representatives here and I think that there have been some illustrations here where employers and employees have come very close and I am impressed with what you said, Mr. Bonacum, as to what Kaiser Permanente has done. And the testimony of the auto industry is also a model where they are getting pretty close. And I think what Mr. Sparlin said about the OSHA bureaucratic response is understandable too. May not be so much the regulations, but the way OSHA enforces them or interprets them which really requires a lot more supervision so that you get to the important spots but you do not create a climate where there's so much resistance because of excesses.

So Mr. Fruman's testimony I think is important in identifying companies which have gone along a way and I'd be interested to find out why some of those companies didn't come in to testify.

I have a lot of questions but it is now past noon and we have another panel, so I am going to thank you all very much.

Mr. SPARLIN. Mr. Chairman, before we adjourn it is unfortunate that this forum was used as a means to impugn this particular company, UPS, but may I be afforded an opportunity to briefly respond.

Senator SPECTER. Sure. I do not know that we've impugned them, but go ahead.

Mr. SPARLIN. Well, there was an accusation about UPS and——

Senator SPECTER. Well, it was said they didn't come in to testify.

Mr. SPARLIN. Well, it was said that they—I believe it was a little stronger, but the record will speak for itself.

Senator SPECTER. That is okay, if you want to reply, go ahead.

Mr. SPARLIN. Yes. UPS has never made a secret from anyone that it is engaged in ergonomic programs and having a great deal of success. But what Mr. Frumin and many others seem to fail to appreciate is that any time you use the E word, it doesn't necessarily mean the same thing.

UPS does not vigorously oppose an ergonomic standard simply because it likes to pay lawyers to engage in a big battle. It is opposing the ergonomic standard because it does not believe, and I believe your observations are very much on point, that the direction that OSHA is taking is a proper one and moreover, it is very concerned that this is not frankly something that can be articulated. I mean, you've articulated the goals as to what we might want to accomplish.

But frankly you have two paradigms. One is the proposed standard where OSHA basically went to employers and said if you find a problem, go forth and fix it and they didn't give much guidance. And so employers didn't know what to do. So they complained about that and OSHA gave us a final standard which they didn't give us a right to comment on which gave eight specific hazard identification tools.

Senator SPECTER. They did not give you a right to comment——

Mr. SPARLIN. On the final standard, that is correct. And the problem there was those particular tools lacked scientific support, were inconsistent with one another, and frankly did not achieve the goal of backing away from the excesses that we believe are appar-

ent here. So that is the problem we're faced with and frankly, it is a very difficult challenge but from the economic perspective what we need to do is get away from just the notion of coming up with anecdotes and, you know, anything that we can label ergonomic we make claims about it and we put a price tag on and even as we change the standard we do not change the price tag. We have got to be very specific about what it is we are expecting from employers, what we expect to gain from it, what we expect it to cost, be honest about doing the calculations and do them very carefully and with hard data support.

Senator SPECTER. Well, Mr. Sparlin, you made some valid points. It may be that the input from a lot of companies which have had success will be very helpful in formulating a standard and then it may be that the application and supervision of the standard really ought to have representatives of all sides, business and labor, so that you do not have just OSHA doing it. Too often, and this is not a reflection on the Federal work force, the agencies become excessive in their application. Happens all the time. Lots of lawsuits go up on the administrative process. Maybe we need some umpires from business, from labor, to take a look at it and try to put some balance in the implementation of the regulations.

Mr. Frumin, I see you moving forward in your chair. Having had a reply to you, would you like a surrebuttal?

Mr. FRUMIN. I would appreciate the opportunity, Senator.

Senator SPECTER. Go ahead.

Mr. FRUMIN. Mr. Sparlin's comments regarding a good faith effort by UPS flies in the face of their lack of participation in any constructive form in this process. We did not, OSHA did not, receive the benefit of UPS's detailed cost analysis of their own ergonomics program during the rulemaking hearing or during the years and years and years of earlier discussions, debates, stakeholder meetings, committee meetings, et cetera, et cetera.

What are the actual costs of the employers who have implemented ergonomics programs? OSHA begged industry and their representatives to provide that information repeatedly since 1991 and companies like UPS and others preferred to sit on the sidelines, withhold their real world information and shoot at OSHA for doing the wrong thing. Other companies which had spent the money, most of them unfortunately did not provide that information.

Senator SPECTER. Mr. Frumin, the subcommittees will make an inquiry on the UPS, what you've suggested. If you have other companies, let me know.

Mr. FRUMIN. Well, we invite you to come to Lewistown and meet one.

Senator SPECTER. Okay, I go to Lewistown with some frequency. I'll do my best to stop in.

We're moving now to panel five. It says Mr. Fellner again. It couldn't be true that it is Mr. Fellner again, could it?

Mr. Sparlin, we have Ms. Seminario again and Jacquelin Nowell and Jerry Wood. Ms. Nowell, let's begin with you, if we may.

STATEMENT OF JACQUELINE NOWELL, DIRECTOR, SAFETY AND HEALTH, UNITED FOOD AND COMMERCIAL WORKERS INTERNATIONAL UNION

Ms. NOWELL. Thank you very much.

Senator SPECTER. Director of Safety and Health, United Food and Commercial Workers International Union.

Ms. NOWELL. Thank you Mr. Chairman. United Food and Commercial Workers represents 1.4 million workers in the United States and Canada, primarily in the retail trades and food processing industries.

The UFCW strongly supported the repealed OSHA ergonomic standard because it contained the basic core elements that we helped develop with our companies over the last 10 years, 12 years, the same elements that OSHA saw was working in companies, those of medical management, job analysis and control, worker involvement, training and surveillance. We had hoped that a standard would get this beyond just our industries and the industries that other panelists have talked about where this is working so that all workers would be protected.

We have been involved in this issue for 20 years. We know that controlling exposure to ergonomic hazards worked. We've seen it happen. Our members were being hurt in record numbers. Ergonomics really was the answer.

I want to raise a couple of issues, one is the issue of guidelines. I brought with me a copy of the red meat guidelines that Secretary Chao has referred to in her submitted testimony.

Contrary to her testimony, these must be taken in context. These came out in 1990 right in the middle of intense enforcement activity by the agency in this industry. There were record numbers of injuries in here, rampant medical mismanagement of workers. There was major enforcement activity, very high fines for lack of record keeping, for example, for not treating workers medically.

In that context, these guidelines were developed and they were developed in the context of OSHA moving forward on a standard. They would not work in a vacuum. They only were successful because they were part of that whole picture, so that needs to be in this record. We have participated in these types of programs over the years, including the corporate-wide settlement agreements that came out of this massive enforcement effort that was done in the meat packing industry.

Let me get at a few of the statistics which are very real, not only from the Bureau of Labor Statistics but from the industries themselves. The Bureau of Labor Statistics, if you look at their statistics from 1991 to 1996 there was a 38 percent reduction in the rate of MSDs, right at the heart of again, enforcement, the red meat guidelines and a push for a standard from the agency and the department itself.

The AMI itself testified during the hearings that there was in 10 years since the enforcement and guidelines reduced levels of injuries and illnesses by a third and half of the lost time injuries had been reduced.

The Food Marketing Institute, one of the trade groups that was foremost in trying to trash this whole process of a standard states that there was a 30—there has been a 33 percent reduction in the

number of injuries and illnesses caused by ergonomic hazards in the course of their work trying to reduce them.

One meat packing plant reports a 75 percent reduction in turnover and having recouped all of their investment, economic investment over a 2-year period of first putting in this program. Another over 10 years reports a 78 percent reduction in MSDs.

PREPARED STATEMENT

I want to speak to the injuries themselves. Senator Harkins spoke of Gloria Boyd this morning. Not only was she injured on the job but when she had to move off a job that the company refused to fix, so that all workers could work it, she lost about $100 a week. That is not only a physical injury but a financial injury to these workers. Workers need protection programs that—programs work but only in the context of enforcement. We must have a standard for all workers. Thank you.

[The statement follows:]

PREPARED STATEMENT OF JACQUELINE NOWELL

Good morning, my name is Jacqueline Nowell and I'm the Director of the Occupational Safety and Health Office, the United Food and Commercial Workers International Union, UFCW.

The UFCW is the largest private sector union in North America, representing 1.4 million workers in the retail food, warehousing, healthcare, garment and textile, footwear and chemical industries. We are the largest organization of food processing workers in the United States. We put breakfast, lunch and dinner on the table for America's families. To feed America's families, thousands of food processing workers are needlessly crippled and maimed each year. Meatpacking and poultry processing have some of the highest incidences of repetitive motion injuries in the country.

The UFCW strongly supported OSHA's ergonomics program standard. We have been actively involved in this issue for nearly 20 years, since the early 1980s. Our members were being hurt in record numbers. We began by educating them about the problems of musculoskeletal disorders, MSDs, and the lack of programs and fixes for them in our industries. We filed OSHA complaints in the meatpacking, poultry and cat fish industries. We pressed Labor Secretary Elizabeth Dole for a standard to address the workplace hazards causing MSDs. We worked closely with the Department of Labor and Secretary Dole in developing the Red Meat Guidelines, issued in 1990. In 1991, the UFCW, AFL–CIO and 29 other unions petitioned OSHA for an Emergency Temporary Standard. In 1992, under Secretary Lynn Martin, the Department of Labor agreed with the unions that available information supported initiation of Section 6(b)(5) rulemaking under the OSH Act to address ergonomic hazards. The OSHA ergonomics standard was 10 years in the making, begun by a Republican administration, and long overdue. This standard that was designed to prevent crippling MSDs, the nation's number one job safety problem, was debated in the Senate for 10 hours, while the House gave the issue one hour of consideration. It was finally killed when the President signed the repeal on March 20, 2001, two months after it had gone into effect.

My testimony today will focus on why a standard is needed, through worker stories and successful ergonomics programs in our industries. I would be remiss, however, if I did not take this opportunity to let you know how disappointed our members were with the elimination of the ergonomic standard. By using the Congressional Review Act, a previously unused and untested legislative tool, the ergonomic standard was obliterated. Workers now feel, with some justification, that the Federal government has turned it's back on their ergonomic injuries. I would like to submit for the record a copy of a letter that was sent by our International President, Doug Dority, to Members who killed the worker safety standard. At the same time, we feel nothing but gratitude to those who stood up when workers needed it most.

MSDs are real injuries—they often lead to disability and can have a lifetime affect on workers lives. Caroline Shebora is a cashier in a grocery store in Alexandria, Virginia. She's had bilateral carpal tunnel surgeries and is fearful that it's coming back. Her company fought her worker's compensation claim for over 1½ years, and she feels devastated by that after working for this one company for 27 years. Jan

Garrett works in a poultry plant in Kentucky, where she worked salvage, until she started having problems with her hands. She's also had bilateral carpal tunnel surgeries. Her job, at a line speed of 140 birds per minute, was to cut off broken wings, broken legs, cut skin off that had gall stains, cut tail gland if the machine missed it, anything USDA sent down because they knew Jan would wash, cut, trim and vacuum trying to salvage any of the bird at all. Her life has been completely changed, both at work and home. She can't hang out her laundry, can't clean her house, especially using cleaners that come in spray bottles. Her family bought their first home last summer and her husband and sister had to clean it. To this day, she still hasn't been able to wash the windows. She is afraid, now that she's back on a knife job at the plant, that she won't be able to keep up, and the plant will tell her they have no work for her. Gloria Boyd has worked at the IBP pork processing plant in Waterloo, Iowa for nine years. She was diagnosed with carpal tunnel syndrome as a result of the job she did, cutting bone from picnic hams. She couldn't do anything, couldn't especially grip a knife. She was off the job, on light duty for six months. Getting injured was a real financial as well as physical hardship. She lost her incentive, her pay was reduced $100 a week. She was never able to go back to the higher paying knife job, because every time she tried, the CTS would come back.

The UFCW has many ergonomics programs with full union participation in our represented industries that are working to reduce MSDs. Many industries we represent have recognized the problem for more than 15 years, and have developed ergonomics programs. These include meat, cat fish, retail and boot and shoe. One meatpacking company reduced its worker's compensation costs by nearly 60 percent, reduced turnover by 75 percent and recouped all of their investment in the first two years of the program. In the first two years of the program, the number of diagnosed cases of MSDs was halved and the number of surgeries in the plant fell by 40 percent. Another collectively-bargained ergonomics program in meatpacking has a worker doing most of the ergonomic changes in the plant. That plant has reduced the number of MSD cases in the 10 years of the program by over 78 percent! In a boot and shoe plant, MSD cases were reduced by 70 percent in two high-hazard departments after the company began an ergonomics program. The standard was programmatic rather than specification-based, meaning it was a flexible set of requirements that business would have been able to adapt to its establishments. And it was based on the experience of companies like our, ones that have developed and implemented successful ergonomic programs.

The retail industries have recognized the problem of poor ergonomic design for years. One chain, Stop and Shop Supermarket Company, has a joint program with the UFCW that addresses the high hazard areas of the stores and provides training for the Safety and Ergonomics Committees in each store. The Food Marketing Institute, a trade group for the industry, has educated themselves and their members about the issue of MSDs and back injuries related to job design as well as commissioned and gathered scientific data on the issue. As well, they claim that the injury rate has declined 33 percent in 10 years of voluntary grocery industry efforts to reduce worker injuries. Unfortunately, this same trade group made exaggerated claims about the ergonomics standard, telling its members that they would suffer greatly from a mandatory standard, including that they would have to hire baggers, that customers would have to bag their own groceries and that the price of groceries would increase as a result of the standard. They also claimed that baggers, according to the standard, would be prevented from lifting more than 15 pounds. These scare tactics we believe aimed at generating opposition to the standard rather than concrete criticism of the standard itself, which would have been far more useful for all parties.

Workers are being hurt—Jan, Gloria and Caroline are but examples of the hundreds of thousands of workers—you can see these workers when you go into your own neighborhood grocery store—in the United States who are developing MSDs. They come from small plants and large ones; union ones and non-union ones. The point is it doesn't matter where they work, they need protection. We've been working to get those protections for them. We think an ergonomic standard is the answer.

Thank you for the opportunity to speak to you about this important issue for workers.

Attachment:

UNITED FOOD & COMMERICAL WORKERS
INTERNATIONAL UNION, AFL–CIO & CLC,
Washington, DC, April 12, 2001.

Hon. ____,
U.S. Senate, Senate Office Building, Washington DC.

DEAR SENATOR ____: The more than 600,000 workers who are injured and crippled each year from ergonomic hazards in the workplace feel betrayed by the congressional vote on the ergonomics standard. Hundreds of thousands more workers will now suffer preventable pain and injury as well as needless job and income loss. In addition, thousands of employers will face additional costs in health care, workers' compensation, and reduced productivity.

The campaign waged against the ergonomics standard was marked by misstatements, distortions, and lies. There were no congressional hearings, no public forums, and no opportunities for workers to share their real-life experiences either as casualties of ergonomic hazards or as participants in programs that have successfully eliminated such hazards. We believe that many votes against the standard were the direct result of the misinformation campaign.

On behalf of the 1.4 million members of the United Food and Commercial Workers International Union (UFCW), I extend to you an invitation to meet with workers, and to visit workplaces that will give you a broader understanding, and allow you to make a more informed judgement of both the problems and solutions regarding ergonomic hazards. UFCW has nationally recognized model programs that have both significantly reduced injuries and decreased costs for employers.

UFCW is happy to arrange the meetings with workers and the workplace visits to meet your schedule.

Secretary of Labor Elaine Chao took the opportunity to meet with workers on March 14, 2001, at UFCW headquarters. We believe that her willingness to hear from workers can be an important step in building a consensus on a solution to ergonomic hazards. As Secretary Chao noted, Congress must be part of the consensus-building process.

We hope you wilt take this opportunity to gain a firsthand understanding of this issue, and to see the devastation of workers' lives that comes with ergonomic hazards. Please contact the UFCW Legislative and Political Affairs Department at your earliest possible convenience to discuss a workplace visit.

America's workers are counting on you to hear their concerns and act on their needs for safe workplaces. We hope to hear from you soon.

Sincerely,

DOUGLAS H. DORITY,
International President.

Senator SPECTER. Thank you Ms. Nowell. We now turn to Jerry Wood, legislative chairman, Local 7800, Communication Workers of America.

STATEMENT OF JERRI WOOD, LEGISLATIVE CHAIRMAN, LOCAL 7800, COMMUNICATION WORKERS OF AMERICA

Ms. WOOD. Good afternoon, Senator Specter, Mr. Chair. I am Jerry Wood, the legislative chair for the Communication Workers of America Local 7800 in Seattle and I am also a customer communications technician with over 28 years of service for Qwest Communications, formerly US West and Pacific Northwest Bell.

I really appreciate the opportunity to testify before you and your committee today. I would like to address two important issues regarding workplace ergonomics, the first involves achieving economic—excuse me, ergonomic changes in the workplace. I will illustrate this concern by presenting a success story between my union, the Communication Workers of America and our employer of record at that time, US West which is now known as Qwest. The second deals with what still needs to be accomplished regarding workplace ergonomics.

Mr. Chairman, in 1990 when our company was US West, we had a work group known as the centralized mail remittance center that

processed all incoming payments for our—from our company's customers. The job entailed the following procedures: workers loading mail into a machine that sliced the envelopes open, removing the mail like the bills, checks, cash from the envelopes, keying in the payment information and processing the received checks and cash and then finally collecting and bundling the paper documents.

The performance of this work involved extensive repetitive motions performed in very hot and extremely dusty and dirty working conditions. In turn, these conditions laid to the occurrence of a high rate of employee repetitive motion illnesses, cases of skin rash and resultant Workers Compensation claims and awards. In addition, worker morale and productivity were extremely low. It was not a very pretty picture.

Initially my union attempted to resolve these issues with US West through our collective bargaining process. For an extended period of time, affected employees complained to the management and to the local union stewards of the inadequate ergonomic working conditions and the related health problems.

In turn without success, the union utilized the contract's grievance process. However, lacking—excuse me—lacking agreement from the employer to provide safe and healthful working conditions necessary to minimize or eliminate the identified repetitive motion problems, CWA filed a complaint with WISHA, which is our Washington State Industrial Safety and Health Administration for relief.

In 1992 after citing the company under the general duty clause of the Occupational Safety and Healthy Act for violations regarding inadequate ergonomic working conditions, WISHA and the employer negotiated a settlement agreement intended to resolve the identified areas of concern.

Mr. Chairman, the settlement agreement resulted in US West providing ergonomic and safe and helpful working conditions for all affected employees in that workroom. Components of the settlement agreement included the establishment an ergonomic task force, the development of a workplace ergonomics training program—excuse me—program. Subsequently initial and refresher training was provided to all current and new employees. Training topics included the principles of ergonomics, appropriate body postures, the proper positioning of your hands, your wrists, your legs, illumination and glare, and the use of physical exercises and stretch breaks and the reporting of occupational injuries and illness.

The creation of an ergonomics program. This program included the conducting of periodic work site inspections. In turn, short and long-term recommendations for improvements in working conditions remains. The implementation of lighting fixtures and the provision of appropriate workplace illumination. The provision of appropriate physical workplace accommodation such as foot rests, wrist rests and back supports and I'll hurry up as I see the yellow light is lit.

All of these topics are important components of a comprehensive ergonomics program and standard and since the negotiation and implementation of this settlement agreement, our members have not experienced any complaints of pain, discomfort or illness associated with repetitive motion or cumulative trauma and that is been

for almost 8, 9 years now. No one has had a problem in this work group.

Mr. Chairman, when this problem was identified nearly everyone in this work group had suffered some form of musculoskeletal or cumulative stress disorder. And what does that mean? For business it means money. The return on investment is great. With fewer illnesses and injuries the productivity is up. Less money is spent on medical management and Workmans Compensation. For the employees, they can come to work and not worry about being injured. There is no loss of earnings and they are able to have a pain free life both on and off the job.

It is a dollars and cents issue. Unfortunately this is not the——

Senator SPECTER. The time is up. If you could summarize, please.

PREPARED STATEMENT

Ms. WOOD. What I would like to say is that we need a Federal standard. In our State, in Washington State where I live and work, we have a proactive ergonomics work rule that was adopted in May of 2000 and we're in the process of that now. But US West, Qwest as we're now known, we do not have an ergonomic standard that is a 14 state wide standard. We have individual work groups that negotiate agreements with managers based on personal relationships or, you know, how the business is in that area.

Senator SPECTER. I think we have your point.

Ms. WOOD. The point is we really do need this standard. Once the pain starts, it doesn't stop.

[The statement follows:]

PREPARED STATEMENT OF JERRI WOOD

Good Morning Mister Chairman. I am Jerri Wood, the legislative chair for the Communications Workers of America, Local 7800 in Seattle, Washington and a customer communications technician with over 28 years of service for Qwest Communications, formerly US WEST and Pacific Northwest Bell Telephone.

I appreciate the opportunity to present testimony before the Subcommittee on Labor, Health and Human Services, Education of the Senate Appropriations Committee. I would like to address two important issues regarding workplace ergonomics. The first involves achieving ergonomic changes in the workplace. I will illustrate this concern by presenting a success story between my union, the Communications Workers of America, and Qwest. The second deals with what still needs to be accomplished regarding workplace ergonomics.

Mr. Chairman, in 1990, when our company was US West, we had a work group, known as the Centralized Mail Remittance Center, that processed all incoming payments from the company's customers. The job entailed the following procedures:

—workers loading mail into a machine that sliced the envelopes open,
—removing the mail, i.e., bills, checks, and/or cash, from the envelopes,
—keying in the payment information,
—processing received checks and cash, and, finally,
—collecting and bundling the paper documents.

The performance of this work involved extensive repetitive motions performed in very hot and extremely dusty and dirty working conditions. In turn, these working conditions led to the occurrence of a high rate of employee repetitive motion illnesses, cases of skin rash, and resultant workers' compensation claims and awards. In addition worker morale and productivity were extremely low. It was not a pretty picture. Initially my Union attempted to resolve these issues with US West through the collective bargaining process. For an extended period of time, affected employees complained to management and Local union stewards of inadequate ergonomic working conditions and related health problems. In turn, without success, the Union utilized the contract's grievance process. However, lacking agreement from the employer to provide safe and healthful working conditions necessary to minimize or eliminate the identified repetitive motion health problems, CWA Local 7800 filed a

complaint with WISHA (i.e., the Washington State Industrial Safety and Health Administration) for relief. In 1992, after citing the company under the General Duty Clause of the Occupational Safety and Health Act for violations regarding inadequate ergonomic working conditions, WISHA and the employer negotiated a settlement agreement intended to resolve the identified areas of concern.

Mr. Chairman, the settlement agreement resulted in US West providing ergonomic and safe and healthful working conditions for all affected employees. Components of the settlement agreement included:

—The establishment of an ergonomics task force;

—The development of a workplace ergonomics training program. Subsequently, initial and refresher training was provided to all current and new employees. Training topics included the principles of ergonomics; appropriate body postures; the proper positioning of hands, wrists, arms, and legs; illumination (and glare); the use of physical exercises and stretch breaks; and the reporting of occupational injuries and illnesses;

—The creation of an ergonomics program. This program included the conducting of periodic worksite inspections. In turn, short and long-term recommendations for improvements in working conditions were made;

—The implementation of appropriate lighting fixtures and the provision of appropriate workplace illumination levels;

—The provision of appropriate physical workplace accommodations such as foot rests, wrist rests, and back supports. (US West made sure to have an ample supply of these items so as to eliminate delays in providing them to affected employees);

—The development of procedures that called for the rotation of job functions within affected work groups;

—The establishment of a medical management program. In part, this involved the medical surveillance of workers and a review of ongoing employee cumulative trauma disorders. In addition, affected occupational and management employees were provided education materials regarding the causes and early symptoms of repetitive motion illnesses; and

—The introduction of equipment that would eliminate or significantly minimize the amount of paper dust within the workplace.

All of these topics are important components of a comprehensive ergonomics program and standard.

Since the negotiation and implementation of the settlement agreement, our members have not experienced any complaints of pain, discomfort, or illness associated with repetitive motion or cumulative trauma. In addition, exposure to paper dust has been greatly minimized.

Mr. Chairman, when this problem was identified, nearly every employee in the centralized mail remittance center work group suffered from some form of musculoskeletal or cumulative trauma disorder. Today, there are no reported cases of repetitive motion illness. What does that mean?

For the business it means money. The return on investment is great. With fewer illnesses and injuries, productivity is up. Less money is spent on medical management and workers' compensation. For the employees, they can come to work and not worry about being injured. There is no loss of earnings. They are able to have a pain free life both on and off the job. They can participate fully in their family life, without limitations. These things cannot be measured in dollars and cents. This is a success story that CWA and US WEST learned a lot from.

Unfortunately, this is not the case in all corporations, and even at Qwest, some lessons need to be revisited. We still have work groups where ergonomics and work place safety are unheard of. As we sit here today, many of our members will be hurt and continue hurting after their workday is finished because the emphasis is on the bottom line, the all-mighty dollar. For some reason, we as a nation are willing to play the game of chicken, pitting the financial health of our businesses and the physical, emotional and financial well being of their employees against this mighty bottom line.

If you can prevent an injury from happening, you save money in lost time wages, doctors and therapy visits, prescriptions, hospitalization and so on. Dollars spent in this manner produce no positive return on the employer's investment. In fact, they actually take money away from the bottom line. If employers spend money, as US WEST did in 1992, creating a safer work place, educating their employees to work safer and smarter, and providing the necessary accommodations to lessen the impacts of repetitive motion, the employer will experience an increase in productivity, morale, and employee and customer retention. These are items necessary for successful employers and a healthy, thriving, and growing economy.

Mr. Chairman, why do we need a Federal OSHA ergonomics standard? This question is particularly important for employers with multi-state operations, such as Qwest. A Federal standard would provide for consistent policies and procedures within all states. On the other hand, the establishment of different standards among different states such as Washington, California, and others would present employers with burdensome policy and economic scenarios. In addition, with the establishment of consistent workplace ergonomics policies and procedures, workers would prefer a Federal standard knowing that they have a greater opportunity to be provided ergonomic and safe and healthful working conditions.

As stated in the success story that I described, US WEST was not fully motivated by a collective bargaining agreement or by some sense of doing the right thing in correcting their problems. An outside governmental agency, i.e., the Washington Industrial Safety and Health Administration, with the authority to inspect, issue citations, and levy disciplinary action was needed to convince the company to take the necessary protective action. However, WISHA was limited insofar as they could only use the OSHA General Duty Clause to investigate, issue citations, and take the necessary corrective action. The establishment of a Federal OSHA ergonomics standard would allow state OSHA plans that do not have an ergonomics standard to more efficiently and effectively respond to complaints and resolve inadequate workplace ergonomics.

Mr. Chairman, I have first hand knowledge of the ergonomics and repetitive motion illness problem. I suffer from carpal tunnel and tendonitis in both of my arms due to my job function at Qwest. I know that if my manager had accommodated my need for an ergonomic keyboard, I would not be suffering to the extent that I am today. For the lack of this $25 keyboard, my employer spent over $45,000 in lost time wages, orthopedic and therapy appointments, prescriptions and braces and independent medical examinations, not to mention significant administrative costs. My family lost my ability to help them at some crucial times in their development. My customers lost my service to them. I am a great technician. However, due to my repetitive motion illnesses, my co-workers had to work harder; some working overtime to cover for my absence. My company lost money, because I wasn't there to help them make money.

Unfortunately, once the pain and suffering associated with inadequate workplace ergonomics and the occurrence of repetitive motion illness starts, it never stops.

Mr. Chairman, I urge you to help ease the pain and suffering of millions of American workers who, as a result of inadequate workplace ergonomics, have developed repetitive motion illnesses by working to have a comprehensive Federal OSHA Ergonomic Standard established.

Thank you for your consideration of this matter.

Senator SPECTER. Thank you. Thank you very much. Going now to panel number five, Mr. Fellner, Mr. Sparlin, Ms. Seminario. When you have 26 witnesses, you get sort of repetitive.

Mr. Fellner, it is your turn. I see you are marked down here for 3 minutes, I do not suppose you will need that long, will you?

STATEMENT OF BARUCH A. FELLNER

Mr. FELLNER. Well, as a matter of fact, I may surprise you, Senator Specter, and during the course of my——

Senator SPECTER. I am just kidding, Mr. Fellner, take all 3 minutes.

Mr. FELLNER. I appreciate that, but during the course of—the reason that I may surprise you is because I think that the search for the Holy Grail of consensus this morning may breed more success than you had initially predicted or thought. But before I indicate to you where that consensus might be I'd like to correct the record.

In response to the distinguished chairman's question directed to Dr. Barondess as to whether interventions are effective in addressing MSDs and to the NAS's conclusion with regard to that, he said yes. Dr. Barondess misrepresented his report. In Appendix C, which is the panel response to the single descent, the NAS reports

states, and I quote in its entirety, this is at page 458, the report states that interventions influenced pain reports and not the occurrence of specifically defined disorders of the upper extremities. The studies are summarized in table 8.3. The report does not state that interventions prevent carpal tunnel syndrome or indeed any other upper extremity disorder. The emphasis rather is on the amelioration of symptoms which is the end point in the relevant literature.

Furthermore, the comments on upper extremity interventions carefully state that interventions influence symptoms, not the incidence of specific disorders. With that proposition we agree, and that means if we return, Senator Specter to where I began, the NAS defines disorders as an interruption in a human being's sense of wellness. If that is what this morning's hearing is about, Senator Specter, we can all agree that the workplace does have some influence on individual sense of wellness. Come Monday morning I suspect even you, Senator Specter, are reluctant to come to the Senate. I know I am today.

If that is what ergonomics regulation is about, if OSHA has the authority, if we are entering 1984 Orwellian period where a Federal agency has the authority to regulate an individual's sense of wellness, then we have come very far. Before we do so, Senator, I think that the Department of Labor must take a good, long look at the process and at the science and I appreciate it.

Senator SPECTER. We'll take a close look at the voluminous report and contrast Dr. Barondess statement with your challenge and see if your challenge is well-founded.

Ms. Seminario, I have you down for 3 more minutes.

STATEMENT OF PEG SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY AND HEALTH, AFL–CIO

Ms. SEMINARIO. Just to make a couple of points, Mr. Chairman, as I've said earlier we've long advocated an OSHA standard. We have recommended that such a standard be based on the good employer practices that have worked. Those practices are the ones that are incorporated into the red meat guidelines. They are the practices that are in place in the UAW program, they are the practices that were in the settlement agreement at Qwest. They are the practices that are in the settlement agreements in meat packing.

If you line up all of these documents and all of these programs, they have very common elements. Most of them take a programmatic approach that include employer commitment, employee involvement, identification of problem jobs, development of controls, training and education, and appropriate medical management, and that is the practice. And the risk factors that are addressed, the exposures that are addressed again are the similar common exposures that workers have with respect to the development of MSDs.

They are exposure to excessive reputation, force, awkward postures, vibration, jobs involving a lot of manual handling as Dr. Barondess indicated. So there is commonality when you look at the practice in the workplace and our advice to the Department of Labor in developing their rule is to look at that practice and to codify that into a regulation.

Does that mean that every employer do exactly what the UAW does or what's done at Qwest or, you know, in the meat packing industry? No, there are, you know, obviously real differences in risk. There are real differences in operations, but the programmatic approach, the basic elements are the same and then within that, the control measures are obviously ones that are tailored to a particular workplace.

But at the heart of all this has got to be the reduction in exposure. If you just have a program on paper, if you have a program and a process that is not resulting in reductions and exposure, you are still going to have injury.

Now, much has been said about the fact that there are not only physical factors but psychosocial and organizational factors and we agree with that. But when you look at OSHA's authority to regulate, the physical factors resulting from the jobs are the ones that they are best able to deal with. If OSHA got into trying to deal with management structures in the workplace, they got into dealing with management relationships that have—that are at the heart of the psychosocial work organizational factors in the workplace, you would hear much greater screams from the employers than you have already heard. And when we asked them about this at the hearing, should OSHA then address the work organization and psychosocial factors, they said no.

So OSHA tried to deal with what was in its purview and what really was the focus of its effort. Was dealing with all risk factors? No. It was attempting through the standard to deal with those risk factors that they felt could be regulated related to the workplace and related to hazards.

So that is our recommendation is to look at these practices and then to codify them into a regulatory approach to reduce injuries.

Senator SPECTER. Thank you very much, Ms. Seminario and thank you all. In my experience having been here for some time, this has been a very unusual hearing and the subcommittee has gone into a lot more detail to try to understand this problem because of our determination to see something done.

We labored long hours on conferences on this issue, year after year after year after year and the process that has brought us to where we are today with the regulation having been rescinded and we have a statement by the new Secretary of Labor that, quote, I intend to pursue a comprehensive approach to ergonomics which may include a new rulemaking that addresses the concern levied against the current standard. The word may leaves latitude for not.

We intend to press on the time frame. What I hear today is not likely to lead to consensus but is very adversarial and I am not unused to the adversarial process and I can see the adversarial process at work to try to influence the decision maker. That is not unusual either.

You take an extreme position, you may end up closer to where you want to be than if you take a conciliatory position. That is sort of par for the course in adversarial litigation which I think we have here. But through all of it there's been a lot of progress through ergonomics with the companies and we've heard employers who have come to terms.

And a big part of the problem is the administration by OSHA of which we hear complaints everywhere and this subcommittee has defended OSHA's budget trying to look more for reconciliation and prevention than for adjudication and punishment and what is going to have to happen really in the long run is that the OSHA administration is going to have to be populated by people who understand the concerns on both sides.

Business is going to have to put one of your high, your really well qualified people into a key OSHA position to see to it that OSHA doesn't overstep the bounds.

The employees at OSHA do not earn what some of the witnesses do have testified here today and there has to be a safety check from labor having someone there who will see to it that they do not go too far in either direction. But the governmental administration is a monumental task. But this is a really very—I do not have to say this, it is been said by everybody, an extraordinarily important program this and this subcommittee intends to pursue it and it is my hope that we can find some information from some of these companies which haven't come forward and try to find some standard to address the concerns on all sides because I think at bottom there is a good faith effort to try to deal with workers problems, biggest impacts on corporate profits, we know that. We all have to live together on the planet earth.

It is exactly 12:30. That is the longest hearing this subcommittee has had. It is over.

SUBCOMMITTEE RECESS

Thank you all very much for being here. The subcommittee will stand in recess until 9:30 a.m., on Wednesday, May 2, when we will meet in room SH–216 to hear from Department of Labor Secretary Elaine L. Chao.

[Whereupon, at 12:30 p.m., Thursday, April 26, the hearing was concluded and the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, May 2.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

WEDNESDAY, MAY 2, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:33 a.m., in room SH–216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Harkin, and Murray.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF ELAINE L. CHAO, SECRETARY OF LABOR

ACCOMPANIED BY JAMES McMULLEN, DEPUTY ASSISTANT SECRETARY, BUDGET

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. The Subcommittee, of the Appropriations Committee on Labor, Health and Human Services, and Education will now proceed.

We welcome Secretary of Labor, Elaine Chao, to this first hearing on her Department's budget.

I note at the outset that the administration's discretionary budget request for fiscal year 2002 for the Department of Labor is $11.338 billion, which is a decrease of some $562 million below the current budget, noting that the total funding for the Department including mandatory programs is $44.4 billion.

There are some increases including funding for the disability employment policy, somewhat in excess of $20 million; for the consumer price index improvements, a little over $8 million; and for the unemployment insurance work load program, an increase of $65 million.

But there are some major decreases in the area of youth activities, dislocated workers, training programs for incumbent workers, the safe schools healthy students program, youth offenders, and international labor affairs.

In preliminary staff inquiries, we have been advised that some of these cuts, may be accommodated by the fact that States have spending levels at a lower rate than expected.

But there is a real concern here. Earlier this week, I visited a Healthy Start Center in Harrisburg, which is devoted to trying to deal with youngsters who are at risk and may be predisposed to criminal activity.

I was really startled to hear that the time for dealing with at-risk children is when they are 16 months old. It seemed fanciful to me until I heard their approach.

They say that at 16 months, children start to learn which space is theirs, not to be aggressive and pushing other children, learn scheduling so they have some structure in their life. And that conduct begins at that age.

And they were very much concerned about the programs in Healthy Start, which has had enormous improvement. Although it is not funded by this Department, but funded by the subcommittee, the Healthy Start staff were concerned as to what is going to happen in the summer programs. That is a question which the Congress has faced repeatedly and this subcommittee has taken a very strong position trying to provide for summer jobs for young people.

And the issue was raised as to daycare. What is going to happen to daycare in the summer. So when I look at these cuts, I am really concerned.

I talk about 16-month-olds, because I think that is a bit of information which is sufficiently startling to take just a few minutes this morning to tell you what the avant garde thinking is on this subject.

Well, Madam Secretary, we do not have 25 witnesses behind you today, which will give us a little more of a chance to discuss matters. And we look forward to—I was about to say we look forward to your statement, but timing is everything.

And, Senator Harkin, among his many, many talents, has a way of arriving at precisely the right moment.

My distinguished partner, Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman. And I will just ask my statement be made a part of the record. You are so gracious. I will just put it in the record and let us move ahead.

Senator SPECTER. Oh, I see that statement. It is too long. We cannot afford all of that on the record. We are going to have—you will have to summarize that for——

Senator HARKIN. We will have to get a new appropriation just to print all this stuff, right?

Senator SPECTER. By the time we finish talking, I think we will need several new appropriations.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Thank you, Mr. Chairman. And thank you Secretary Chao for coming here today. It's nice to see you again so soon. Now you know that when this Committee says that we want to work closely with you, we're not kidding!

Budgets are about priorities. In America, where we spend our money reveals a great deal about what we value. The discretionary funding in this year's Department of Labor budget is down $600 million. In a year of unprecedented surplus, it is shocking that we are sitting here discussing deep cuts to an agency whose mission is to protect our Nation's workers—the very people who worked so hard to produce a surplus.

Before I get into the concerns I have, I do want to note a positive step made in this budget. I am pleased to see that the Department has requested a doubling in

the funding for the Office of Disability Employment Policy, which we created last year. This office will focus on integrating individuals with disabilities into worker training programs, improving access to one-stop centers and coordinating with other agencies to ensure that people with disabilities have transportation and community-based attendant services. In many cases, a small amount of assistance is all that is required to give these individuals the independence that a job affords.

Aside from that shining star, I believe this budget is simply short-sighted. First and foremost, I am confounded by the logic of making large cuts in worker training programs just as the country experiences rising unemployment rates. Week after week, we see news reports about lay-offs at major companies, yet your budget calls for a $200 million cut from training programs for dislocated workers.

If we are to encourage innovation in the marketplace, industry NEEDS highly skilled workers and it is in our best interests to provide those workers here in America. I am disappointed to see that, out of the $600 million cut in overall Department of Labor funding, $473.9 million of that comes from Employment and Training Programs. That is 79 percent of the total decrease in the Department!

Another example of the short-sightedness of this budget is this Administration's proposal to cut the Bureau of International Labor Affairs by 65–75 percent. In this era of globalization, American workers are now pitted against workers throughout the global economy in tough, hard-nosed competition as never before. Their jobs and living standards are at unprecedented risk.

Now I am not worried about the productivity of American workers to compete and win on a level playing field. But the sad truth is there are many trading countries that deliberately refuse to enforce their own national laws to respect basic worker rights and labor standards, let alone meet their international legal obligations.

I am deeply concerned that this administration is proposing such drastic cuts in the part of the Federal Government which has the greatest expertise in labor standards and international worker rights issues, such as abusive child labor. These cuts could not come at a worse time: U.S. policy-makers need ILAB help more than ever including President Bush, who says there are legitimate trade-related worker rights issues that must be addressed in the impending fast-track debate.

Finally, I am disturbed by the reductions in worker safety and health standards. In the last year, workforce data has illustrated that Americans are working more hours than ever before. There is a $1.2 million reduction in safety and health standards, a $3 million cut in training grants, cuts in state programs, technical support and a reduction of 94 full-time staff!

Cutting support for worker training, global workforce and basic safety and health standards for our workers—these actions are classic examples of cutting off your nose to spite your face. The surplus was built on the backs of America's workers and if we as a Nation want to prosper in the 21st century, we will need a workforce that is well-trained, highly-skilled, and does not have to fear being injured due to hazardous working conditions. To do any less is to put America's prosperity in danger.

SUMMARY STATEMENT OF HON. ELAINE L. CHAO

Senator SPECTER. Well, in a very unusual move, Secretary Chao, Senator Harkin has deferred to you. I do not think he would have done it to anybody else.

Senator HARKIN. You are in rare form this morning.

Senator SPECTER. The floor is yours.

Secretary CHAO. Thank you very much. And, of course, to the ranking member, I appreciate that courtesy.

Mr. Chairman, now that I know what the lights are for, I have made my statements very short to fit into the time frame. And I do have a written record—statement that I would like to be submitted for the record.

Senator SPECTER. The full statement will be made a part of the record. Madam Secretary, with only one witness, we do not use the lights.

Secretary CHAO. Oh, okay. Thank you.

I do want to address your issues because they are important as well. I do have a little summary.

As you mentioned, the Department's overall fiscal year 2002 budget request is $44.4 billion. It is up from $39.2 billion from the previous year. It is about a 13.27 percent increase. The FTE's is approximately 17,483. The discretionary request is $11.3 billion.

I think it is important to point out here that the Department of Labor's budget is part of the entire administration's budget, prepared with the assistance of all the Cabinet Secretaries and under the guidance of the President and the Office of Management and Budget.

The President's budget, which will grow about 4.1 percent per year, protects Social Security and Medicare, pays down the national debt and provides working families with meaningful, needed tax relief.

At my confirmation hearing 3 months ago, I identified five key areas for the Department that are reflected in the budget that we have submitted today.

And these priorities are obviously: One, to ensure the safety and health of every workplace; to guarantee an honest day's pay for an honest day's work; to fight discrimination; to protect workers from coercion and intimidation; and to make sure workers' pensions are protected.

And, of course, there is the overriding theme that I have worked a great deal on, and that is workforce training and development.

The Department of Labor has done a great deal to protect workers, but needs to do more to prepare workers for the new economy, for dislocations that result from trade, and for changes in skill needs.

And so to bring focus and drive to this mission, a new Office of the 21st Century Workforce has been created within the Department. It is funded out of existing resources.

The Department will hold a summit on the 21st Century Workforce on June 20 of this year, where leaders from business, labor unions, government, and academia will address the fundamental changes affecting our country's workforce and economy.

Let me comment a bit about the five goals. The first goal is to ensure the safety and health of every workplace. There is no question that the Department needs to be in the business of assisting workers through employers before an accident occurs.

Enforcement is a critical part of the Department's job. I am fully committed to that. And OSHA, indeed, has issued about 38 fines of over $100,000 in the last year. But what I have tried to emphasize also is that after-the-fact enforcement is not going to ease a family's grief when a loved one is injured or killed.

And so I would like to put more emphasis on compliance assistance, so that we can truly help workers, to protect them before an accident occurs. OSHA's budget request is $426 million for the 2002 fiscal year. MSHA's is $246 million.

The second goal, of course, is to guarantee an honest day's pay for an honest day's work. And the Department needs to enforce our common sense laws about labor practices, and not just a reflexive one-size-fits-all approach.

The Department's request maintains our worker protection agencies at 2001 levels. We are expanding our efforts in 2002 on compliance assistance activities. And if I can just point out, since 1996,

the Department has realized a 36 percent increase in worker protection programs.

The Employment Standards Administration, which includes the Wage and Hour division, has a fiscal year 2002 budget of $284 million.

The third goal was to fight discrimination. And we are thankful to the ranking member to have helped in the establishment of the Office of Disability Employment Policy.

Mr. Harkin, I know how strongly you feel about that, and we look very much forward to working with you in making sure that the mission of this office is totally fulfilled.

We have allotted $20 million extra on top of last year's. And we expect to have ten FTE's for this office in 2001. And as you well know, the President feels strongly about this as well, because of his new freedom initiative.

The Department also has an important role in worker protection abroad. And as the chairman mentioned, we do have the Department's Bureau of International Labor Affairs.

This Department's program has increased 77 percent over fiscal year 1999. And for fiscal year 2002, the Department is requesting a smaller amount of $72 million, but 100 FTE's for international labor activities. And I will speak more to that, I am sure, as we go on this.

The fifth goal is to make sure that workers' pensions are protected. And I have recently met with Attorney General Ashcroft to ensure that the Departments of Justice and Labor will work together and to protect our workers' pension funds. And Pension Welfare Benefits Administration, which guards the integrity of our Nation's pension funds has a budget request of $108 million.

This pretty much is an overview of the plans for the Department of Labor. I emphasize once again how important it is for the Department not just to react to change, but try to anticipate them.

We want to help workers adjust to a 21st Century workforce. And that is why we are spending a great deal of time on training and development.

There are concerns about the 5 percent reduction in the budget. And as the chairman has pointed out, a great deal of that decision was based on the overhang of unexpended funds.

We do have an unexpended fund balance of $1.7 billion. Usually, the unexpended funds balance is about $1 billion. So this year, we have well over $700,000,000.

So while the budget has been cut back, $542 million, that, again, is more than taken care of by the larger than usual excess from the previous year.

We are also spending $80 million on new technology to ensure that the Department is up to speed. We are spending another, I believe, $40 million on BLS to ensure that the Bureau of Labor Statistics is providing up-to-date and truly relevant information. And it is a wonderful organization.

PREPARED STATEMENT

But I am kind of rambling on, so I will stop here and be happy to answer any questions.

Senator SPECTER. Thank you very much, Secretary Chao.

[The statement follows:]

PREPARED STATEMENT OF HON. ELAINE L. CHAO

Mr. Chairman, and distinguished Members of the Subcommittee, thank you for the opportunity to appear before you today to present the Department of Labor's fiscal year 2002 Budget.

The President's 2002 budget moderates the Federal Government's recent rapid growth in spending while funding national priorities, paying down the debt, and providing tax relief. The Department of Labor's budget request for 2002 follows this responsible approach and will serve as the foundation for us to become a 21st Century Department of Labor.

Before I discuss the specifics of the Department's 2002 request, I would like to highlight a new addition to the Department of Labor. We at the Department of Labor need to provide a beacon of hope, finding solutions for the problems facing our Nation's workers and the economy as a whole. Thanks to the bipartisan work of Congress, we have a new road map—the Workforce Investment Act—to lead us toward this goal. Along with states and localities, the professionals in our Employment and Training Administration are diligently implementing this new legislation. But we need even more fresh ideas, fresh approaches, and new partnerships to help us succeed in this journey. That is why I am creating within the Department a new Office of the 21st Century Workforce to bring focus and drive to this mission.

This Office will be funded out of existing resources and its first responsibility will be to hold a Summit on the 21st Century Workforce on June 20, 2001. At the Summit, I will call on leaders from business, labor unions, government, and academia to address the structural changes affecting our workforce and our economy.

We need to review every aspect of this Department's work to ensure that we are helping, not hindering, the development of a workforce that is ready for the future. We want to give workers the flexibility to custom-design their work to fit their lives—and not the other way around. But I want to make clear that this focus on the 21st Century workforce is about a lot more than just making sure Silicon Valley has enough engineers. Every worker should have the opportunity for a fulfilling and financially rewarding career.

Given everything we are setting into motion with our 2002 budget request, our mission at the Department of Labor must not be just to react to changes, but to anticipate them and help the Nation's workforce adapt to them. Better yet, the workforce should be able to take advantage of those changes. We need to recognize that the 21st Century economy is not the same one we grew up with and that America's 21st Century workforce has to adjust. To help people do that—to give workers constant hope in a changing world—we need to become a 21st Century Department of Labor.

At the Department of Labor, it is about making sure that no worker is left behind—like those who have been laid off from jobs because their company could not keep up with technological changes or foreign competition, those who did not get a full education, or those who made a wrong turn at some point in their lives and are trying to make it back. And, as the President has insisted, we must reach out to those who have been denied the opportunity for a productive, meaningful work life because of a disability. At the Department of Labor, we are prepared to do just that.

As for our fiscal year 2002 budget, the Department's overall request is 17,483 Full-Time Equivalents (FTE) and $44.4 billion in budget authority, of which $13.6 billion is subject to the annual appropriations process and is now pending, Mr. Chairman, before your Subcommittee. The request for discretionary programs is $11.3 billion in budget authority, which is $564 million less than 2001—with a net reduction of 184 FTE. In a country experiencing a current skills gap and a long-term worker shortage, this is a budget request that will allow America to achieve its full potential while still maintaining a responsible fiscal approach with precious taxpayer resources.

EMPLOYMENT AND TRAINING PROGRAMS

The Department's fiscal year 2002 budget for Employment and Training Programs is $6.8 billion. Included in this total is $2.3 billion, which is targeted for employment and training programs for adults—including $1.4 billion for employment and training activities for dislocated workers. In addition, $2.7 billion is requested for youth employment and training programs—including $1.4 billion for Job Corps—to help young people make a successful transition to the world of work and family responsibility.

This budget represents a net decrease of $474 million from 2001, which is largely due to decreases of $359 million in formula grants related to the availability of large amounts of State unexpended carryover which can be used in lieu of new budget authority. I want to be clear, Mr. Chairman: there will be no diminution of service. We are prepared to serve the same number of participants as in 2001. It is estimated that $1.6 billion in unexpended youth, adult, and dislocated worker funds will be carried into 2002—approximately $600 million more than what is typically realized, which is due largely to the implementation of the Workforce Investment Act.

DISABILITY EMPLOYMENT POLICY

The 2002 budget provides $43.2 million and 67 FTE to fund the Department's work toward eliminating policy barriers that impede the employment of people with disabilities.

A particular highlight for the Department is the new Office of Disability Employment Policy (ODEP). The 2002 budget includes $40.6 million and 57 FTE for ODEP, an increase of $20.3 million and 10 FTE over 2001, to support key elements of the President's New Freedom Initiative in areas that focus on integrating Americans with disabilities into the workforce.

The increase includes $6 million and 3 FTE to expand one-stop accessibility grants and support the process of ticket-to-work through One-Stop Career Centers; an additional $6 million and 3 FTE to build on the Youth-to-Work Grant program and ensure that young people with disabilities benefit from youth programs under the Workforce Investment Act; and $8.3 million and 4 FTE for an Olmstead grant program to assist persons with significant disabilities in making the transition from institutional settings to the community and employment.

The Task Force on the Employment of Adults with Disabilities will continue its efforts to create a coordinated and aggressive national policy to bring adults with disabilities into gainful employment. The Task Force will deliver its fourth and final report to President Bush by July 26, 2002, the twelfth anniversary of the Americans with Disabilities Act. The 2002 budget includes $2.6 million and 10 FTE for the Task Force to complete its mission.

WORKER PROTECTION/COMPLIANCE ASSISTANCE

The Department's 2002 request maintains our worker protection agencies at 2001 levels, and we are expanding our efforts in 2002 for compliance assistance activities. An example of prior rapid growth in spending can be found in our worker protection programs. Since 1996, the Department has realized a 36 percent increase for worker protection programs, which significantly outpaced inflation. From providing for the safety of every worker's pension, to ensuring the safety of every workplace, and from ensuring that Federal contractors provide equal opportunities to their workers, to ensuring that all employers comply with the Nation's wage and hour laws, a responsible fiscal approach will allow us to moderate recent growth in Federal spending while still realizing the same levels of worker protection.

I want to be clear on what we wish to achieve: we will continue to make administration of labor laws a top priority, but with an eye toward a common sense, flexible approach that aims to protect workers and help employers comply with the law. To more effectively and efficiently administer our laws, our worker protection agencies will be emphasizing more—and better—compliance assistance as our initial strategy in preventing workplace injuries and illnesses and violations of labor laws.

One example of more and better compliance assistance is the Occupational Safety and Health Administration's approach to implementing its new "Needlestick" rule. We have a proactive strategy to ensure that employers understand this new rule—which includes extensive outreach and educational efforts before rule enforcement. This approach will allow everyone involved—the Department, employers, and workers—to focus on the prevention of needlesticks and other similar injuries to workers.

Worker protection laws are only as effective as the degree to which they are understood and followed. By emphasizing compliance assistance, we help both employers and workers understand not only a rule's requirements but also how best to avoid the injury or illness the rule is designed to prevent. Each time I hear about safety violations that were discovered after an accident that cost the life of an employee, I cannot help but feel great sadness. After-the-fact enforcement cannot ease a family's grief when a loved one is injured or killed on the job. If we really are going to protect workers, we must put more emphasis on prevention. By enforcing laws before injuries or illnesses occur, and by helping employers provide the necessary levels of protection and meet their compliance obligations, we can and will save workers' lives.

LABOR STATISTICS

The 2002 request includes $25 million in additional funding for the Bureau of Labor Statistics, including $8.1 million and 40 FTE for a key step in fundamentally changing the manner in which the Consumer Price Index (CPI) is revised and updated. For some time, the Bureau has worked to improve the accuracy and timeliness of the CPI. The additional funds requested in 2002 are critical to the continuation of this effort, which has as its goal the production of a more up-to-date CPI and should substantially reduce the need for large periodic increases like those historically requested.

INTERNATIONAL LABOR AFFAIRS

The Department requests $71.6 million and 100 FTE for international labor activities in 2002. This request recognizes the importance of promoting international labor standards and reducing abusive child labor throughout the world. I believe the Administration's request helps us to effectively balance our priorities on these critical issues while maintaining sensible spending policies.

Our 2002 request preserves the Bureau of International Labor Affairs' (ILAB) core responsibilities and allows the Department to integrate activities in ILAB with the overall foreign policy of the Administration. In this budget, ILAB continues its work on the global HIV/AIDS initiative begun in fiscal year 2001 and continues bilateral and multilateral projects to assist developing countries in establishing basic labor protections, enabling more and more workers to enjoy fundamental employee rights.

UNEMPLOYMENT INSURANCE

The fiscal year 2002 budget includes a request of $2.4 billion for Unemployment Insurance administration. This is an additional $50 million above the fiscal year 2001 appropriation level, to reflect the increased unemployment insurance claims workload under the President's economic assumptions. The increase reflects an average weekly insured unemployment (AWIU) rate of 2.622 million compared with the 2.396 million level set in the fiscal year 2001 appropriations.

ENERGY EMPLOYEES' OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

The Department's budget includes $136 million and 413 FTE for administration of the Energy Employees' Occupational Illness Compensation Program. In addition, $597 million will provide compensation and medical benefits to eligible workers and survivors.

ADVANCE APPROPRIATION

The Administration proposes to reverse the budget practice of using advance appropriations simply to avoid spending limitations. Accordingly, the amount requested to be appropriated for the 2002 budget is sufficient to provide normal funding, and no advance appropriation is requested. In order to avoid overstating discretionary budget authority in fiscal year 2002, language is proposed to designate the Department's advance appropriation budget authority of $2.463 billion as direct spending. The Administration is committed to resolving this issue in the fiscal year 2002 Budget.

VETERANS' EMPLOYMENT AND TRAINING SERVICE

For 2002, the Department requests $211.7 million for the Veterans' Employment and Training Service (VETS), the same funding level as for 2001. This request includes 250 FTE to accomplish the VETS mission of providing employment and training opportunities for veterans through the public employment service and other employment and training programs, as well as protecting veterans' employment and re-employment rights. The 2002 request continues the funding of the Homeless Veterans Reintegration Project at $17.5 million. This program, as authorized by the Stewart B. McKinney Homeless Assistance Act and title 38, will provide employment and training assistance to homeless veterans, with expected job placements of approximately 10,000.

INFORMATION TECHNOLOGY

A total of $80 million—an increase of $43 million over 2001—is requested for the centralized Information Technology (IT) account to fund the Department's IT investments within four cross-cutting areas: $40.5 million for Enterprise Architecture; $10.6 million for a Common Office Automation Suite; $19.7 million for Security and Privacy; and $9.1 million for Common Administrative Systems. This request will

support the second year of our efforts to replace duplicative and disparate systems with a coordinated approach to provide centralized information technology investments managed by the Department's Chief Information Officer. These IT resources will help ensure program effectiveness among DOL programs and are key to my renewed commitment to compliance assistance through maximum use of technology.

GOVERNMENT PERFORMANCE AND RESULTS ACT

There is a small—but important—amount of $5 million in our 2002 request for a centralized fund to finance program evaluations, primarily in the Department's worker protection agencies. These funds will be used to improve overall program effectiveness and data quality pursuant to the Government Performance and Results Act (GPRA) of 1993. The Department has made significant strides in implementing the provisions of GPRA and we believe that funding for program evaluations will provide data that can be used to further evaluate and improve program effectiveness and data quality. In addition, the Budget request for the Employment and Training Administration includes $9 million to evaluate job training programs, including an evaluation of the Workforce Investment Act's performance management system.

GRANT ACCOUNTABILITY

$1.8 million is requested to improve the Department's administration of grant funds to improve the timeliness, accuracy, and usefulness of financial and performance information. $1.5 million of this increase would go to the Employment and Training Administration to increase its financial management capacity and strengthen program management through specialized oversight and assistance to states and other grantees. The Office of the Chief Financial Officer will use the remaining $300 thousand to develop financial tools for grant programs and provide added oversight to grantee cost reporting.

FEDERAL EMPLOYEES' COMPENSATION ACT SURCHARGE

The President's 2002 budget includes a proposal to amend the Federal Employees' Compensation Act (FECA) to provide for a surcharge, to be paid by each agency, to finance the administration of the FECA program. The surcharge will replace the $80.3 million in budget authority to finance fiscal year 2002 program administrative costs and will be based on the amount of the workers' compensation benefits paid by each agency. The purpose of this surcharge is to boost Federal agency incentives for improving safety in their respective workplaces.

TRADE ADJUSTMENT ASSISTANCE (TAA)/NORTH AMERICAN FREE TRADE AGREEMENT-TRANSITIONAL ADJUSTMENT ASSISTANCE (NAFTA-TAA)

For fiscal year 2002, $415.7 million is requested for the Employment and Training Administration's Federal Unemployment Benefits and Allowances. Legislation will be proposed at a later date to reauthorize the TAA and NAFTA–TAA programs, which expire on September 30, 2001.

Mr. Chairman, this is an overview of what we have planned at the Department of Labor for fiscal year 2002. While the President's 2002 budget presents a responsible approach to meet the needs of America's workers—including funding national priorities, paying down the debt, and providing tax relief—it will also ensure that our Nation's workers are prepared for the 21st Century workplace.

I will be happy to answer any questions you may have about the Department of Labor's budget request.

Senator SPECTER. The balances, which are higher than expected, would not cover—or would it cover the Youth Offenders, where there is a reduction of $55 million?

Secretary CHAO. The Youth Offenders has been combined with another program. And I have Jim McMullen, and Jim is the Deputy Assistant Secretary for Budget and——

Senator SPECTER. That would be fine. We would be glad to hear his response.

Secretary CHAO. Okay. Basically $20 million has been injected. The whole program is $75 million over 2 years. That is the short answer.

Senator SPECTER. Well, to sharpen my question——

Secretary CHAO. I was afraid of that.

Senator SPECTER. Will the Youth Offenders—we have 5 minutes for Senators. We do have lights for Senators. That is true.

Secretary CHAO. It is an important program.

Senator SPECTER. Will the program have less money for fiscal year 2002 than 2001?

Secretary CHAO. Yes.

Senator SPECTER. And——

Secretary CHAO. But over a 2-year period, there will be more. So this has been—the Youth Offender program has been consolidated with another program, so that over a 2-year period, there will be more money and there will be no compromise in the quality of the program.

Senator SPECTER. What is the other program with which it is consolidated?

Secretary CHAO. May I ask Jim McMullen to take it?

Senator SPECTER. Yes. That is fine. If——

Secretary CHAO. Okay. Jim.

Senator SPECTER. We are moving into a lot of technical information and we would be glad to have Mr. McMullen supplement your answers, Madam Secretary.

Mr. MCMULLEN. What we have pending before you right now, Mr. Chairman, is a reprogramming request in fiscal year 2001 to move $20 million out of the Incumbent Worker program into the Youth Offender program, to make it a program totaling $75 million over the 2-year period, between 2001 and 2002.

Senator SPECTER. Well, so are you saying that with the reprogramming, if it is approved, that there will, in fact, be no cut in the Youth Offender program for fiscal year 2002?

Mr. MCMULLEN. No. That is not what we are saying. What we are saying is that we are proposing to increase the amount that you appropriated in 2001 to spread it over a 2-year period. But there is no new budget authority request for the Youth Offenders in 2002. That is correct.

Senator SPECTER. Well, is the program eliminated or simply cut by $55 million in 2002?

Mr. MCMULLEN. It is not eliminated. It is continued through 2002 by this reprogramming request.

Senator SPECTER. And what happens after 2002?

Mr. MCMULLEN. We will address that in the 2003 budget.

Secretary CHAO. I understand your concern.

Senator SPECTER. Well—so I am not following. Will the Youth Offender program have less money in 2002 than in 2001?

Mr. MCMULLEN. Yes.

Senator SPECTER. How much?

Mr. MCMULLEN. Well, the $75 million is for a 2-year period. So you had appropriated $55 million. So if you——

Senator SPECTER. Could you skip the——

Mr. MCMULLEN. If you assume——

Senator SPECTER [continuing]. The reasons and tell me how much?

Mr. MCMULLEN. If you assume the $75 million equally spread over 2 years, it would be $37.5 million.

Senator SPECTER. It's $37.5 million less?

Mr. MCMULLEN. No. That is a total——
Secretary CHAO. No. That is a total——
Senator SPECTER. Well——
Mr. MCMULLEN. No. That is a total over——
Secretary CHAO. Right.
Mr. MCMULLEN. $37.5 million each year——
Secretary CHAO. Right.
Mr. MCMULLEN. [continuing]. 2001 and 2002. So——
Senator SPECTER. Is that the appropriation, or is that the reduction?
Mr. MCMULLEN. That——
Senator SPECTER. This is the sixth time I have asked the question.
Mr. MCMULLEN. The appropriation was $55 million in 2001. And we are proposing to move $20 million more into it to make it a $75 million program to be operated over a 2-year period. If you assumed even——
Senator SPECTER. So $75 million divided by two is $37.5 million——
Mr. MCMULLEN. $37.5 million, right.
Senator SPECTER [continuing]. And if it had been at $55 million, that is a $17.5 million cut.
Mr. MCMULLEN. That would be about a—that is correct.
Senator SPECTER. Which is about a third.
Mr. MCMULLEN. That is correct.
Senator SPECTER. Well, okay. We have the standing to make some modifications in it, obviously, but——
Mr. MCMULLEN. That is correct.
Senator SPECTER [continuing]. That is a danger signal.
And how about the youth activities at $102 million, which is being reduced in 2002 compared to 2001?
Secretary CHAO. If I can ask Mr. McMullen to take a look at that also.
Mr. MCMULLEN. Yes, sir. We are proposing a reduction in the youth area, assuming that the reprogramming that we have pending before you be reduced by about 13 percent from 2001 to 2002.
Senator SPECTER. So is the figure accurate as provided by my staff to me, that youth activities will be decreased—second time I am asking this question—by $102 million in 2002, less than 2001?
Mr. MCMULLEN. Yes.
Senator SPECTER. Well, Madam Secretary, on a priority public policy matter, what is the justification for that?
Secretary CHAO. I think the President was trying to ensure a budget that had fiscal discipline, that was able to meet the key priorities of our Nation, protect Social Security and Medicare, and hopefully also put some money back into the pockets of working men and women in—of America.
Senator SPECTER. You are not going to tell me that the tax cut is taking this money. That is going to very materially weaken the case for the tax cut.
Secretary CHAO. Well, this is the beginning of a dialogue that I am having with the committee. And so what I am learning, obviously, is the concerns and the priorities of the committee. And so I appreciate the opportunity to learn about this.

Senator SPECTER. Well, I really do not think that these cuts do impact on the tax cut. I just made that comment, when you say putting money back into the pockets of the taxpayers, which I think is a good idea.

And we are really looking at an overall budget. And my red light is on, so I will just make this brief comment and turn to my colleague Senator Harkin.

We are looking at a decrease in budget which is very material, $562 million, and when you have an overall increase that the President has proposed by four percent—and that may be adjusted upward.

I do not know what is going to happen. The Budget Committee has not yet concluded its work. And I realize that you have to negotiate with the Office of Management and Budget. And that is the executive branch and these figures have to be worked out.

Our interest on the subcommittee level is to try to get, to the extent we can, the administration's thinking, as we try to establish a total budget for our subcommittee, which was at about $108 billion last year; and then how we make the allocations to all the departments.

But as I take a look at some of these cuts, I think we will have some suggestions for you.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

Madam Secretary, several years ago, the Department of Labor, at my urging and Senator Specter's, began to—began a process of taking a look at the use of child labor around the globe and how that was impacting our country and impacting world trade.

The Department of Labor, U.S. Department of Labor, has put out five volumes. I recommend them to you. You do not have to read every one of them, but I recommend you at least take a cursory look at those.

Five volumes over the last—how many years? Seven years, maybe—about 7 years, on various aspects of child labor around the globe, including child labor in this country. As that process moved forward, we began on this committee to take a look at our obligations in the international labor organization and what we might do to help a program called IPEC, the International Program for the Elimination of Child Labor.

I felt at that time, and I think a lot of people felt that the United States ought to stand as a leader, as a beacon to the rest of the world in terms of eliminating child labor, that we should not just get along and go along, but that we ought to take concrete action to help reduce the incidents of child labor around the globe.

To that extent, this committee and, along with the House, began to increase funding for that program that is called the IPEC, the International Program for the Elimination of Child Labor. And so we started putting money into it. And that went up to—the final appropriation last year was $45 million for that, up from $30 million the year before.

Concurrently, along with that, one of the problems that I have seen as I have traveled around the world and looked at the issue of child labor in other countries, is the problem of education, that you cannot just take these kids and take them out of some of these

factories and plants and—surgical instruments and clothing and things like this, most of whom are girls, women, young girls, and dump them out.

So the—there is a program that was started that was an educational aspect of this program to provide support for educational programs for these children who were taken out of these plants and out of these factories in some of these countries.

And so we began a bilateral program with other countries for education. Now, I have, on my own, seen the results of this in some other countries and what has happened.

And it really has been startling to see these young girls, some of them 10, 11, 12 years old, and they have been working in these plants for 2, 3, or 4 years, since they have been 8 years old. They do not know how to read. They do not know how to write. They do not know basic arithmetic.

They have been taken out of these plants. They have been sent to school. They have been given materials. The families have been given a little bit of a stipend to replace some of the lost wages.

And if you ever want to have an uplifting experience, go to one of these countries—I do not need to name them all here—and just see some of these young girls, who are now 13 years old. And they can read. And they can write. And they can do basic arithmetic and math. What has happened to them just in the last 2 or 3 years has been remarkable.

And so the United States is now taking a lead in this; and I think for good cause and for good outcomes and to help end the discrimination that we see around the globe on child labor.

Well, we put $45 million in it last year, into IPEC. We added $37 million for the education program. Your budget cuts the IPEC program by, considerably, from $45 million to $30 million, and you eliminate the educational aspect that we put $37 million in last year. And it cuts 17 FTE's in that program.

Well, Madam Secretary, I think this is a vitally important program. It is one that we have been making slow progress on over the last several years through the Department of Labor. I think the Department of Labor has moved to the forefront of this.

I believe in the international community, as I have met with international labor organizations and others, they are now looking upon the United States as being a leader in the elimination of child labor and the promotion of educational benefits for these kids.

I think it really is a step backward for us to try to zero this out and to reduce the funding for it. And I would just like to have your comments on it.

Secretary CHAO. I would be pleased to. You mentioned visiting countries in which these child labor practices occur. I have visited them. I have been with the Peace Corps, and I have visited many countries. There is no doubt that this is a serious issue, and we all care deeply about it.

I think the larger issue is whether an office such as International Labor Affairs Bureau, is able to absorb the money because in 1996, the budget of the ILAB was about $9 million. In 2000, the funding was increased to about $76 million. And in 2001, the funding was increased to about $147 million.

That is beyond the capacity of one office to absorb. And one way obviously to absorb that money is to contract out $70 million of it.

I do not know whether that, indeed, is a responsive way of doing it, and certainly you can contract out $170 million or whatever to organizations overseas.

So please be assured that we are not differing at all in terms of the goal. We want to work with you on this. The issue is how best to do so, and how we can work and how ILAB can absorb all this money in such a short period of time. But the commitment, I assure you, is absolutely there. And we look forward to working with you on that.

Senator HARKIN. Well, I will work with you on it.

All the indications I have is that this money is well utilized and they could absorb this increase.

I would be delighted if you want to give me some written documents to show that this money is not being utilized well.

Every indication I got was that it was well utilized and that they were able to handle this. If you are telling me it was not, I would like to have some information on that.

I just think to go from $37 million to zero is really turning it—I mean, obviously they could do more than zero on education.

Secretary CHAO. But the budget of the whole office is the International Labor Affairs Bureau. I think I was asking for clarification as to the difference between ILAB and IPEC.

ILAB, itself, under which this program falls, has a budget of $74 million that went up to about $140 million. So that is a lot. And I think that was the absorption issue.

Senator HARKIN. Over 3 years. That is because of IPEC and the education.

Secretary CHAO. Yes.

Senator HARKIN. So——

Secretary CHAO. And so a large part of that was just contracted out. And if you want to build the infrastructure, internally, that will take some time.

Senator HARKIN. But my staff just said—you are talking about ILAB, but the IPEC program is something that has been going on for years.

Secretary CHAO. Yes.

Senator HARKIN. This is not something new. It has been going on for many years.

Secretary CHAO. This is part of ILAB though. And the funds are fungible.

Senator HARKIN. The program, IPEC——

Secretary CHAO. Yes.

Senator HARKIN [continuing]. International Program for the Elimination of Child Labor has been going on for a long time. This is not something new.

Secretary CHAO. I have been told it is new. Let me look into it for you, and clarify that.

Senator HARKIN. Well, okay. Just——

STAFF. The education part is——

Senator HARKIN. Yes. The education part was new. That is what we started. I look forward to working with you. I just think it is not right to be backing off on that right now.

Let us see. I just had one other area. According to the OSHA strategic plan, you specifically cite the Susan Harwood training grants as one of the main tools your Department intends to use in OSHA's mission, which is improving workplace safety and—and health.

These grants provide funding to non-profit organizations to conduct safety and health training and education in the workplace.

Yet on March 29, you sent a letter to the 2001 awardees, informing them that you rescinded the funding, citing budgetary reasons. One of the grantees, Kirkwood College in Cedar Rapids, Iowa, had received a $381,000 award. These grants were funded through the fiscal year 2001 money that this committee appropriated last year.

Secretary CHAO. Yes.

Senator HARKIN. So, again, I wonder: What are the budgetary circumstances that necessitated taking this funding away? If, in fact—you also said that you specifically cited the Susan Harwood training grants as one of the main tools. Then you send a letter out saying that you are going to rescind the funding.

Secretary CHAO. Let me backtrack a little bit. These grants were given on a 3- to 5-year basis. And so the grants were given basically on the basis of an old budget. In our going through the budget this time, we found that there was not enough money.

So let me just also say I have heard a great deal of concern expressed on this, not only from you, but from other people. I have received lots of letters. And so that is another area that I will be looking at.

These grants will not be terminated. We are asking for new solicitations for a 1-year term. So those grants will go forward. Instead of the 3- to 5-year time frame that was being talked about, we are going to go for 1-year grants and take a look at receiving applications for 1 year.

We are encouraging people, in fact, to reapply. Although, it will be a 1-year term instead of 3 to 5 years.

Senator HARKIN. These grants that went out were not 1-year grants.

Secretary CHAO. No. They were not. They were 3 to 5 years. And we did not have the funding at that time, which is why we are going out with a new process.

Senator HARKIN. Okay, explain—let's take Kirkwood College in Cedar Rapids. They had received a $381,000 award. We put the money into it. We appropriated the money for that program there.

Now, you write a letter saying "We are rescinding that money." Why?

Secretary CHAO. Yes. Because it was for a commitment of 3 to 5 years that this administration was not ready to commit to at this point. So we would like to start the program anew and go out with a 1-year application process.

Senator HARKIN. But I mean at least the money that went out——

Secretary CHAO. Yes.

Senator HARKIN [continuing]. Why did you rescind that money? If you want to do something else next year, come in and do something this year. But as I understand it, you are trying to rescind this money.

Secretary CHAO. Well, people are just restructuring the program from a commitment of 3 to 5 years to 1 year.

Senator HARKIN. So——

Secretary CHAO. We are encouraging people to apply.

Senator HARKIN. So Kirkwood is going to receive their $381,000 then?

Secretary CHAO. I do not know whether that is a 1-year or a 3- to 5-year commitment, but we encourage them to apply again for a 1-year grant. And I certainly would understand your concern with that.

Senator HARKIN. My staff tells me that Kirkwood got 1-year money with the possibility that it could be extended beyond that.

Secretary CHAO. Well, they are, again, invited to apply again for the 1-year grant.

Senator HARKIN. Well, I do not really understand that.

Secretary CHAO. Instead of making a commitment for 3 to 5 years, we are saying: This is a new administration. We would like to have the opportunity to review some of these grants. But please apply for a 1-year timetable, instead of a 3 to 5. So that gives us some time to evaluate some of these grants.

And it is not a political process. I mean, the same people will be going through it, the same career professionals. So we, in fact, would like people to apply for a new grant, but just a 1-year grant.

Senator HARKIN. Well, I will take a look at that. I do not know. I——

Secretary CHAO. And I appreciate your bringing that up to me. Clearly, you are concerned about that one.

Senator HARKIN. Yes. We have got to take a——

Secretary CHAO. I am very much aware of that.

Senator HARKIN. We have to take a look at that.

Can we go back to ergonomics here for a second?

Secretary CHAO. Yes.

Senator HARKIN. Last week, I asked how much of the budget would be dedicated to reviewing the—this whole issue of ergonomics with this—I—and as I understand, what you are doing is you are moving ahead to develop a new standard.

You said that there was some problems in the rule. It needed to be more thoroughly reviewed. Okay. Fine. That is certainly that is your power to do that as Secretary and this administration, because the old rule was done away with.

But as I understand from your statements that you want to move ahead with a new rule, with looking at a new rule and—and getting information on looking at the problems of the old one.

Okay. If you are going to do that, then it is my understanding that the budget for the development and evaluation of Occupational safety standards is cut by $1.2 million. So, again, given your statements that, "The rule was problematic. We need to thoroughly review it and come up with a new rule," how can we cut the budget by $1.2 million?

I was asking you also last week how much funding does your budget allow for review of this issue?

Secretary CHAO. Right. The OSHA standards budget is approximately $14 million. Now, not all of that will be for ergonomics, be-

cause it has not been earmarked. But potentially all of that can be available. So that is the—the overall pot.

We have an overlay—you know, an overhang of $1.7 billion. So a lot of that overlay is going to be funding. Because the cut in the budget is only $562 million, the larger-than-usual increase in the overhang of unexpended funds is over $700 million.

So that is why I was saying that enforcement will not be compromised, that none of these programs will be compromised, because, again, we have this overhang of unexpended funds.

Senator HARKIN. My staff informs me that all of that unspent money is in training, not in OSHA.

Secretary CHAO. You are right. I stand corrected.

Senator HARKIN. So what—okay. Then we come back to OSHA again.

Secretary CHAO. The OSHA also—some of the decrease also is because of the cost of living adjustments in terms of FTE's.

Senator HARKIN. Well——

Secretary CHAO. So that took up some parts of the budget.

Senator HARKIN. Again, Madam Secretary, I want to ask you again, with all due respect, you know, if we are moving—I am taking you at your word. And I am taking the administration at its word, since you represent the administration, that you had problems with the old ergonomics rule, that you want to look at the problems that were in it, and you want to come up with a new rule.

Is that my understanding, or am I wrong in understanding that?

Secretary CHAO. No. I have not committed to any course of action. So I have not committed to a rule.

Senator HARKIN. Well——

Secretary CHAO. I wanted the opportunity to take a comprehensive look at this whole issue.

Senator HARKIN. So you are not committed to coming up with—because I—we got into a little bit of a debate a week ago about a time frame. So now you are telling me you are just going to look at it.

Secretary CHAO. No. I never said that I was coming up with a rule.

Senator HARKIN. So you are not coming up with a rule.

Secretary CHAO. I am not dismissing it either. But I have never said that I was going to come out with a rule.

We have been in office basically since February—or January 20. The C.R.A. did not occur until March 20. So until the C.R.A., there was an existing rule. So we have had less than a month.

Senator HARKIN. Well, I just—your statement here on March 28 said—you say in your own statement is that, "However, musculoskeletal injuries accounted for nearly one-third of all the injuries. This finding demonstrates the need for a solid comprehensive approach to ergonomics."

Secretary CHAO. I totally agree with that.

Senator HARKIN. But that does not mean a rule?

Secretary CHAO. Well, I have not decided yet. I am not saying there will not be a rule either. I think the responsible way to approach it is that there is a new team in town. And I think we have to feel comfortable with taking the appropriate course of action. And we need to talk with the administration.

Senator HARKIN. Well, unfortunately, I wish I knew what that course of action was going to be. I mean, I have just——

Secretary CHAO. Well, I cannot——

Senator HARKIN. I mean——

Secretary CHAO. I wish I knew as well. But if I did, I would be working out of a preconceived position. And I said that I would keep an open mind and that I would talk to stakeholders, that we would review the past record, that we would talk to all different groups.

And, in fact, in my previous testimony, I had talked about certain principles that we would have going forward. And that was basically to go from a basis of prevention. We all agree that reducing occupational injuries and musculoskeletal injuries is our goal. And the question is how best to do that.

And I listed six principles. One is prevention. Two is some program based on sound science. Three that it be incentive driven, so employers would really embrace it as well. Four, some flexibility.

Senator HARKIN. Well——

Secretary CHAO. "One size fits all," I do not think does it. Five is feasibility; and six, clarity. So at this point we have not made a decision.

Senator HARKIN. Well, that is fine, but——

Secretary CHAO. We are proceeding in good faith to address this issue.

Senator HARKIN. Fine. And every time you are here, I am going to ask you the same question.

Secretary CHAO. I understand that.

Senator HARKIN. I am going to try to find out when we are going to start moving on this.

And, fine, if you do not have a timetable now, well, we will ask it the next time. And we will see when we are going to get some timetable and move ahead on this.

Secretary CHAO. I understand, yes. I would love to have a timetable. I think that would be very comforting.

But what we have seen on this issue is that when artificial time lines are imposed, workers do not benefit. None of us benefit because——

Senator HARKIN. Well, Madam——

Secretary CHAO. I——

Senator HARKIN. Madam Secretary, also workers do not benefit when this dribbles along year after year after year, and nothing is ever done.

Secretary CHAO. But we are not talking about years, obviously.

Senator HARKIN. More injuries continue to happen. More people suffer. And so if I get my druthers, I would rather have a time line because it forces people to do something and get something done by a certain time. But if you do not have time lines, it just dribbles on year after year after year.

Secretary CHAO. I understand exactly what you are saying. I am very concerned about it. If I may just add one last thing, we had a time line before with the previous administration and it did not work. So I want to make sure there is not a repeat of any action that can be reversed.

Senator HARKIN. Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Harkin.

Madam Secretary, on the worker protection line, the President's budget maintains the activities at last year's dollar level, but as a result of inflation, there will be a reduction in staff enforcement.

That leaves less staffing than is in effect for this fiscal year for OSHA enforcement, mine, safety and health administration, and employment standards administration.

Is it not, simply stated, a bad idea to reduce staff on those very important lines of enforcement?

Secretary CHAO. I said before—I am trying to answer the question directly. There is no question that we are for enforcement. And in looking over this budget, there is no compromise to the quality nor the intensity of enforcement. We are going through all of these reductions through attrition.

And also I think one has to make the assumption—one has to look at whether these positions were the right numbers to begin with. And so we are committed to going through, looking at the numbers to see whether this, indeed, is the enforcement that we need, but there is no lack at all in commitment—in backing down in commitment on enforcement.

Senator SPECTER. Well, Madam Secretary, when you say you are committed to enforcement, there is no showing that there are too many people in these enforcement lines. And if you reduce the number, the enforcement is, simply stated, going to suffer. Well, we will take a look at that too, but that is a big problem.

We have already gone over the cuts in the job training programs, the youth program, the Workforce Investment Act, and the dislocated worker programs. We will review those here.

Let me take up a different subject with you on medical resident work hours. The Federal Government limits the number of hours that truck drivers and airplane pilots can work, among others. And there is a big issue on medical resident work hours, where physicians work up to 80 hours a week, without a day off, and sometimes more than that.

And there is a good bit of evidence accumulating about sleep deprivation associated with these long hours resulting in automobile accidents, depression, and giving birth to premature infants. I am reading a list of the factors, which have been called to the subcommittee's attention.

And then you have the basic problem of people who are being treated by these residents who are, simply stated, groggy, and simply cannot perform.

There was a petition filed on April 30 to OSHA from healthcare professionals seeking a Federal limit on the number of hours medical residents can work. What do you think?

Secretary CHAO. I just learned about the petition on Monday, so I have not had an opportunity to review it. Obviously, if the Chairman is concerned about it, I am concerned about it. And I will take a——

Senator SPECTER. Well, perhaps we ought to have a hearing on that specifically. I realize that it has just been filed and there is always a reluctance to increase Federal jurisdiction. Especially when you talk about hospitals with the Balanced Budget Act, their economies and sort of an unwritten code that if you want to be a

high and mighty doctor, you have got to suffer a lot going through on the resident process, and the argument is made that they make up for it later.

But this is a real problem for those who are going through it. And it is a real problem for people who are in hospitals that received their services.

Secretary CHAO. I might also add, probably we have to talk to HHS about this as well.

Senator SPECTER. Turning to still another subject, there has been a long-standing problem with the Amish—a good many of whom are in Lancaster County and are constituents of mine—on an effort to have Amish youth, 14 to 18, work in sawmills.

The House of Representatives has twice passed legislation to allow that. We have had legislation pending in the Senate, which I have introduced. What I would like you to do is to take a look at that.

It is a fairly involved and fairly technical subject, unless you already have a view on it. Tell us what you think about that.

Secretary CHAO. I am very sympathetic. And, obviously, as I have said before, concerns by members resonates strongly with me. I will take another look, but the preliminary response that I have gotten from Wage and Hour is that this has to be a legislative fix.

Senator SPECTER. It has to have a legislative fix?

Secretary CHAO. Yes, and that they do not have very much flexibility in reinterpreting that.

But on the other hand, I do not have my solicitor in place or lots of other people in place. I will take another look.

Senator SPECTER. Well, take a look. It is a little early for you to really be expected to have a comprehensive view of that, but it would not be unkind to say that it may be a bureaucratic response to say there has to be a legislative fix.

Secretary CHAO. Well, I am hoping that, you know, as I get my team staffed up, that we will be more responsive, and we will be able to answer a whole host of questions.

Senator SPECTER. The President has a lot of discretion. And he has delegated that discretion to the Secretary of Labor, so let us take a look.

Secretary CHAO. I will do so.

Senator SPECTER. I think administratively would be a much better way to handle that.

My red light is on again. So I am going to yield to my colleague. Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman.

And, Secretary Chao. Welcome. It is good to have you here, and I am—let me just say at the beginning, I am encouraged by what I see in your Department's proposed budget.

Increasing funding for the Department by $5.2 billion, I think, is a positive sign in providing adequate resources for programs like Job Corps and funding for the Office of Disability Employment Policy and other critical assistance programs, I think, is essential.

I am concerned, however, about some of the decreased investments for job programs that help at-risk youth and funds employment and training activities for dislocated workers.

And let me start by asking you about at-risk youth. I think we all know that the job requirements, the education requirements, the training requirements for our work force have changed dramatically in the last decade. And today, more than ever, our workers need more education and training to develop the skills they need for the—the jobs that are out there today.

And I am really very concerned that your budget provides $222 million less for youth employment and training programs. We cannot leave young people out of our country as we move forward. And I would appreciate it if you would address that cut in your budget.

Secretary CHAO. There is no commitment, obviously, to backing away from helping youths at risk. It is an issue that I feel strongly about, and I have worked with in the past.

I mentioned before that there was about $1.7 billion in unexpended funds. And the usual carryover is about $1 billion. So we have an extra $700 million. The cuts from the budget is only about $562 million. So the carryover still takes care of the overall reduction.

The youth carryover is about $480 million, so we can maintain the service levels.

Senator MURRAY. The carryover from last year's budget?

Secretary CHAO. So we, again, do not expect any diminution of service or commitment, obviously. But that we believe that we can maintain the service levels.

Senator MURRAY. Were those funds that were appropriated and not spent?

Secretary CHAO. Yes.

Senator MURRAY. I hope then that you have a commitment to make sure that those grants and opportunities move out there for our young people. There is a high increasing demand for that.

Secretary CHAO. We will do so.

Senator MURRAY. Okay.

Secretary CHAO. And there is also a reprogramming request of $20 million that makes for a 2-year budget request of $75 million. So we went over that a little earlier. But participants will not go down because, again, the number of participants will not go down and the quality of the program will remain undiminished.

Senator MURRAY. I think it is—good. Yes. I think it is really important that we emphasize that we do not want to see our kids on the street with no skills.

Secretary CHAO. Yes.

Senator MURRAY. Second, I am very concerned about dislocated workers. In my end of the country, we have seen a lot of dislocation, unexpected, in the last year or two, particularly with the current energy crisis that has shut down some of our mills and aluminum companies and threatens more, very—in the very near future. We have seen over 2,000 layoffs at this point and we will be seeing more.

Boeing has had some layoffs. Our high-tech industries are not employing and—and having layoffs. And I am very concerned that your budget has decreased adult employment and training programs by $257 million.

I think the demands for these dislocated workers are increasing. And if you could address that, I would appreciate it.

Secretary CHAO. There is also some talk about a softening economy, so this is obviously an area that we are concerned about. We want people to be able to find assistance.

The dislocated workers program, again, is one of those programs that we do not expect any diminution of service nor quality, because of excess funds from the previous years.

I know that in your particular State, you have got special concerns. And I will be more than glad to work with you on those concerns, as well.

Senator MURRAY. Okay. I would really appreciate your doing that, because we are seeing a lot of dislocation. We are going to see more. And we want to make sure that these people land. So I would very much like to work with you on that.

In a place where we are seeing a lack of workers is the nursing shortage that we are currently seeing that I am very concerned about. Our healthcare facilities, our long-term facilities are very concerned about the lack of healthcare workers that are coming into—into that.

And we are currently working in the Senate now on legislation to provide $500 million a year for the next 3 years in grants to States to promote the nursing profession and to help long-term care providers, to recruit and train and retain caregivers at all levels.

Would you be supportive of that kind of an approach?

Secretary CHAO. I have talked a lot about the skills gap. I think this is clearly one example. So I have set up a new office called the 21st Century Workforce. And this is one of the areas that we are going to address, for example, at the summit that we are holding on June 20, and as we go forward as well.

Senator HARKIN. Okay. Well, Secretary Thompson testified before the committee last week that part of the solution might be tied to allowing more foreign nurses and healthcare workers to immigrate to the United States to help fill that void.

Would you be willing to work your Agency with his to talk to the Department of Justice and Immigration and Natural Service to try and enact something like that?

Secretary CHAO. We would be interested in exploring this option further with him.

Senator MURRAY. Okay. I think it is important that we look at all ways to meet that need.

Secretary CHAO. Right.

Senator MURRAY. So I encourage you to do that.

On an entirely different topic, I want to talk about asbestos for a minute. Most people in this country think that asbestos has been banned and they do not have to worry about it. But asbestos has not been banned in this country and in some cases, it is still being used to manufacture automotive brakes and roofing materials.

And we are seeing it show up in consumer products like crayons, garden fertilizers and insulation. Because asbestos is a contaminant found in deposits of other minerals, that is why we are seeing that.

Evidence has suggested that workers have died from exposure. The case in Libby, Montana, where 192 people have died has been very prominent in the news. And 375 people are currently suffering from fatal diseases caused by that exposure.

I was curious whether you were familiar with the Inspector General's report on MSHA's handling of inspections in the mine in Libby and with the recommendations that are in that report.

Secretary CHAO. The I.G. has handed that report to me about, I would say, 3 weeks ago. We are in the process of going through that.

I do not have an MSHA administrator yet. He has been announced and nominated. We hope that he will be confirmed soon, so that he can tackle this issue as well.

Senator MURRAY. Well, when he is in place or even before, I would like to work with your Agency to make sure that we address that and implement the recommendations that require rule—rulemaking as quickly as possible.

And I see that my time is up. Thank you.

Senator SPECTER. Thank you very much, Senator Murray.

Senator Harkin, do you have one more question or——

Senator HARKIN. Just one more question.

Just picking up on what Senator Murray was talking about on the employment and training money that you said there was this carryover. First of all, I understand that the amount—that even though you have a large carryover, the amount varies per State.

Secretary CHAO. Yes.

Senator HARKIN. And so dislocated worker funds go to States on a formula basis.

Secretary CHAO. Right.

Senator HARKIN. Therefore, every State will take the same percentage cut even though some States may have a big carryover and some States may not have much carryover.

Well, here is the point I am getting to: My staff at my direction requested an analysis, because I wanted to know what was happening in Iowa, obviously, my State. I wanted an analysis of the unexpended carryover funds in employment training programs by State. About a month ago, my staff requested this breakdown by State.

They were told by your staff that a table—there was a table. We have asked repeatedly as late—as late as yesterday to get this, but your Department will not release it. So I am asking: Will you release to me the information that will allow us to understand the impact on the cut to my State—and our States?

Secretary CHAO. I see no reason why you cannot have that at all. So I am not aware of that request. But you will have it.

Senator HARKIN. If you can get that, because I would like to see, because it does vary State by State.

Secretary CHAO. Sure.

Senator HARKIN. And if you are going to take a cut that is percentage, some States may be fine. Some States may not be fine. And I think we, as appropriators, need to take a look at that. And I would appreciate it.

Secretary CHAO. I think that is a very reasonable request.

Senator HARKIN. I appreciate it. Thank you very much, Madam Secretary.

Thank you.

Senator SPECTER. Thank you. Thank you, Senator Harkin.

Madam Secretary, the hearing that we had on last Thursday on ergonomics showed a very, very deep split between some segments of the business community and those representing the workers.

And I know your schedule precluded you from attending the full hearing, but we have given you the transcript. We ordered expedited transcripts so that we could take it up today.

Do you think that there is any realistic likelihood that there can be a consensus on an ergonomics rule?

Secretary CHAO. No, I do not; 100 percent consensus, no. But I think there has to be some critical mass upon which to move forward because without that critical mass, I do not think any program is going to be successful.

So I am keeping an open mind and I do not have any preconceived notions. I am keeping all options open. As I mentioned in my letter, it may include rulemaking. I have not ruled anything out. I have not made a final decision.

We have only had since March 20 when the C.R.A. was pleased to take a look at this. And I can assure you that we are proceeding with full speed and with absolute seriousness and intent to try to address the ergonomics and musculoskeletal injuries.

Senator SPECTER. When you say that you are proceeding at full speed, precisely what are you doing?

Secretary CHAO. We are meeting with—well, this is a new team also. And I think we need to be given time to, No. 1, meet with the shareholders, and go through the past record.

In terms of making up a new rulemaking, we cannot go back to the previous record and draw—well, there is some question as to whether—and you know better than me. There is some question as to whether we can go back to the previous record and just utilize the information of the previous record, because there were issues expressed about, not only the substance, but also the process.

So I think at the very start, we need to go back and talk with all the stakeholders. I think we have done a good job. We have met with multiple groups in an effort to listen to everyone, first of all, and then try to craft some program for moving forward that will not be stymied right from the outset.

Senator SPECTER. Well, Madam Secretary, I think it is reasonably clear that you can go back and look at the information which was compiled before.

Secretary CHAO. Yes.

Senator SPECTER. You are going to have to satisfy yourself as to an evaluation of it and to have an opportunity for people to comment about it. But you can take a look at what has been presented in the past.

Secretary CHAO. That is true.

Senator SPECTER. This subcommittee wants to, in its oversight capacity, monitor what you are doing on a time line.

I take it from your response to Senator Harkin's question that when I asked you to go back and take a look to see if you could give us a time line or a concluding date, that you have thought about that but do not think you can give us a target date.

Secretary CHAO. I would love to, if I could, but I just do not think I can. I do not think that is a responsible way to approach it. I am

not going to drag this out. I can assure you of that. But I think for me to come out with a deadline would be very irresponsible.

Just to let you know, we have met with United Commercial Food Workers. This was in my testimony last time. We have met with the AFL–CIO, Service Employees International Union, United Brotherhood of Carpenters and Joiners. We met with a lot of labor groups, a lot of—American Occupational Therapy Association, Food Marketing Institute, certainly on the other side, American College of Occupational Environmental Medicine.

So we are conducting our due diligence in meeting with these various groups. We are going back to the record. There were 11,000 comments on the old rule in just a 12-month period. We are not obviously going to go through the whole thing, but there have been criticisms of the process.

And while we can go back, obviously, and take a look at the previous record, there has been some criticism as to whether that record is inclusive of other types of information.

And also there have been concerns about—comments were submitted by citizens, you know, that were farmed out, paid outside consultants. I mean, this is pretty—this is a very complicated issue. It is very complex.

I am not interested in slowing it down, but I do want to do it right. And, again, I want to do it right because we have got to do the right thing; otherwise, another overturned action can occur. And I am not so sure that benefits anyone.

Senator SPECTER. Well, I daresay that something that the Bush administration comes up with is not likely to be overturned. The action by the Congress was highly unusual. And I supported overturning the regulation, because I thought it was excessive and others did too, where there were some expressed commitments made by legislators, by Senators that there would be a new rule.

Now, they do not bind you, but this is something we will be talking about within the Senate, where we have a lot of experience on this issue. And the people who were strenuously opposed the rule were able to persuade a number of us to vote to overturn that rule on the representation that there would be a new rule.

Now, I understand the articulation you have made. And they do not bind you, but we are all players in the process, and we all have a role in the process. And those who made those representations to secure votes on the Senate floor have some impact and some weight.

Let me raise a question as to your use of the term "irresponsible" to come up with a——

Secretary CHAO. Well, let me answer the previous point. If other people have made representations, then those are the people that should—that should be—that this matter should be discussed with.

I stated very plainly in my letter that I was not ruling out rulemaking, but I was not committed to it either. So, again, if there are other people who made other representations, then they should be talked to.

Senator SPECTER. Well, you can bet they are being talked to. You can be sure of that.

I have already made it abundantly clear that I understand they do not bind you. There is this doctrine called separation——

Secretary CHAO. I am very interested in having a good relationship with this committee and especially with the chairman and the ranking, so I hope you will realize that I will—I am looking at this from a long-term point of view. I would never play any short-term games or anything like that. And I hope that you understand that.

Senator SPECTER. Well, I was about to say I understand the doctrine of separation of powers and that you are an Article II officer, and we are Article I officers. And we do not really rate very high anyway.

Secretary CHAO. That is not true at all, not——

Senator SPECTER. Since——

Secretary CHAO. You rate very high in my book.

Senator SPECTER. Since *Marbury* v. *Madison,* neither Article I nor Article II officers rate very high. The Court decides everything these days.

But I was starting to raise a question about the use of the word "irresponsible." To say that it would be irresponsible to accept a time line when the subcommittee is pressing for a time line, I question that characterization.

I do not think we are asking for something which is irresponsible. There is——

Secretary CHAO. I think that it is irresponsible on my part. It is not to say that there is any—that is not to attribute that to anybody else but me.

Senator SPECTER. Well—but if the subcommittee is asking for a time line, and a time line is irresponsible, somebody might raise the inference that we are asking for something which is irresponsible. So I just——

Secretary CHAO. And I certainly did not imply—I did not mean to imply that.

Senator SPECTER. I just question the use of the word "irresponsible." Unrealistic, impossible, difficult—"irresponsible" is a word that has a lot of——

Secretary CHAO. I will use one of the other words from now on.

Senator SPECTER. I know you are familiar with Senate bill 598, which proposes legislation to establish a time limit of 2 years for the enactment of a rule. What do you think about Congress telling you that you have 2 years to make a rule?

Secretary CHAO. I know that you are a co-sponsor of that.

Senator SPECTER. Senator Harkin is not, though. He is still safe.

Secretary CHAO. I know that you are a co-sponsor of that and, obviously, we are very cognizant of the amendment. We are working with—we would like to work with Senator Breaux and the sponsors on this.

A 2-year time frame, as told to me by the career professionals in the Department, is unrealistic. It is very hard to say pro forma how long a particular rulemaking would take. But 2 years for this kind of rule seems overly ambitious. But, again, we want to be in discussion on this issue.

Senator SPECTER. Well, okay. I mentioned the bill, because the Breaux bill does set a time limit. And it is possible that bill could be enacted.

And my preference would be not to have the time limit come from the Congress. My preference would be to have the time limit come from the Secretary.

So I would ask you, on behalf of the subcommittee and the committee and the Senate and the Congress to take another look at this issue to see if you cannot give us some idea as to how long it is all going to take.

Secretary CHAO. I will certainly do that. Let me also say, you know, given all the pressure that I am under, it would be a lot easier for me just to give a deadline. It would make my life a lot easier. It would make a lot of—certainly, would make my life a lot easier.

But I have been there for, again, for 3 months. I want to do the right thing. I do not have an OSHA administrator yet. I have only got two people that are confirmed in the Department.

You know, Mr. Harkin was talking about responsiveness from the Department. The career professionals are wonderful. I devote a great deal of time cultivating the relationship with them. But we are a new team. We want to be responsive. We are not there yet. I fully understand that.

But as we get staffed up, as we get more familiar with some of these issues, I hope that you will think that we are responsive as well.

But, again, let me say, from a personal pressure point of view, it would be so much easier for me to say, "I can give you a deadline." But, again, I do not think that that is something that will benefit any one of us in promulgating a truly good program.

So let—and as I have said before, I want to work with you and also Senator Breaux on this amendment. And so my staff, I believe, has been talking to all of you. And I would hope that that will continue.

Senator SPECTER. Madam Secretary, we have taken a look at the plans at Levi Strauss, Xerox, Consolidated Edison, United Auto Workers, all of which have put ergonomics programs into effect with very beneficial results.

One of them, Xerox, had a 24 percent decline in the number of worker's compensation cases. So we would commend to you what is going on in the private sector as a model.

Secretary CHAO. Yes.

Senator SPECTER. And we understand UPS also has done some good work. And we have written to UPS. And the point was made that some of the companies have not responded to the Department of Labor, like UPS, on giving them the benefit of their thinking and their successes. And this subcommittee is in a position to help you. Do you——

Secretary CHAO. Well, I appreciate that.

Senator SPECTER. Do you know if you have the subpoena power to compel, say, a company to come forward and tell you what their experience has been?

Secretary CHAO. No, I do not. But I think that is a pretty bad example, if we have to compel them. I am not so sure their results were—what—are ones that I want to hear.

Senator SPECTER. Well——

Secretary CHAO. We are looking at best practices and we are interested obviously in finding out what the private——

Senator SPECTER. Well, if a company does not respond to what their experience has been, the Congress is not reluctant to issue subpoenas. And I do not know what——

Secretary CHAO. I will certainly find out if we do have the authority to do that.

Senator SPECTER. I do not know whether you do, but this subcommittee would have no reluctance to find out what companies are doing.

Secretary CHAO. I have no reluctance either. I was making a little bit of a—of levity, which was probably not appropriate. But I was going to say that if they did not want to share their results, I am not so sure they are worthy to be shared. But your point is a very good one about the subpoena.

Senator SPECTER. Well——

Secretary CHAO. And I will find that out.

Senator SPECTER. Well, I do not know that UPS has not responded. That representation was made. Whether it is so or not, I do not know. We are making an inquiry.

Secretary CHAO. And we are talking to other companies on best practices.

Senator SPECTER. Okay. But these companies which have experience, which would be useful to the Department of Labor, I expect them to make it available.

Secretary CHAO. Yes.

Senator SPECTER. And if they do not, this subcommittee has subpoena power. And I have had some experience at issuing subpoenas——

Secretary CHAO. Yes.

Senator SPECTER [continuing]. And effectively. So I want to help you.

Secretary CHAO. Thank you.

Senator SPECTER. Madam Secretary, we are going to give you some questions from Senator Stevens for response in the record.

My final question to you—or let me not put it in the form of a question.

I would like for you to give this subcommittee a periodic report as to what you are doing, since we have not gotten to the point of a time line. I would like you to let us know every 90 days, if that is not too burdensome. I was thinking about 60 days, but let us make it 90 days, if you could give us a brief summary as to what you have done on the ergonomics issue.

Secretary CHAO. I would be delighted to.

Senator SPECTER. Okay.

Secretary CHAO. Let me—may I also add one last thing?

Senator SPECTER. Sure.

Secretary CHAO. Going back to the Youth Offenders program, let me also take another look at that, because my understanding was that the participants would not go down because of the carryover funds. And so if that is not the case, then I will take a look.

But that—my understanding was that the quality of the program was not going to be diminished, and number of participants will

not go down—again, because we had this excess funds. But if that is not the case, I will get——

Senator SPECTER. Well, that is an especially important——

Secretary CHAO. I will get back to you on that.

Senator SPECTER [continuing]. Important program. When you talk about rehabilitation, if we do not do it with the Youth Offenders, it is just a revolving door and recidivism. And that is a critical point of intervention.

Secretary CHAO. Right.

Senator SPECTER. So I appreciate your taking another look at it.

Anything you care to add, Secretary Chao?

Secretary CHAO. I think that is it. Thank you for having me.

Senator SPECTER. Mr. McMullen, I will give you more of a speaking part here.

Mr. MCMULLEN. Nothing to add, sir.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

COMPANIONSHIP SERVICES

Question. What is the Labor Department's plan regarding the Clinton Administration proposal to change the rule on "companionship services" under the Fair Labor Standards Act, specifically regarding an analysis as to the impact on the elderly and the disabled?

Answer. The rulemaking proposal was published on January 19, inviting comments for 60 days. Because of the continuing interest expressed in the proposal and in response to requests, on April 23 the Department reopened and extended the public comment period for 90 additional days (until July 23). The background and history to the statutory provisions covered by this rulemaking, as well as its perceived impact on recipients of companionship services, will be carefully reviewed. In addition, all public comments received on the proposal during the extended comment period will be given very careful consideration before reaching any final decision in this matter.

Question. Regarding the proposed rule on companionship services, has the Department given full consideration to the impact of the change on Federal and State programs that pay for much of the care that will be affected by the proposal? If the costs to provide the care go up, will the costs go up to the Federal and State programs that pay for these services?

Answer. HCFA previously estimated that the proposed rule would have a negligible effect on Medicare costs, as this service is not a significant component of Medicare. Annual Medicaid program expenditures may increase somewhere within a $30 million to $40 million range, of which 57 percent would be the Federal share. Assuming an equivalent magnitude of increase in the private sector would suggest the maximum possible combined (public and private) increase of no greater than $75 million. (See preamble of regulatory proposal, at 66 *Fed. Reg.* 5486, January 19, 2001.)

Question. If this rule is implemented, will it exacerbate the shortage of this workforce as workers may be restricted to less than 40 hours per week to avoid obligations for overtime compensation?

Answer. Implementing the proposed rule is not expected to exacerbate any workforce shortage in this industry. To the contrary, improving the wage structure to include minimum wage and overtime protections may contribute to attracting additional workers to this industry.

Estimates from the home care industry indicate that most workers in this industry are not working overtime hours, on the average. The data also indicate that there are many low-wage workers in this industry.

HARWOOD GRANTS

Question. I am troubled by your Department's recent decision to withdraw a number of OSHA's "Susan Harwood" Grants. This action will have a significant negative impact upon efforts nationwide to curb devastating workplace injuries. Particularly, I am advised that the Graphic Communications International Union Locals within Pennsylvania will lose a grant for $296,000 per year for five years and would be forced to stop offering their members training via the safety and health program that is now being funded by this grant. Please provide me with your justification for withdrawing these grants.

Answer. I can appreciate that there are disappointed groups in your State. The Pennsylvania Foundry Association in Plymouth Meeting, Pennsylvania, was affected by the decision to rescind the grants. However, the funding for the Graphic Communications International Union Locals is unaffected. They were not one of the 19 groups whose grants were rescinded.

In reference to the decision affecting the 19 groups: we did not believe that we should commit to higher cost long-term grants of 3 to 5 years. These grants, which were approved during the last month of the previous Administration, are larger and longer-term grants than have typically been awarded under this Program. In choosing among many competing priorities for funding, the Department concluded that it was preferable to provide targeted, short-term grants and maintain Departmental flexibility to respond to emerging safety and health issues. Therefore, OSHA will revert back to one-year grants in targeted subject areas.

We published a new solicitation under the Susan Harwood Training Grants program on April 18, 2001. Grants will be tailored to provide short-term targeted training in: (1) construction; (2) bloodborne pathogens; (3) ergonomics; (4) electrical power generation; and (5) training programs for hard to reach workers. We have specifically asked prior applicants to reapply for grants under the new solicitation. I will ensure that, in fiscal year 2001, OSHA awards fully the $11.2 million available for training and education grants. These grants will be geared to our team's strategic plan and new approach to safety and health of the Nation's workers.

As I stated when I was sworn in, "If we are going to protect workers, we must put more emphasis than ever before on prevention and compliance assistance—rather than just after-the-fact enforcement." As you know, the Harwood Training grants are but one of many compliance assistance tools used by OSHA. Others include onsite consultation, training provided by the OSHA Training Institute and its affiliates, and easy-to-use interactive electronic tools to help employers and workers understand and comply with OSHA standards.

OFFICE OF THE 21ST CENTURY WORKFORCE

Question. Tell us about your plans to create, with existing funds, a new "Office of the 21st Century Workforce". Where will the funds come from to create this new office? What do you anticipate this new office will accomplish?

Answer. The mission of the Office of the 21st Century Workforce is to ensure that every worker has the opportunity to pursue fulfilling and financially rewarding careers and to make sure that no worker becomes a casualty of the global economy of this new millennium. Its initial mission is to address our current skills gap and worker shortage. Funding for the permanent staff of the Office is from the Office of the Secretary's Departmental Management account.

TRANSITIONAL LIVING PROGRAM

Question. You are requesting $8.3 million for a new grant program to assist persons with significant disabilities in making the transition from institutional settings to the community and employment. This sounds very much like the $50 million program of the Health Care Financing Administration at the Department of Health and Human Services. Are there are any differences?

Answer. Yes, the two programs are different in that they would be focused on providing different types of services even though they are focused on the same target group—individuals with disabilities who are making the transition from institutional settings to the community. The two programs would be designed to complement, not duplicate, each other.

The Department of Health and Human Services' (HHS) $50 million grant program is for support services. These grants will promote the design and delivery of home and community-based services that support people with a disability or long-term ill-

ness to live and participate in their communities. The HHS grants will focus on meeting housing needs, personal assistance, expanding public-private partnerships to meet long-term needs, technology, and technical assistance. The United States Supreme Court's *Olmstead* decision, which is the basis for the HHS grants, clearly holds many implications and opportunities with respect to employment opportunities for people with disabilities. However, the HHS grants do not specifically target the employment and vocational needs of individuals transitioning from institutions to their communities.

The proposed $8.3 million for a DOL Olmstead grant program would support the educational and professional development of individuals with disabilities. The grant program would provide funds to build professional competence within the workforce system to be able to effectively partner with other systems so that movement of people from institutions to the community includes planning for their employment. We plan to work closely with HHS and other relevant agencies, such as the Department of Education and the Department of Housing and Urban Development, to coordinate with and complement their efforts.

INFORMATION TECHNOLOGY (IT) CROSS-CUT BUDGET

Question. You have requested more than double the funding of information technology at the Department of Labor from $37 million to $80 million. What do you anticipate that increase in funding will accomplish? Is this increase in funding to be expected in subsequent budgets?

Answer. The central IT fund comprises cross-cutting initiatives to comply with laws like the Clinger-Cohen Act and which benefit the entire Department. These initiatives fall into four categories:

Security and Privacy.—This necessary component includes security planning and plan implementation, risk management and mitigation, contingency planning, installing firewalls and intrusion detection systems, and related support contracts.

Enterprise Architecture.—This focuses on upgrading the Department's outdated core infrastructure, a necessary step to implement the Department's IT Architecture. Investments will be made in Local Area Networks (LANs), software, cabling, and telecommunications equipment.

Common Office Automation Suite.—This moves the Department to a single suite of office automation tools (word processing, spreadsheet, graphics, e-mail, database) to permit full interoperability among DOL agencies.

Common Administrative Systems.—We must also address applications that are used by most or all DOL agencies, such as Human Resources, Payroll, Travel, and inventory management functions.

Together, these initiatives are designed to ensure an integrated, Department-wide approach to IT investments in support of the Department's missions, goals, and objectives. Compliance with Section 508 of the Rehabilitation Act also has been built into the IT cross-cut budget. The initiatives are managed in accordance with DOL's IT capital planning and investment control process.

The increase in funding will support an IT infrastructure capable of supporting E-government objectives, the implementation of our common office automation suite strategy, a more secure IT environment in accordance with the Government Information Security Reform Act, and implementation of applications supporting enterprise-wide administrative functions such as financial and human resources. The only department-wide IT fund, this approach has been identified as a "best practice" by the Office of Management and Budget (OMB).

These IT improvements are ongoing initiatives and are essential to help the Department be as responsive as possible to the needs of workers and to secure its data and IT resources. We have not, however, made decisions on future budgets.

OSHA, MSHA AND ESA STAFF REDUCTIONS

Question. Your budget request would maintain funding for OSHA, the Mine Safety and Health Administration, and the Employment Standards Administration at essentially current levels. Due to the impact of inflation, this would reduce staffing at OSHA by 94 full-time equivalent positions, 47 mine safety positions, and 93 jobs at the Employment Standards Administration. Is this justifiable? Are these agencies currently overstaffed? Is it your intention not to hire the additional enforcement staff approved by Congress for fiscal year 2001?

Answer. Worker protection budgets have increased significantly during the last 5 years. While worker protection continues to be a high priority for the Department, we have, in the interest of responsible budgeting, carefully reviewed each agency's FTE needs with an eye to eliminating unnecessary management layers and ineffi-

cient work processes. The budget proposes to redirect these resources to higher priority areas like front-line service delivery.

OSHA, for example, has reviewed its current organizational structure to look for completed activities or those functions which are better integrated into the front-line work of the agency. Overall, the fiscal year 2002 budget reflects a reduction of 94 FTE—42 management FTE and 52 FTE associated with the previous Administration's re-invention initiatives. Since OSHA is not reducing safety and health compliance officer staffing, the agency plans on hiring all of the additional enforcement staff approved by Congress in fiscal year 2001.

The three ESA enforcement programs anticipate a slight reduction in enforcement staff in fiscal year 2002. Approximately 60 percent of the reduction in the enforcement programs will be taken in overhead staff, which comprises about one-third of the total enforcement program staffing. A reduction of 93 FTE amounts to approximately a 2 percent reduction in staffing and most, if not all, of that can be absorbed without negative consequences for enforcement. Within ESA, the Office of Workers' Compensation Programs anticipates employing the same number of claims examiners in fiscal year 2002 as in fiscal year 2001 for the Federal Employees' Compensation, Longshore and Harbor Workers' Compensation, and the Black Lung Compensation Programs.

With respect to MSHA, during the past five years, the number of coal mine enforcement FTE remained roughly level even as the number of coal mines decreased by 19 percent. Given this situation, the Agency believes that it can absorb the 47 position reduction in FTE in the coal program without compromising worker safety. MSHA fully intends to hire the additional 40 FTE approved by Congress for the metal and nonmetal enforcement program in fiscal year 2001.

CUTS IN WORKFORCE PROGRAMS

Question. You have proposed reductions for programs authorized under the Workforce Investment Act due to the slow expenditure of funds in the first year of implementation. Do you think it is possible that demand for those funds may increase in the next fiscal year since many States and communities are now planning and implementing programs based on that funding? If so, is it wise to scale back these programs at this time?

Answer. In projecting expenditures for the remainder of Program Year (PY) 2000 and PY 2001, and budget needs for PY 2002, DOL assumed that State Workforce Investment Act (WIA) programs would be fully implemented by June 30, 2001. DOL also projects State expenditures in succeeding years will be greater than would have been possible had unexpended balances not increased last year and during the first six months of this year. There will be no scaling down of programs nationally as a result of the reduced request for PY 2002. In fact, total spending for WIA State programs is estimated to be $174 million more in PY 2001 and in PY 2002 than the PY 2001 budget authority.

Question. How would the proposed cuts affect those States and communities that are fully spending their funding allocation? Have you heard from any of these groups since your budget proposal was released?

Answer. DOL staff regularly and routinely speak with States, local communities and their representatives. There is widespread acknowledgment that spending has been lower than expected and that the causes are many. In fact, through mid PY 2000, only two States (Delaware and Vermont) had spent more than 50 percent of the funds available to them in PY 2000. Federal, State and local partners have joined forces to review the causes and work together to propose policy changes and assistance that would address the issues.

A few communities might find themselves with fewer resources as allotments are reduced and they do not have as large an unspent balance as others have. However, we believe that underspending is widespread and the number of communities that are fully using funding are few. Most communities will find themselves with sufficient carry-over from earlier years to offset reduced allocations. For those few that do not have substantial carry-in, we would hope the impact of the proposed reductions can be ameliorated, in part, through reprogrammed monies to the youth formula program in 2001, State reallocation of funds among local areas, State targeting of funds available for Statewide activities, and Federal award of National Emergency Grants.

With respect to the latter, Dislocated Worker funding is provided to States and local communities by formula; the Secretary maintains a reserve of 20 percent of total Dislocated Worker funding, most of which is used for National Emergency Grants. These grants are available to States and local communities which have fully spent their formula funds and find themselves needing additional allocations for

Dislocated Worker assistance. As a result, we do not expect dislocated workers to be denied services as a result of the small reduction requested for the program.

WORKER LAYOFFS

Question. In light of the recent sluggish economy, what kinds of worker layoffs do you expect in the next fiscal year?

Answer. There were 1,445 mass layoff actions in April 2001 as measured by new filings for unemployment insurance benefits during the month, according to data from the Bureau of Labor Statistics. Each action involved at least 50 persons from a single establishment, and the number of workers involved totaled 175,064. In January 2001 through April 2001, the total number of events, at 5,995, and initial claims, at 719,781, were higher than in January–April 2000 (4,889 and 535,327, respectively).

In April 2001, manufacturing industries accounted for 42 percent of all mass layoff events and 44 percent of all initial claims filed. A year earlier, layoffs in manufacturing accounted for 34 percent of events and 32 percent of initial claims. Manufacturing industries with the highest number of initial claimants were transportation equipment (12,583, mostly in motor vehicles and car bodies), electronic and other electrical equipment (11,552, largely in semiconductors), and industrial machinery and equipment (11,312, primarily in farm machinery and equipment). Services accounted for 25 percent of events and 28 percent of initial claims filed during the month. Layoffs in services were highly concentrated in business services (particularly in help supply services, which accounted for 12 percent of the total number of initial claimants). We also have seen a significant upswing in trade petitions for last five months.

With the slow economy, we expect this trend to continue through part of the next fiscal year.

However, the unemployment rate remains low, meaning that many dislocated workers are able to find new employment with little or no governmental assistance because they have transferrable job skills. Those who are permanently laid off with little opportunity to return to their previous occupation or industry often need assistance to find or prepare for new jobs.

Under the Workforce Investment Act, Dislocated Worker services are provided through the One-Stop system. Dislocated workers who require assistance in finding new jobs can access a range of services at their local One-Stop Career Centers, ranging from job search assistance to assessment, counseling and retraining.

Question. In your opinion, will a $207 million reduction in the Dislocated Worker program hurt the chances of those dislocated workers finding new jobs?

Answer. The requested level for the Dislocated Worker program will allow our State and local partners to meet the employment and training needs of the affected workers. As a result of efficiencies in administration and service delivery as well as carry-in funds from prior years' appropriations, Dislocated Worker programs will have levels of resources comparable to previous levels. States and local areas whose needs exceed available resources may request assistance through National Emergency Grants to provide additional Dislocated Worker funding for workers affected by economic downturns.

ONE-STOP COORDINATION

Question. One of the cornerstones of the Workforce Investment Act was the coordination of resources at the One-Stop, particularly those provided under that Act and the Wagner-Peyser Act. Are the One-Stops coordinating resources with the State Employment Service? Are those two offices often located in the same building? If not, what are your thoughts on how we could improve that coordination?

Answer. The clear intent of WIA is that State employment services authorized by the Wagner-Peyser Act be delivered solely as part of the locally designed One-Stop systems. In addition, Wagner-Peyser employment and information services, including labor exchange services, employment statistics and labor market information, are critical core services that make One-Stop systems responsive to the universal population. Wagner-Peyser re-employment services are also critical to the linkage of unemployment insurance claimants to both employment services and more specialized services available within One-Stop centers/systems.

Nationwide, State employment services are entering into memoranda of understanding regarding how services will be delivered in One-Stop systems. WIA allows for different physical configurations within a One-Stop system. Each local area must have at least one physical location, a comprehensive One-Stop center, which provides core services and where access to all "required" One-Stop partner services is available. In addition, the law permits affiliated sites with specialized services as

long as the sites are part of the broader One-Stop system. The design of One-Stop systems varies as it relates to Wagner-Peyser employment services. There are three primary options for configuring how employment services fit in a One-Stop system: (1) the employment service office is the location of the comprehensive One-Stop center; (2) employment service staff are fully integrated into the comprehensive One-Stop center which is operated by another entity; or (3) an employment service office is an affiliated office with staff assigned to the comprehensive center.

It is the position of the Department of Labor that Wagner-Peyser services must be integrated as closely as possible within a One-Stop system. Therefore, we are working with our State partners to promote integration in a number of ways including, but not limited to:

—developing policy guidance flowing from WIA and the regulations on the role and "fit" of Wagner-Peyser employment services within One-Stop systems;
—developing and providing technical assistance to State employment service agencies, local boards, and One-Stop operators to help facilitate the integration of Wagner-Peyser employment services; and
—identifying best and promising practices and models for integration to share among the States and local areas.

Question. The justification for flat-funding Job Corps assumes that costs in the Job Corps program may have risen at the economy-wide rate of inflation in the 2001 budget year, and that substantial funds will be carried over into 2002. However, Job Corps centers are currently experiencing inflation rates that are significantly higher than the economy-wide rate of 2.1 percent. If, as a result of higher costs in 2001, the carryover anticipated for 2002 were not available, what would be the impact on the quality of Job Corps operations?

Answer. Job Corps' ability to continue current services without an inflationary increase is due primarily to savings from unplanned delays in new center openings. These savings, combined with some cost containment efforts, will adequately address our resource needs in PY 2003. Flat funding Job Corps in fiscal year 2002 will not impact the quality of Job Corps operations.

Question. What would be the impact on the three new centers scheduled to open in 2002? Would Job Corps have to close centers or reduce the number of students served?

Answer. As indicated above, Job Corps' ability to continue current services without an inflationary increase is due primarily to savings from unplanned delays in new center openings. We will submit a report to Congress detailing the status of those center openings and the reasons for the current delays. Let us be clear that these center opening delays are the result of a variety of unplanned events that are in no way related to the fiscal year 2002 Budget level. Job Corps will not close centers or reduce the number of students served.

ADDITIONAL YOUTH PROGRAM FUNDING

Question. DOL proposes to revise the fiscal year 2001 appropriation for the youth program by adding $45 million to it from funds reprogrammed from other WIA programs. What is the rationale for adding funds for 2001, then cutting funding in fiscal year 2002?

Answer. For fiscal year 2001, DOL proposes to reprogram the $25 million increase in 2001 from Youth Opportunity Grants and the initial $20 million from the Safe Schools/Healthy Students initiative to move funds from targeted programs to core job training programs, as described in President Bush's *Blueprint for New Beginnings.* The Workforce Investment Act was enacted to establish the core youth, adult, and Dislocated Worker programs, and we believe our emphasis should be on ensuring the success of these programs. The increase in Youth Opportunity Grants in 2001 would have resulted in additional sites that our fiscal year 2002 budget would not be able to sustain, as would also be the case for the Safe Schools/Healthy Students initiative. We are confident that, with the unexpended funds available from previous years, our fiscal year 2002 request of $1 billion for Youth Activities will be sufficient to serve the same number of young people in need of WIA services as are projected to be served in 2001.

FISCAL YEAR 2002 FUNDING LEVEL

Question. Does the fiscal year 2002 request reflect a one time adjustment in funding as a result of lower than expected levels of expenditures (due to the amount of time it is taking States to implement WIA)? If so, does the Administration expect to request funds in fiscal year 2003 to restore the cuts it is proposing in fiscal year 2002?

Answer. Yes, our fiscal year 2002 request does take into consideration the fact that unexpended balances are roughly $600 million greater than the traditional level. Any fiscal year 2003 request will consider expenditure data between now and when PY 2003 funding levels are finalized, as well as the Administration's assessment of the relative size of unspent balances carried into PY 2003.

STATE FLEXIBILITY FOR TRAINING NEEDS

Question. By decreasing funds, which effectively will decrease carry over, is the Administration reducing the flexibility States have to meet unexpected training needs that might occur if the economy continues to weaken and more laid off workers need training to obtain jobs?

Answer. As previously indicated, the Department and its State partners will continue to address the needs of laid off workers through awards of formula funds, supplemented, where necessary, by National Emergency Grants.

FUNDS REVERTING TO THE TREASURY

Question. Given the level of spending by States, would you expect any fiscal year 2000 funds to revert to the Treasury if funding were not reduced for the formula grant programs in fiscal year 2002?

Answer. States have the Program year of Federal award and the two succeeding Program years to spend funds under WIA. Because of this, we do not expect that these unspent funds will revert to the Treasury. They will remain in the grant and carried over for use in future years.

UNSPENT FUNDS LISTED BY STATE AND BY GRANT

Question. Could you please provide to this committee a list of the amount of unspent grants expected for fiscal year 2000 and fiscal year 2001 for each State by formula grant program? If you have information on projected unspent funds based on data more recent than December 2000, would you provide them to this committee?

Answer. The Department does not have projected end of year carryover by State or program; the attached table shows aggregate estimates by State for expenditures through December 2000 and is submitted for the record. Our assumptions about expenditures for PY 2001 and PY 2002 are not State-by-State. Estimates may not be accurate if applied to individual States given differences in State plans and spending rates.

EMPLOYMENT AND TRAINING ADMINISTRATION STATE REPORTING OF FORMULA SPENDING WIA YOUTH ADULTS AND DISLOCATED WORKERS PROGRAMS COMBINED

State	Unexpended carry-in to PY 2000	PY 2000 allotments			Total available 7/1/00–12/31/00 (& PY 2000 Youth: 4/1/00–6/30/00)	Expenditures 7/1/00–12/31/00 (& PY 2000 Youth: 4/1/00 – 6/30/00)			Unexpended balance as of 1/1/01		
		PY 2000 portion excluding advance funding	FY 2001 advance funding	Total allotments (includes advance funding available beginning FY 2001)		Total	% of allotments	% of available	Total	% of allotments	% of available
Alabama	$7,204,025	$21,569,576	$18,435,358	$40,004,934	$47,208,959	$12,944,260	32.4	27.4	$34,264,699	85.7	72.6
Alaska	453,000	6,220,665	6,804,719	13,025,384	13,478,384	2,734,243	21.0	20.3	10,744,141	82.5	79.7
Arizona	6,170,133	22,265,696	18,050,796	40,316,492	46,486,625	10,087,539	25.0	21.7	36,399,086	90.3	78.3
Arkansas	8,941,265	17,060,263	15,813,292	32,873,555	41,814,820	7,910,502	24.1	18.9	33,904,318	103.1	81.1
California	50,370,517	310,532,858	319,358,288	629,891,146	680,261,663	136,440,050	21.7	20.1	543,821,613	86.3	79.9
Colorado	3,804,877	11,133,399	10,794,033	21,927,432	25,732,309	5,900,041	26.9	22.9	19,832,268	90.4	77.1
Connecticut	3,620,292	12,391,413	11,276,123	23,667,536	27,287,828	7,063,815	29.8	25.9	20,224,013	85.5	74.1
Delaware	1,694,396	3,603,138	2,887,440	6,490,578	8,184,974	4,167,507	64.2	50.9	4,017,467	61.9	49.1
District of Columbia	1,384,000	9,011,879	10,103,668	19,115,547	20,499,547	6,051,585	31.7	29.5	14,447,962	75.6	70.5
Florida [1]	65,279,463	62,533,829	56,846,081	119,379,910	184,659,373	86,121,969	72.1	46.6	98,537,404	82.5	53.4
Georgia	11,966,905	32,680,141	29,305,954	61,986,095	73,953,000	13,874,807	22.4	18.8	60,078,193	96.9	81.2
Hawaii	5,462,399	11,851,140	13,166,154	25,017,294	30,479,693	5,058,091	20.2	16.6	25,421,602	101.6	83.4
Idaho	3,697,810	7,068,503	6,933,051	14,001,554	17,699,364	4,665,156	33.3	26.4	13,034,208	93.1	73.6
Illinois	6,425,117	62,507,353	54,649,207	117,156,560	123,581,677	28,274,929	24.1	22.9	95,306,748	81.3	77.1
Indiana	7,134,777	17,145,854	14,928,500	32,074,354	39,209,131	16,609,855	51.8	42.4	22,599,276	70.5	57.6
Iowa	2,717,190	5,718,570	5,734,756	11,453,326	14,170,516	3,501,904	30.6	24.7	10,668,612	93.1	75.3
Kansas	2,346,659	6,217,232	6,430,585	12,647,817	14,994,476	4,065,239	32.1	27.1	10,929,237	86.4	72.9
Kentucky	34,811,212	23,190,724	19,259,988	42,450,712	77,261,924	18,029,020	42.5	23.3	59,232,904	139.5	76.7
Louisiana	12,202,135	34,855,558	31,745,279	66,600,837	78,802,972	13,427,930	20.2	17.0	65,375,042	98.2	83.0
Maine	100,000	5,918,650	5,323,098	11,241,748	11,341,748	3,940,588	35.1	34.7	7,401,160	65.8	65.3
Maryland	11,977,850	22,762,126	21,383,922	44,146,048	56,123,898	14,054,255	31.8	25.0	42,069,643	95.3	75.0
Massachusetts	3,070,000	20,596,131	18,433,727	39,029,858	42,099,858	15,477,068	39.7	36.8	26,622,790	68.2	63.2
Michigan	10,625,065	43,150,489	35,227,909	78,378,398	89,003,463	25,246,367	32.2	28.4	63,757,096	81.3	71.6
Minnesota	4,862,114	12,661,947	11,192,310	23,854,257	28,716,371	11,136,597	46.7	38.8	17,579,774	73.7	61.2
Mississippi	7,545,109	19,849,458	17,445,585	37,295,043	44,840,152	8,407,897	22.5	18.8	36,432,255	97.7	81.2
Missouri	9,220,801	22,537,168	20,531,057	43,068,225	52,289,026	11,812,901	27.4	22.6	40,476,125	94.0	77.4
Montana	874,719	7,330,069	7,429,328	14,759,397	15,634,116	4,751,724	32.2	30.4	10,882,392	73.7	69.6
Nebraska	1,562,920	3,843,427	3,370,955	7,214,382	8,777,302	1,593,856	22.1	18.2	7,183,446	99.6	81.8
Nevada	1,023,781	6,236,289	6,052,345	12,288,634	13,312,415	3,126,560	25.4	23.5	10,185,855	82.9	76.5
New Hampshire	352,571	3,796,677	3,276,886	7,073,563	7,426,134	1,695,816	24.0	22.8	5,730,318	81.0	77.2
New Jersey	18,918,820	39,764,126	38,034,164	77,798,290	96,717,110	27,749,286	35.7	28.7	68,967,824	88.6	71.3
New Mexico	888,554	16,388,725	21,437,086	37,825,811	38,714,365	9,060,603	24.0	23.4	29,653,762	78.4	76.6

New York	163,730,964	148,728,129	156,225,476	304,953,605	468,684,569	42,802,149	14.0	9.1	425,882,420	139.7	90.9
North Carolina	13,648,284	23,561,472	21,935,374	45,496,846	59,145,130	15,529,729	34.1	26.3	43,615,401	95.9	73.7
North Dakota	735,455	3,522,617	2,725,413	6,248,030	6,983,485	2,234,580	35.8	32.0	4,748,905	76.0	68.0
Ohio	18,566,094	61,982,728	50,847,933	112,830,661	131,396,755	15,795,680	14.0	12.0	115,601,075	102.5	88.0
Oklahoma	3,965,403	15,582,047	13,092,549	28,674,596	32,639,999	5,553,484	19.4	17.0	27,086,515	94.5	83.0
Oregon	7,288,406	28,275,038	30,992,014	59,267,052	66,555,458	14,705,981	24.8	22.1	51,849,477	87.5	77.9
Pennsylvania [1]	43,473,437	55,552,160	51,169,069	106,721,229	150,194,666	39,674,951	37.2	26.4	110,519,715	103.6	73.6
Puerto Rico	82,022,985	103,556,318	111,940,940	215,497,258	297,520,243	51,195,386	23.8	17.2	246,324,857	114.3	82.8
Rhode Island	732,708	4,082,645	3,811,684	7,894,329	8,627,037	2,536,074	32.1	29.4	6,090,963	77.2	70.6
South Carolina	5,651,400	18,242,679	15,239,431	33,482,110	39,133,510	8,681,128	25.9	22.2	30,452,382	91.0	77.8
South Dakota	1,524,676	3,541,195	2,762,797	6,303,992	7,828,668	2,434,662	38.6	31.1	5,394,006	85.6	68.9
Tennessee	11,326,551	27,717,111	23,061,871	50,778,982	62,105,533	12,670,648	25.0	20.4	49,434,885	97.4	79.6
Texas	67,300,071	134,094,193	111,733,955	245,828,148	313,128,219	119,541,113	48.6	38.2	193,587,106	78.7	61.8
Utah	3,219,027	5,433,280	4,965,519	10,398,799	13,617,826	3,497,324	33.6	25.7	10,120,502	97.3	74.3
Vermont [1]	590,542	3,455,742	2,590,847	6,046,589	6,637,131	4,657,829	77.0	70.2	1,979,302	32.7	29.8
Virginia	7,300,000	20,744,067	17,994,165	38,738,232	46,038,232	8,246,066	21.3	17.9	37,792,166	97.6	82.1
Washington	12,731,724	35,864,208	34,182,597	70,046,805	82,778,529	20,479,984	29.2	24.7	62,298,545	88.9	75.3
West Virginia	10,000,000	20,886,759	23,332,050	44,218,809	54,218,809	13,094,672	29.6	24.2	41,124,137	93.0	75.8
Wisconsin	2,688,907	15,799,916	14,706,901	30,506,817	33,195,724	14,471,966	47.4	43.6	18,723,758	61.4	56.4
Wyoming	2,688,907	3,688,545	3,059,298	6,747,843	9,436,750	2,819,580	41.8	29.9	6,617,170	98.1	70.1
Total Formula	765,894,017	1,636,703,922	1,558,031,527	3,194,735,449	3,960,629,466	925,604,946	29.0	23.4	3,035,024,520	95.0	76.6

[1] Revised/corrected expenditures for Florida and Vermont; corrected carry-in for Pennsylvania.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM (EEOICPA)

Question. In a televised interview (*McLaughlin's "One on One"* from 3/23/01) I understand you said the DOL has "no capability, no infrastructure" to carry out the nuclear workers compensation program. I am surprised at this statement given the history of Office of Workers' Compensation Programs in administering the Federal Employees' Compensation Act, as well as compensation for coal mine workers and longshore and harbor workers. What capability and infrastructure do you need to build?

Answer. My comments centered on the statutory deadline for the Department to implement this large new program. This reality poses significant challenges, thus warranting my public concern. While the Energy Employees Occupational Illness Compensation Program bears some resemblance to ESA's other compensation programs, its size, covered population, and unique requirements have necessitated the establishment of a new claims processing and adjudication infrastructure. The Department has created a unit within ESA, with its own dedicated staff, to handle the large number of expected claims. This unit will be responsible for accepting and adjudicating claims under the program, which will include such tasks as determining the probability that an individual's cancer was as likely as not due to radiation exposures and adjudicating all disputes arising from the claims process.

Question. Given your concerns, what are your plans to bring in expertise to start the program?

Answer. Since EEOICPA's enactment, the Department has been working with the Departments of Energy, Health and Human Services, and Justice to implement this program in a fair and equitable manner. We have utilized private-sector contractors to a great extent. In our efforts to build the organizational structure to administer this program, we are reaching out in a very broad way to recruit the staff necessary to operate this program. This will include staff to adjudicate claims and those with technical expertise in areas such as radiation measurements and exposures. Simply put, we are utilizing every available resource to assure the timely and effective implementation of this program.

Question. Would you consider setting up an outside advisory committee to help address some of the issues? Could you use the Department of Energy's Office of Environment, Safety and Health Public Advisory Committee, which already has dealt with this program, for this purpose?

Answer. As you know, the EEOICPA established an Advisory Board on Radiation and Worker Health. In addition, as you note, the Department of Energy's Office of Workers' Advocacy has also established an advisory committee. We have been engaged with, and will continue to participate in, the DOE Advisory Committee and will participate in the Advisory Board on Radiation and Worker Health when it is established. We will use these forums as well as continuing to meet with stakeholders in a variety of other settings to get input on administering this program. These avenues for obtaining input have seemed most beneficial at this point, especially given the July 31 implementation deadline the Department must meet. In light of this deadline, we have had to focus our efforts on ensuring that eligible claimants receive benefits as soon as possible after this date. At a later date, we will consider whether there is a need to establish another advisory body.

Question. Last year the DOL proposed some amendments to the EEOICPA, including adding an option of providing a sick worker with lost wages. Do you support these proposed changes?

Answer. In January of this year, the previous Administration forwarded a set of proposed amendments to the EEOICPA to Congress. The extremely short deadlines for publishing regulations and implementing this program have required DOL to focus exclusively since then on efforts to promulgate regulations and create procedures and systems necessary to undertake our responsibilities under EEOICPA and Executive Order 13179. Thus, consideration of possible legislation must await our completion of the initial implementation of the program. We will consult with the Office of Management and Budget and other agencies with responsibility under EEOICPA to assess the need for a legislative proposal.

Question. I understand you recently recommended to OMB that "the Administration support technical legislation that will soon be introduced to remedy some of the remaining deficiencies in the EEOICPA." What are these deficiencies, what amendments to EEOICPA will you recommend, and when you do expect the legislative proposal to be introduced?

Answer. EEOICPA contains virtually no provisions concerning administration of the program or review of decisions made on claims for benefits. In drafting

EEOICPA, Congress recognized that the statute did not create a comprehensive compensation system when it directed submission of further legislation to implement the program. In addition to the almost total lack of administrative and review provisions, it also contains ambiguous or unclear provisions and certain provisions that appear to have adverse consequences that may not have been intended. As noted in the previous response, however, extremely short deadlines for implementing EEOICPA have required DOL to focus on that task. We do intend, however, to further review this legislation and consult with the Office of Management and Budget and other agencies with responsibility under EEOICPA to determine the appropriate nature and timing of a legislative proposal.

Question. I understand you said that DOL could not meet the statutory deadline to begin accepting applications. When do you expect to be ready to accept applications, and when should workers who qualify expect to begin receiving compensation?

Answer. As a result of the extraordinary effort and dedication of DOL's career staff, interim final regulations were published on May 25, 2001 and will take effect 60 days thereafter. This will allow us to begin officially accepting applications on July 31, 2001, the date that the legislation provides for the statute to take effect. For straightforward cases, we expect to begin paying EEOICPA benefits by early fall.

However, it must be recognized that there will be a surge of claims filed in the first days of this program for illnesses and deaths occurring over more than a half century. While we are making every effort to address this up-front claims workload, it will be very difficult to process this volume of cases immediately. Based on our knowledge of this population, we expect that many claims will require significant work on the part of DOL, DOE, and HHS to piece together decades-old work history and exposure data. Claimants whose cases will require complex adjudication—especially of those for whom HHS must complete an individual radiation dose reconstruction—will need to realize that it may take many months for all aspects of their case to be fully reviewed.

Question. How do you expect to handle workers with covered radiogenic cancers for whom dosimetry records do not exist? How will they be considered for inclusion in a Special Exposure Cohort?

Answer. The Department of Health and Human Services' National Institute on Occupational Safety and Health (NIOSH) has been assigned responsibility for developing methodologies for "reconstructing" reasonable estimates of radiation doses received by individuals, and for carrying out individual dose reconstructions in each case where the claimant is determined by DOL to be a covered employee, but is not a member of a Special Exposure Cohort. In the absence of complete dosimetry data, these estimates will be used by DOL to determine the probability that an individual's cancer was as likely as not due to occupational radiation exposure. In addition, HHS is developing a process for designating additional members to the Special Exposure Cohort, with the advice of the Advisory Board on Radiation and Worker Health. These issues will be addressed in the regulations being developed for EEOICPA by HHS.

Question. How do you expect to coordinate with the Department of Energy for workers whose illnesses may have been caused by radiation or by hazardous substances?

Answer. The EEOICPA does not preclude filing for benefits under both EEOICPA and State workers' compensation. EEOICPA provides for assisting workers in obtaining State workers' compensation benefits through the DOE Office of Worker Advocacy. We anticipate that individuals who were exposed to both radiation and other toxic substances will file claims under both programs. We are coordinating with DOE in many areas, but particularly through the establishment of joint DOE/DOL resource centers near nine major DOE nuclear sites, where claimants will be able to get direct assistance in filing under either, or both, programs.

Question. Does the budget include sufficient funds for timely implementation of the program?

Answer. The funding for EEOICPA is sufficient and will not affect our ability to meet the established time frames. The difficulties in meeting the time frames are related to the tremendous amount of work to be done, and the lack of lead time available to acquire and gear up the staff and other resources necessary to be at peak capacity at the inception of the program. Establishing the organization structure, acquiring office space, purchasing equipment, hiring and training staff, developing essential data, communications, and financial systems, and developing detailed procedures for administering such a complex program these are all major undertakings. I assure you that we are doing everything possible to stay on schedule.

STAFFING SHORTAGES

Question. What is the Labor Department's strategy in addressing the existing shortage of female-dominated jobs, such as nursing, day care and teaching?

Answer. Within a few decades, some demographic experts believe the American workforce simply will not be large enough to meet the demands of a continually growing economy. Nurses, day care providers, and teachers are a large part of this "incredibly shrinking workforce."

These professions are of tremendous value to our communities. Every day they care for our neighbors and educate our children. The President has begun the process of elevating the appreciation for the individuals in these careers. We must show consideration for the value of these professions not only in dollars and benefits, but also in respect.

The Department will continue to evaluate the Nation's current skills gap and worker shortage and identify methods, including those that cross Departmental lines, that allow us to address this problem—both short- and long-term. We are, in fact, already working to address some of these shortages. For example, under the Workforce Investment Act of 1998, our locally-driven workforce investment boards may certify occupations that are in demand in their area in which an eligible individual may select training. For example, Certified Nursing Assistants (CNAs) represent an occupation that is very much in demand in most local areas. Therefore, an individual who goes to a One-Stop Career Center and becomes eligible for training will likely see CNA training offered as a response to one of the occupational choices. Many One-Stop Career Centers also offer access to training in advanced skills that require certification, such as medical laboratory technicians, operating room technicians, and inhalation therapists.

BUREAU OF INTERNATIONAL LABOR AFFAIRS (ILAB)

Question. Madame Secretary, in this era of globalization, American workers are now pitted against workers throughout the global economy in tough, hard-nosed competition as never before. Their jobs and living standards are at unprecedented risk. Why are you proposing such drastic cuts in the Bureau of International Labor Affairs? This is the office of the Federal Government that has the greatest expertise in international worker rights issues (i.e. abusive child labor), and labor standards at a time when President Bush is requesting trade authority and even says there are legitimate trade-related worker rights issues that must be addressed in the impending fast-track debate.

Answer. The President's fiscal year 2002 request for ILAB preserves the Bureau's core responsibilities and recognizes the importance of eradicating all forms of abusive child labor and promoting international labor standards throughout the world. Funding for these programs has multiplied dramatically over the past years. The proposed spending levels help us to effectively balance our priorities while maintaining management controls and sensible spending policies that are crucial to our domestic well-being.

The budget request includes funding for ILAB's core mission, and provides $30,000,000 to support projects that remove children from exploitative work and provide them with an education and their families with viable economic alternatives; $10,000,000 to support work on an HIV/AIDS through workplace-based prevention and education programs and technical assistance to improve the working environment of employees living with AIDS; and approximately $19,000,000 to continue multilateral and bilateral projects to help developing countries establish labor protections so that workers everywhere can enjoy fundamental rights and principles at work and help strengthen the ability of developing countries' to implement social safety net policies and programs to foster economic growth.

Question. Madame Secretary, I am troubled by reports I've heard that no appointment for the position of Deputy Undersecretary of Labor for International Affairs is expected before this coming fall. Is this true and, if so, how can you leave this important position vacant for so long and still claim to be giving priority treatment to child labor, enforcing worker rights law on the books, advancing trade-linked worker rights issues and promoting greater respect for internationally-recognized worker rights?

Answer. We plan to fill this position as soon as we have identified a person with the qualifications and expertise we seek. In the meantime, the Bureau is in the capable hands of experienced career professionals.

PENSION AND WELFARE BENEFITS ADMINISTRATION

Question. Last year, I worked with the Pension and Welfare Benefits Administration to expand the assistance program through which they help retirees understand their rights under the Employee Retirement Income Security Act of 1974 (ERISA). I am disappointed to see that your budget for this activity under the Policy, Regulation and Public Services Account is cut by $1 million.

The retirement of the baby boom generation doesn't just affect Social Security, it also creates a large influx of retirees that need to understand their pension rights. In addition, the volatility of the stock market rightly has all concerned, acutely affects retirees with defined contribution and 401K plans. Given the increasing demand for retiree assistance and the increasing importance of that assistance in light of the changing economy, how do you justify cutting the one Federal service that counsels retirees about their pension rights?

Answer. We have not reduced the request levels for benefit advisors that counsel retirees and other participants about their pension rights, nor have we reduced the levels of advisors that provide assistance to employers in plan operations. The Pension and Welfare Benefits Administration (PWBA) is committed to providing participant assistance. There are currently 105 FTE dedicated to participant assistance—16 in the national office and 89 in the field offices. In fiscal year 2000, these Benefit Advisors assisted over 150,000 participants. Also in fiscal year 2000, PWBA adopted—for the first time—a Strategic Plan for Outreach, Education and Assistance. The plan includes specific performance measurements. PWBA also is beginning a pilot project to implement an 800 number. Assisting participants in health and retirement plans to make sure they understand their rights and receive the benefits to which they are entitled is a priority for me and the Department. PWBA will continue to fulfill this mission to the fullest extent possible.

DISPARITY IN WIA BUDGET REQUEST REDUCTIONS

Question. This budget requests a $473.9 million cut in employment and training programs, claiming that unexpended carryover funds from last year will allow States to maintain service levels while taking that large of a cut. Madame Secretary, although large amounts of carryover may exist in some States, the amount varies per State. Dislocated Worker funds go to States on a formula basis. Therefore, every State will take the same percentage cut in funding, regardless of the amount of carryover they have.

First, how do you deal with the disparity between States with small amounts of carryover and large cuts in fiscal year 2002 funds? Doesn't this method of cuts actually punish States who have implemented the new Workforce Investment Act quickly and efficiently?

Answer. Information received to date indicates very few States are without significant carry-over available to maintain 2001 projected service levels through 2002. The Department is prepared to assist these States however possible. For example, the Department maintains a sizable reserve for National Emergency Grants where Dislocated Worker formula funds are insufficient to meet worker needs. As always, we will move quickly to make these awards where the need is demonstrated.

Question. Second, these cuts will not go into effect until July of 2002 and your analysis of unexpended carryover is as of January 1, 2001. Do you not expect WIA to be fully implemented and working as planned in the next 18 months?

Answer. The Department expects WIA to be fully implemented by June 30, 2001, and program spending to have resumed to levels commensurate with amounts appropriated. As you indicate, the spending projections are based on unspent balances as available December 31, 2000 and what we believe to be reasonable estimates of increased spending through the remainder of this program year. Based on these estimates and our expectation that the WIA implementation issues that limited program spending will be resolved and the program fully implemented, we have projected an amount available on June 30, 2001 that, when added to available PY 2001 funds and the amounts requested for PY 2002, will allow spending, nationally, at levels greater that what was provided by the Congress for 2001.

PERSONAL PROTECTIVE EQUIPMENT

Question. Another important standard has been developed that clarifies who pays for personal protective equipment that is required by the employer. Some employers actually charge workers for ear plugs, rubber boots and protective gloves, even though this is the primary means of protection that the workers have, for example, from the hazards of noise, slippery floors, and sharp knives. The OSH Act requires the employer to pay for engineering controls, such as ventilation and machine

guards. When employers require workers to pay for PPE, they are passing along the economic burden of controls to workers, often those in the lowest paying jobs, such as poultry processing. It is our hope that you would examine this issue, look at the regulatory record, and urge final approval. This is not a major regulation, and it is not a major issue to most employers. However, it is a major cost to many low-wage workers who have to spend an additional portion of their hard won paychecks in order to do their jobs.

Can you tell me the status of the proposed regulation? Can you give me a timetable on when it might be completed?

Answer. As discussed below, the new Administration has not completed its review of OSHA's regulatory agenda. Until that review is completed, I am unable to give you a timetable for this proposal.

LUMP SUM PENSION DISTRIBUTIONS

Question. Please provide me with a detailed explanation of where DOL and Treasury are regarding taking actions on the lump sum issue discussed [in my request] and what the Pension and Welfare Benefits Administration is doing to improve its ability to ferret out significant broad failures of plans to properly inform plan participants of their rights or to properly provide benefits.

Answer. I am familiar with the concerns raised in your January 2000 letter to Secretary of Labor Herman and Secretary of the Treasury Summers concerning the information disclosed to pension plan participants about their benefit distribution options. I believe that pension plan participants need and deserve sufficient information about their plan and benefits, including distribution options, to make informed decisions about their retirement. We are reviewing this issue and will respond more comprehensively when we have reached any conclusions.

FAIR LABOR STANDARDS ACT (FLSA)

Question. As you know, the Fair Labor Standards Act provides the most basic labor standards for working Americans, including child labor, minimum wage and overtime protections. In recent years, enforcement of the Act has suffered from lack of funding for investigators that are far too few in number to adequately enforce the law in the many thousands of workplaces across the country.

Will you ensure that wage-hour enforcement gets the priority, and the funding that it needs to protect the workers' wages?

Answer. I am committed to enforcement of worker protection laws. One of my goals is to ensure an honest day's pay for an honest day's work. While it is true that the number of investigators in the Wage and Hour Division declined throughout the early 1990s, the number of investigators steadily increased beginning in 1996 and is now at its highest level. There is sufficient funding in the fiscal year 2002 budget to maintain the current level of investigators. In addition to enforcement, compliance education is another strategy for protecting workers' wages. I am encouraging the Department's enforcement agencies to undertake a renewed emphasis on compliance assistance.

Question. While there have been slight increases, there are still significantly fewer investigators than 15 years ago for more workplaces. Will you press for and will you support funding for more investigators?

Answer. At the end of fiscal year 2000, the number of investigators in the Wage and Hour Division was equal to the number of investigators in fiscal year 1985. Wage and Hour currently has 21 percent more investigators than at the end of fiscal year 1996. While I appreciate the fact that there are now more employers covered by the laws administered by the Wage and Hour Division than there were 15 years ago, I am not at this point seeking additional funding for investigators. Rather, I believe that providing compliance assistance to this increased number of employers is an important factor in the equation to improve compliance with worker protection laws.

Question. In September 1999, the General Accounting Office issued a report to the House of Representatives which found that many of the nation's low-income workers were being illegally misclassified as exempt from overtime, often by conferring on those workers fancy titles that disguise the true nature of their work. For example, a cook paid a salary of $200 per week may be called an Executive Chef and misclassified as exempt from overtime.

Are you willing to use the resources of your office to stop this kind of illegal exploitation of low-income workers by (a) increasing enforcement, and (b) providing education to employers about their responsibilities and providing information to workers about their rights?

Answer. The primary goal of the Wage and Hour Division is to increase compliance with labor standards laws and regulations, including those affecting young workers, and workers in low-wage industries. To increase compliance, Wage and Hour has adopted a multi-prong strategy of compliance education, enforcement and partnerships.

Compliance education includes such activities as seminars for employers and employer associations; town hall meetings for workers; and distribution of a variety of compliance materials, including fact sheets, compliance manuals and wallet-sized cards. In addition, the Department has developed Elaws Advisors, an interactive internet-based tool which provides easy-to-understand expert advice on the basic requirements of the Fair Labor Standards Act and the Family and Medical Leave Act. A separate module covers the Federal child labor requirements. In September 2000, Wage and Hour began operation of the first phase of the Technology for Excellent Customer Service program, a national toll-free number to answer questions and refer callers to the appropriate office for service.

The enforcement component of the strategy includes the use of traditional enforcement tools like investigations; the assessment of civil money penalties; targeted strike forces, particularly in low-wage industries; and the use of the "hot goods" provision of the FLSA that prohibits the shipment in interstate commerce of goods produced in violation of the Act.

Establishing various partnerships leverages Wage and Hour's limited resources and broadens the impact of the other strategies. Wage and Hour enters into partnerships with employers and employer associations to urge proactive steps to help ensure current and future compliance, as well as with non-profit and community-based organizations, and States and other Federal agencies to help reach low-wage employees and make them aware of their rights.

Question. The GAO Report also found that the primary cause of this type of exploitation was that regulatory minimum salary levels for workers to qualify for overtime-exempt status had not kept pace with inflation since they were last adjusted in 1975, a quarter of a century ago. For example, in 1975 about 30 percent of the full-time work force would have been automatically entitled to overtime because their pay did not exceed these minimum salary levels. However, in 1998, because of the failure of these levels to keep pace with inflation, only 1 percent of this workforce would be automatically entitled to overtime.

Will you support raising the minimum salary levels to account for the effects of inflation over the last 25 years?

Answer. In May 2000 the House Subcommittee on Workforce Protections of the Committee on Education and the Workforce, U.S. House of Representatives, held a hearing in connection with the GAO's report and received testimony from business and labor representatives, as well as from the Department of Labor. Witnesses at the hearing confirmed GAO's assessment that the ability to move forward with constructive and appropriate changes to the regulations has proven extremely difficult because of the strongly-held views of the many affected and interested parties and the significant impact of possible changes. After that hearing, the Department of Labor began a modest research effort to identify areas in which we would need additional information to analyze the evolution of the overtime-exempt categories of workers and how they are classified by their employers. The regulations are currently scheduled on the Department of Labor's regulatory agenda for upcoming review and possible future revisions. However, there is much more to be learned before we will be fully positioned to offer specific regulatory changes.

OSHA ERGONOMISTS

Question. How many ergonomists does OSHA currently employ? Do you have plans to hire more?

Answer. There is no Federal job classification titled "ergonomist." However, OSHA currently has two certified professional ergonomists; approximately six field compliance officers with advanced degrees in disciplines in industrial engineering, with concentration in ergonomics; between 20 and 30 field people who have extensive training in ergonomic intervention in specific industries, such as meat packing and textiles; and three individuals with extensive ergonomics expertise with the Salt Lake City Health Response Team.

UNDERREPORTING OF INJURIES

Question. OSHA's research and the information collected at the recent hearings show that there is extensive underreporting of MSDs. In fact, based on the record compiled in the recent rulemaking process, OSHA concluded "that for every reported MSD, another MSD goes unreported."

What do you plan to do to correct this problem of underreporting? Are you dedicating any additional resources to addressing this problem?

Answer. The Department is developing a comprehensive approach to addressing ergonomics. One of the many issues we will investigate is the underreporting of MSDs that OSHA asserted during the recent rulemaking. While it is too early to say for certain, I believe that lack of awareness of MSDs and an inability to universally define such injuries are plausible reasons for underreporting. Furthermore, I believe raising awareness of MSDs on the part of both employers and employees will help to prevent MSDs before they occur. I intend to use what I find from looking at the reasons for underreporting to create systems that will disseminate information to employers and employees on the best ways of preventing MSDs.

During the month of July, the Department will hold three forums to address, among other issues, the definition of what constitutes an ergonomics injury. The Department plans to publish a report, based on the information collected from the forums, that will address the issue of underreporting.

ERGO II

Question. You have repeatedly asserted that ergonomics is a priority for this Administration's Department of Labor. Yet, the Administration has indicated that it will nominate Mr. Eugene Scalia for Solicitor General. As Solicitor General, Mr. Scalia would oversee all standard setting or enforcement of ergonomics, yet Mr. Scalia has repeatedly opposed any ergonomics standard, going so far as to call ergonomics, "a questionable science." In fact, Mr. Scalia has written extensively in opposition to any ergonomics standard setting or enforcement by OSHA.

Have you discussed with him the importance of ergonomics in this Administration and is it your sense that he will actively pursue a new ergonomics rule?

Answer. As Secretary, I have pledged to take a comprehensive approach toward ergonomics. I have met with numerous stakeholders and experts to discuss the issue during my short tenure, including representatives of workers, industry, and safety and health professional, and I have outlined certain key principles that will guide the Department's approach toward ergonomics under my leadership. Eugene Scalia, the President's nominee for Solicitor of Labor, has a broad range of experience in labor and employment law and a distinguished record of service in past administrations. I have emphasized to him the importance of the issue of ergonomics to this Administration and to the Congress. I am confident that, as Solicitor, he will faithfully discharge his responsibility to legally represent whatever ergonomics policy we establish.

OSHA ENFORCEMENT BUDGET

Question. There is a $3 million increase for OSHA's enforcement budget, there is also a cut of 64 FTEs. The budget indicates that OSHA will conduct 36,400 Federal enforcement inspections in fiscal year 2002, the same as fiscal year 2001. How will the agency conduct the same number of inspections with fewer enforcement officers?

Answer. None of the FTE being cut are compliance safety and health officers. As a result, the agency will be able to conduct the same level of inspections as in fiscal year 2001. The staffing cuts reflect reductions in management and FTE associated with reinvention, not front line inspector positions.

OSHA STANDARDS

Question. You have laid out a very ambitious health and safety standard setting program and I commend you for that. OSHA expects to issue 15 proposed standards in fiscal year 2002, versus only one in fiscal year 2001, and 6 final standards in fiscal year 2002, versus 5 in fiscal year 2001. Can you give me the status of the following standards and whether you will publish them in final form in fiscal year 2002?

—Tuberculosis
—Employer payment for personal protective equipment
—Glycol ethers
—Signs, signals and barricades
—Exit routes update
—Personal fall protection systems

Answer. The new Administration is still reviewing the regulatory agendas of the Federal agencies, including OSHA. Until that review is complete, it would be premature to specify OSHA's regulatory priorities or timetables for specific projects.

WIA BUDGET REQUEST REDUCTIONS

Question. We are currently in the midst of the first year of implementation of the Workforce Investment Act, and people throughout the country are working hard to change our systems to accommodate the new Act. Many areas have had slow rates of expenditures over the first 6 months of the program, but as they get their systems up and running, the expenditure rates are increasing every day.

However, the effect of these proposed cuts will not be felt until July 2002, when all systems should be running smoothly.

I am concerned about making cuts which are based on projections made only 6 months into the new Act. Can you discuss the implementation of the Act and reassure me that these cuts will not result in cuts in service?

Answer. The transition from the Job Training Partnership Act structure to the new Workforce Investment Act has resulted in much slower spending than originally projected. While many jurisdictions jump started partnership- and system-building activities during PY 1999, July 1, 2000 marked States' and local communities' transition to WIA and its many reforms. Because of the nature of these reforms, full implementation of WIA by States and local communities is taking longer than originally expected, and the current lower than expected expenditures reflect this one-time phenomenon. While fewer participants will be served in PY 2000 than were served in PY 1999, States and local communities will be able to serve many more participants in PY 2001 and PY 2002 because of the availability of the carry over funds.

Major reasons for slower than anticipated activity include:

Implementing Fundamental WIA Changes Takes Time.—WIA requires fundamental system-wide changes in service delivery, the make-up of eligible service providers, and new customer service requirements. In addition, there also were major changes to State and local governance structures.

Workforce Investment System Access to Other Funds.—State and Local Workforce Investment Boards are encouraged to think strategically about how to use WIA and other funds most effectively in order to address labor market needs of the broad population served by WIA. They have used other funds available such as JTPA carry in dollars or Pell grants for low-income, college-ready adults before drawing down PY 2000 WIA funds.

More Emphasis on Universal Labor Exchange.—States and local communities have spent much energy and time on making the One-Stop Center networks under WIA work so that customers can access information about core job training, education, and employment services at a single location.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

Question. I am concerned that the Labor Department budget proposes a workers' compensation surcharge that would cost the Defense Department an additional $36.7 million—and all Federal agencies a total of $80.3 million. What is the rationale for including this legislative proposal in an appropriations bill? If Congress denied this request, where would you suggest making cuts elsewhere in your budget to restore the funds needed to administer workers' compensation programs?

Answer. Ensuring the safety of American workers is a priority of the Department of Labor. In the Federal arena, we see an urgent need to focus the actions of the employing agencies on increasing worker safety, in part, by highlighting for them the full cost of worker injuries, including the cost of administering the Federal Employees' Compensation Act (FECA) program. As you know, Federal agencies are billed each year for cash and medical benefits that have been paid to their employees under FECA, while DOL bears the cost of administering the program. The fiscal year 2002 Budget proposes to integrate benefit and administrative costs by allowing DOL to add an administrative surcharge to the annual bill DOL now sends to Federal agencies for FECA benefits. Because the surcharge is based on an agency's FECA benefits, we believe this proposal would provide an additional incentive for agencies to control FECA costs by preventing injuries and cooperating in return-to-work efforts.

We believe that an appropriations bill is the most efficient vehicle for establishing an appropriate funding mechanism that both ensures adequate funding for the administration of the FECA and enhances the safety of Federal workers by demonstrating the real cost of injuries. Our budget proposal provides for a surcharge that accomplishes this purpose and establishes guidelines and limitations for its use. Further, as the cost of Federal workers' compensation is a budget issue for the Federal agencies, we believe an appropriations bill is the best vehicle for addressing the issue.

Clearly DOL cannot administer FECA absent Federal resources. If Congress decides not to enact this proposal, the Administration will work with Congress to identify alternative resources for the administrative costs of the FECA program.

MASS LAYOFFS

Question. Mass layoffs are increasing. In January alone, employers announced 1,522 mass layoffs, involving the projected loss of more than 200,000 jobs. In the last year, 647,000 workers who lost their jobs due to mass layoffs filed for unemployment compensation. Wouldn't it be better to increase funding for Dislocated Worker training, instead of paying out longer unemployment benefits?

Answer. Under the Workforce Investment Act, dislocated workers receive services designed to meet their individual needs for assistance to help them return to work as quickly as possible. Individualized assessment of worker needs in One-Stop Career Centers helps to distinguish those dislocated workers who might return to work with minimal reemployment assistance from those who require more extensive help. Workers in the latter category include those with obsolete skills, with limited English proficiency, and workers in some communities that lack a diverse economic base.

Services for dislocated workers include a full range of activities, beginning with computerized job matching and resume posting, and extending to in-depth assessment and occupational skill training. Although many workers' training costs can be supported through Pell Grants and other resources, adequate funding for Dislocated Worker training is critical to meeting basic program goals. Our fiscal year 2002 budget request, combined with State unspent funds, will ensure that services to dislocated workers will not decrease from PY 2001.

For Dislocated Worker programs to achieve their goals of timely reemployment at good wages, the choice is not necessarily between longer unemployment benefits and increased funding for Dislocated Worker programs. Because workers who need additional skills to achieve quality reemployment must devote time to acquiring those skills in lieu of working, training for dislocated workers cannot stand alone. It must be supplemented by Unemployment Insurance (UI) benefits which provide needed partial wage replacement so that individuals can meet current living expenses while receiving training. The UI benefit helps reduce the financial hardship caused by loss of employment for individuals while at the same time helping to automatically stabilize the economy. For those workers who continue in training after their UI benefits are exhausted, needs-related payments are an available resource.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

Question. Secretary Chao, what is the Administration prepared to do for aluminum workers and other workers in the Pacific Northwest who lose their jobs due to the energy crisis?

Will your budget request provide sufficient resources to help workers who find themselves suddenly unemployed given the Administration's expressed concerns about a potential recession?

Answer. The Department's discretionary National Emergency Grant (NEG) program is designed to provide reemployment services, supportive services and retraining activities in response to mass layoffs and plant closures affecting large numbers of aluminum workers and other industries. Additionally, all communities have funds available to them through formula grants to serve dislocated workers. For example, in PY 2000 the State of Washington received $28.2 million in formula funds to assist communities in the State in serving dislocated workers, a 103 percent increase over the previous year's funding under the Job Training Partnership Act. Oregon received $30.4 million, a 72 percent increase.

EXPOSURE OF MINERS TO ASBESTOS IN LIBBY, MONTANA

Question. Are you familiar with the Inspector General's recent report on MSHA's handling of inspections of the mine in Libby, and with the recommendations contained in the report? Do I have your commitment that the Department will make it a top priority to implement the recommendations that require rulemaking as quickly as possible?

Answer. Yes, I am familiar with the Office of the Inspector General's (OIG's) report of March 22, 2001, *Evaluation of MSHA's Handling of Inspections at the W.R.Grace & Company Mine in Libby, Montana.* We are extremely pleased that the Senate has confirmed Mr. David Lauriski as the new Assistant Secretary of Labor for Mine Safety and Health. Both he and I are committed to protecting miners' safe-

ty and health, including preventing their exposure to harmful contaminants such as asbestos.

I have asked Mr. Lauriski to review the facts and the OIG's recommendations and consult with the affected parties to develop a course of action.

ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT (EEOICPA)

Question. Secretary, I believe you have said (*McLaughlin's "One on One"* taped on March 23, 2001) the Labor Department has "no capability, no infrastructure" to carry out the nuclear workers compensation program.

What are your plans to develop the infrastructure so you can get this program running?

Answer. My comments centered on the statutory deadline for the Department to implement this large new program. This reality poses significant challenges, thus warranting my public concern. We have been working diligently to develop the necessary regulations, organization, systems, and procedures for carrying out the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) in as timely a manner as possible. In doing this, we have been utilizing our experiences in administering the workers' compensation systems for Federal employees, longshore and harbor workers, and miners suffering from black lung. As I have explained in response to questions from other members of the Subcommittee, while the EEOICPA has some features similar to parts of each of the programs mentioned, its provisions are sufficiently different from any of those programs that is necessary for us to develop a separate infrastructure. Furthermore, the substantial number of claims that we expect to be filed in the first few years also requires a separate organizational unit, with dedicated staffing. This unit will be responsible for accepting and adjudicating claims under the program, a responsibility which will include determining the probability that an individual's cancer was as likely as not due to radiation exposures and adjudicating disputes. We have been working with the Departments of Energy, Health and Human Services, and Justice to implement this program in a fair and equitable manner. We will be utilizing private sector contractors as well as reaching out in a very broad way to recruit the necessary staff to adjudicate claims and supply the necessary technical expertise in areas such as radiation measurements and exposures.

Question. On March 9, you wrote to Mitchell Daniels, Director of OMB, that you recommended that "the administration support technical legislation that will soon be introduced to remedy some of the remaining deficiencies in the EEOICPA." What are these deficiencies and how do you see them remedied? What is the status of this legislative proposal?

Answer. As enacted, the EEOICPA contains few provisions concerning administration of the program or review of decisions made on claims for benefits. In addition, the Act also contains ambiguous or unclear provisions, some of which may have unintended consequences. The extremely short deadlines for implementing this program have required DOL to focus exclusively on efforts to promulgate regulations and create procedures and systems necessary to undertake our responsibilities under EEOICPA and Executive Order 13179. Thus, consideration of possible legislation must await our completion of the steps needed for the initial implementation of the program. We do intend, however, to further review this legislation and consult with the Office of Management and Budget and other agencies with responsibility under EEOICPA to determine whether and what type of legislative proposal is warranted.

WOMEN'S BUREAU EQUAL PAY

Question. The previous administration make bridging the wage gap a priority. What specific steps will the Bush Administration take to solve this serious problem?

Answer. In 1963 the Equal Pay Act was passed, and since then women have continued to make tremendous advancements in the labor force. Today, women earn more than half of all college degrees, and nearly half of all graduate degrees. With this increased education comes increased earning power for women, and the pay gap has narrowed significantly over time.

The Department of Labor, through the Women's Bureau, will continue to pursue a vigorous program of outreach to increase women's awareness of new opportunities for education, training, and employment. In addition, we will continue to inform employers of their responsibilities under the Equal Pay Act and to fight gender discrimination.

YOUTH PROGRAMS

Question. The 21st Century is rapidly approaching and the skills that will be most valuable in our country are ever changing. The workforce must, therefore, have the ability to adjust to the times. Currently, too many Americans are left behind in this sweeping change. The days when one could easily earn a living wage with a high school education are rapidly diminishing. Today, workers need more education and training to develop skills that reflect our changing economy. I am concerned that your budget provides $222 million less for youth employment and training programs. We should be increasing not decreasing our investments that focus on one of our most vulnerable sectors of the workforce, young people.

Fewer resources for programs like the Youth Opportunity Grants program will ensure less children are making productive transitions from school to work.

I must point out that your proposed funding request for the Rewarding Youth Achievement Program is on the right track by focusing on children in high poverty areas and providing them with employment opportunities they wouldn't normally receive. It is very important that the Department of Labor is a valued partner in providing young people opportunities to receive needed job skills to be competitive in the modern workforce.

Secretary Chao, what specific measures will you take to ensure these youth are provided with opportunities to learn needed job skills?

Answer. Although the fiscal year 2002 budget request provides $222 million less for youth employment and training programs, this request does not diminish our investment in one of the country's most valuable resources, America's youth. In fact, the request for WIA youth activities allows the Department to serve the same level of youth as will be served in 2001—721,000 youth. The transition from the Job Training Partnership Act has resulted in significant underspending as State and local programs gear up to fully implement the numerous structural changes in the workforce investment system under WIA. As these unspent funds are carried forward and States become fully operational, service levels will increase creating more opportunities for America's young people. The Department will work vigorously with State and local communities to ensure that systems are in place to provide opportunities for young people to learn the needed job skills and receive the necessary support to achieve academic success.

SHORTAGE OF CAREGIVERS

Question. This past week, HHS Secretary Thompson testified before this Subcommittee on the need to address the current shortage of caregivers nationwide, particularly in our Nation's nursing homes and assisted living facilities where there's a shortage of 250,000 CNAs and 60,000 RNs. This Subcommittee would like to work closely with you in the effort to address this serious problem to ensure that the nation's frail elderly receive quality care.

I am interested in your thoughts on ways to address this shortage of caregivers?

Answer. The Department of Labor is cognizant of the need for more caregivers at all skill levels and is working to address this issue. For example, under the Workforce Investment Act of 1998, an eligible individual may select training in high-demand occupations certified by their local workforce investment board. Certified Nursing Assistants (CNAs) represent an occupation that is very much in demand in most local areas. Therefore, an individual who goes to a One-Stop Career Center and becomes eligible for training will likely see CNA training offered as a response to one of the occupational choices. Many One-Stop Career Centers also offer access to training in advanced skills that require certification, such as medical laboratory technicians, operating room technicians, and inhalation therapists.

In addition, a substantial number of the 190 Welfare-to-Work competitive grantees (representing an investment of nearly $700 million dollars over six years) offer welfare recipients and other low-income individuals training and work experience opportunities to gain employment as a CNA or in other health occupations.

Finally, the H–1B Technical Skills grant program provides specialized, high skill training to American workers desiring to upgrade their skills to fill occupations that are now filled temporarily by foreign workers. In 2001, we expect to have approximately $180 million available for the H–1B Technical Skills grants. Through this program, the Department has recognized health care occupations, particularly registered nursing, as a specialty occupational area in high demand.

Some H–1B Technical Skills grants have focused specifically on health care training, in particular nursing training. In New York, the League/Service Employees International Union (SEIU) 1199 Training and Upgrading Fund received an award that proposed to train 675 employed and unemployed health care workers for high demand nursing positions. Under another grant, the State of Vermont and the

Vermont Human Resources Investment Council will work together to provide a mix of on-the-job training and on-site instruction for critical care nurses to place workers in 16 hospitals. Workforce Essentials, an H–1B Technical Skills grantee in Clarksville, Tennessee is training registered nurses.

LEGISLATION FOR LONG-TERM CARE GIVERS

Question. In the Senate, work is now underway on legislation that would provide $500 million a year for the next three years, in grants to States, to promote the nursing profession and to help long term care providers recruit, train, and retrain caregivers at all levels. Would you be supportive of this approach to addressing the caregiving shortage?

Answer. The Department of Labor is very interested in efforts to address employers' demand for skilled workers while also providing opportunities for unemployed and underemployed individuals to increase their skills and advance in their careers. The Administration is particularly concerned about communities that lack access to care and plans to reform the National Health Service Corps to better define shortage areas and target placements of non-physician providers practicing in communities.

The Administration will carefully review and consider legislation to address this issue. Once the legislation has been reviewed, we will be happy to share our views with you.

IMMIGRATION OF HEALTH CARE PROFESSIONALS

Question. HHS Secretary Thompson testified before this committee last week that part of the solution might be tied to allowing more foreign nurses and health care workers to immigrate to the United States to help fill the void. Would the Labor Department be willing to work directly with HHS, the Department of Justice, and the Immigration and Naturalization Service to create an immigration program that can help meet this need?

Answer. The Department currently is administering the H–1C nonimmigrant nurses program, which is intended to address nursing shortages in areas where there are spot shortages. It previously administered the now-expired H–1A nonimmigrant nurses program. The Department of Labor would be, of course, willing to work directly with HHS, the Department of Justice, and the Immigration and Naturalization Service to develop creative ways to address this problem over the long-term.

QUESTION SUBMITTED BY SENATOR THAD COCHRAN

MIGRANT AND SEASONAL FARMWORKER HOUSING PROGRAM

Question. In the past, this subcommittee has included appropriations report language directing the continuation of a small, but important program that assists farmworkers in gaining better housing. Since at least 1983, I have worked with the Department to ensure a network of local organizations, including one in my State, receives funding to plan, develop, and manage housing for migrant and seasonal farmworkers. There is a well established network of local housing organizations that receive these funds.

In the fiscal year 2001 Labor Appropriations report, language was included to provide $4 million in funding for this network. This amount was an increase of $1 million over the fiscal year 2000 level. I am hopeful that the Department of Labor will continue to support increased funding for this important program.

I look forward to working with you and the Department in the future. Thank you.

Answer. The Department of Labor will provide a total of $4 million for competitive and non-competitive farmworker housing grant activities in Program Year (PY) 2001. Grants totaling $3.6 million will be awarded competitively to fund housing and housing development activities for migrant and seasonal farmworkers. The Department is also funding on a non-competitive basis the Hope Migrant Rest Center for $333,000. The Center provides overnight and temporary lodging to over 40,000 migrant farmworkers and their families who criss-cross the country in search of and en route to seasonal agricultural jobs.

Grants to the National Farmworkers Jobs Program authorized under WIA section 167 will total $72 million for PY 2001. These programs also provide for direct assistance to eligible farmworkers for transitional, temporary, or emergency housing in support of job training activities, or agricultural employment.

Senator SPECTER. Okay. Thank you all very much.

Secretary CHAO. Thank you.

SUBCOMMITTEE RECESS

Senator SPECTER. The subcommittee will stand in recess to reconvene at 9:30 a.m., Thursday, May 10, in room SD–192. At that time we will hear testimony from Dr. Roderick Paige, Secretary, Department of Education.

[Whereupon, at 10:47 a.m., Wednesday, May 2, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, May 10.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

THURSDAY, MAY 10, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:37 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Harkin, Reid, and Murray.

DEPARTMENT OF EDUCATION

OFFICE OF THE SECRETARY

STATEMENT OF DR. RODERICK R. PAIGE, SECRETARY OF EDUCATION
ACCOMPANIED BY THOMAS P. SKELLY, DIRECTOR, BUDGET SERVICE

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen of the subcommittee on Labor, Health, Human Services and Education. The Appropriations Committee will now proceed.

This is the first hearing where we have an opportunity to welcome the distinguished Secretary of Education, Dr. Paige. He brings to this Cabinet position a very distinguished record; a bachelor of science from Jackson State University; a master and Ph.D. degrees from the University of Indiana. He had been the superintendent of the Houston Independent School District, a job of enormous responsibility, where he was innovative and very accomplished. He previously served as Dean of Education and Athletic Director at Texas Southern University.

In addition to the widespread praise and reputation, he has been awarded the 1999 Richard R. Green Award by the Council of Great City Schools, the 2000 Harold W. McGraw, Jr. Prize in Education from the McGraw-Hill Companies, and the 2001 National Superintendent of the Year Award from the American Association of School Administrators.

EDUCATION BUDGET ISSUES

Dr. Paige, you come to present the administration's budget request on a day when, as you know, the Senate is considering the Education bill.

Secretary PAIGE. Right.

Senator SPECTER. A very complicated matter. We have set it aside, briefly, to take up the budget. There are nine pending amendments. To say it is a quagmire would be an understatement. But I have seen, in the time I have been here, that institutionally the Senators are a lot smarter than any of the individual Senators. I would not say that for secretaries, but for Senators and—and the Senate has a way of working through the problems.

There are a great many subjects that we want to ask you about today; the allocations, some of the additional programs, some of the programs which have been cut, the problem of campus crime, the Youth Violence Initiative which this subcommittee put into operation, the issues on class size, more teachers, and the school construction.

And I turn now for an opening statement from my distinguished colleague, Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. And I cannot think of a more timely time to have this hearing than right now, when we are involved in a debate on the Senate floor on the Elementary and Secondary Education Act reauthorization.

We welcome you, Mr. Secretary, for this very important budget hearing. We can talk all we want to about education and how we all love it and how we want to make education better, but if the resources are not there, it is just more of the same old rhetoric.

Now, Mr. Secretary, I have a great deal of admiration for you and for your background and what you have done for education. So, I hope that what I am about to say you do not take personally——

Secretary PAIGE. I will not take it personally.

Senator HARKIN [continuing]. But take it policy-wise.

Secretary PAIGE. Yes. Thank you.

Senator HARKIN. And I had great hopes earlier this year when President Bush was talking about leaving no child behind. When he picked you to be his Secretary of Education, I thought we are going to be on our way. And quite frankly, my hopes, I think, have been dashed. The budget this year is just incredibly inadequate, in terms of education.

SPECIAL EDUCATION FUNDING

Now, I am going to just start, first of all, by reading an article that was in the paper this morning. Now, I do not know if it is true or not, but I am going to read it to you.

It said—it is talking about the education plan. It said, "The administration indicated it was particularly upset—particularly upset—by a vote last week to increase funding for schooling disabled students and to lock it into the Federal budget for the next 10 years by shielding it from the annual appropriations process. Officials described the proposal as 'costly and unwarranted.'"

I hope that official was not you, Mr. Secretary.

Well, after all these years, on both sides of the aisle, talking about getting the Federal Government up to its 40 percent of the average per pupil expenditure for kids with disabilities—and you and I have talked about this personally in my office—the Senate

finally, on a unanimous vote—unanimous, which means when we offered the amendment, we did not even ask for a vote; it was unanimous, because no one objected—unanimously said, "We are going to appropriate, not just authorize, but we are going to appropriate about $181 billion over 10 years to meet this need."

And now, the administration says they are upset about it; that it is costly and unwarranted. I beg to differ.

TAX CUT PACKAGE AND EDUCATION FUNDING

Second—or third, I guess, Mr. Secretary, the Senate adopted an amendment that both of us supported, that would have shifted $250 billion out of the $1.6 trillion tax cut, and put it into education. Well, the House had passed the administration's $21.3 billion for 10 years.

Well, you would think, when it went to conference, they might have compromised someplace in the middle. The budget we got back is zero. The budget that we have, that we are going to vote on today on the Senate floor, has zero increase above baseline for education for the next 10 years. They did not even put in the President's $21.3 billion, let alone the $250 billion that we had supported in the Senate.

And so, I would like to have your thoughts on that and find out, well, why is not the administration saying something?

SCHOOL RENOVATION FUNDING

I am disappointed that they have eliminated the $1.2 billion fund for school modernizations.

The American Society for Civil Engineers recently issued a report—they gave our schools a D-minus. The lowest grade of all of the facility infrastructure in America was our schools.

Finally, the Senate and the House, last year, began the process of reaching out to help modernize our schools, and the administration has zeroed that out.

Well, I know that money alone will not improve schools. I have heard that all the time, but tell me how you are going to repair a roof, if you do not have some money; how you are going to build an extra classroom, if you do not have some money.

Sure, we want accountability, testing—I can work my way through all of those, but if we do not have the resources in there to build decent schools for kids, I am sorry, I am out of here. And I just do not understand where the administration is on this.

STRATEGIC REVIEW OF EDUCATION BUDGET

Well, lastly, I just say this: Next week Defense Secretary Donald Rumsfeld will announce the results of a strategic review of the Defense budget. And then, the President plans to submit a new budget request based on those results. And the rumors I am hearing around here were on Defense appropriations, we are going to commit an additional $20 billion to $30 billion per year.

Why can we not do that for schools? Why would not the President have a strategic review of the education budget, and ask the question, are all our kids ready to learn when they enter school?

In 1989, President Bush, the Governors, we all decided on Goals 2000. We are going to meet Goals 2000 in education. First goal, every child ready and able to learn by the time they enter school. 2000 was last year, and we are not even anywhere near it.

Are our classes small enough to promote learning? Are our schools in good repair? Are teachers well trained?

Well, if the answers are no, why do we not have a strategic review and come back with a budget that will meet these needs? But no, what I read is they cannot even support what we finally decided on a bipartisan basis to do. And that was to meet the needs of special education.

So, Mr. Secretary, I have great respect for you.

Secretary PAIGE. Thank you.

Senator HARKIN. And I mean that, personally. Your background speaks well. But I am telling you, this budget is awful, when it comes to education. And I just hope that you will speak up and fight as hard as you can, as a Secretary, to say that this is unacceptable to everyone.

I am sorry to be so emotional about it, but my gosh, we have got to do something about this education budget.

Thank you, Mr. Chairman. I am sorry.

Senator SPECTER. Well, so much for the level playing field, Mr. Secretary.

Well, Senator Harkin never minces words. We know exactly where he stands.

In the end, we have had a record for coming together in a collegial way. And I am optimistic we will do the same thing here.

EDUCATION 302(B) CONGRESSIONAL BUDGET ALLOCATION

I might just add one more word before you begin your testimony. We are trying to get an allocation for this subcommittee which will accommodate the points that all sides are making, the points the President is making, the points the Secretary is making, what Senator Harkin has in mind, what his caucus has in mind.

Without giving you the bitter experience of last year, this subcommittee set a mark at $106 billion, which was President Clinton's figure, which was candidly more than my caucus wanted to set, but with a lot of effort, that was established. And we re-allocated some of the priorities. And then we had a dispute, and at one point it looked like we were going to $114 billion instead of $106 billion. And we finally ended up at a little over $107 billion.

And this year I am concerned that when we go to the floor, there will be add-on amendments. And 13 republicans, last year, voted with the democrats to add the funds. And as the manager of the bill, I stuck with the figure and cast more bad votes in 3 days than I passed in the past 19 years on my own preferences for allocations.

So, if we get an allocation which can accommodate at the start, I think we will make some headway. Some in my caucus say, "Well, the President will veto a bill which is too high." Okay. But then it comes back to the Congress. And what do you do from there? With a 50–50 split, my very strong conviction is we ought to come to terms at the outset on a total figure, and then work on the priorities as to how we meet it, as opposed to taking one amendment

after another, which will ultimately run the severe risk of leading to gridlock.

With that overly long introduction, Mr. Secretary, we look forward to your testimony.

SUMMARY STATEMENT OF DR. RODERICK R. PAIGE

Secretary PAIGE. Mr. Chairman, thank you so much. And I actually benefitted from those comments. And I appreciate them. I even appreciate the comments of Senator Harkin. I especially appreciate his passion because I know he means that very deeply. We have some points of disagreement on emphasis, but I assure you that I really respect your interests in the children of America, as I do the other members of this fine committee.

Thank you for the opportunity to testify on behalf of President Bush's 2002 budget for the Department of Education. As you know, the President has made education his highest priority, and has reflected that in his budget request.

EXCELLENCE IN EDUCATION MUST BE NATIONWIDE

The reason for this is simple. There is no part of our interest more important to the future of our Nation than the education of our children. And fortunately, in pockets and corners around the country, dedicated teachers in our exceptional schools are safeguarding our future by fixing and giving children rich and exciting experiences in learning. And we congratulate them, because we know of their dedication and commitment. And the children who attend those schools are not being left behind.

Those schools do not represent the norm. Basically, our system is going to be required to be fixed in order to achieve the goal of educating all of our children. And no society has ever attempted that before.

Most societies have even gone so far as to assign or designate those children who should be educated and those who should not. To say that no child should be left behind is a pretty aggressive goal. That requires the system to work. So pockets of excellence will not work here.

And even as we congratulate those schools that are great and those teachers and principals and parents and PTA members who are causing that greatness, we congratulate them, we say it is insufficient and we need to fix the system.

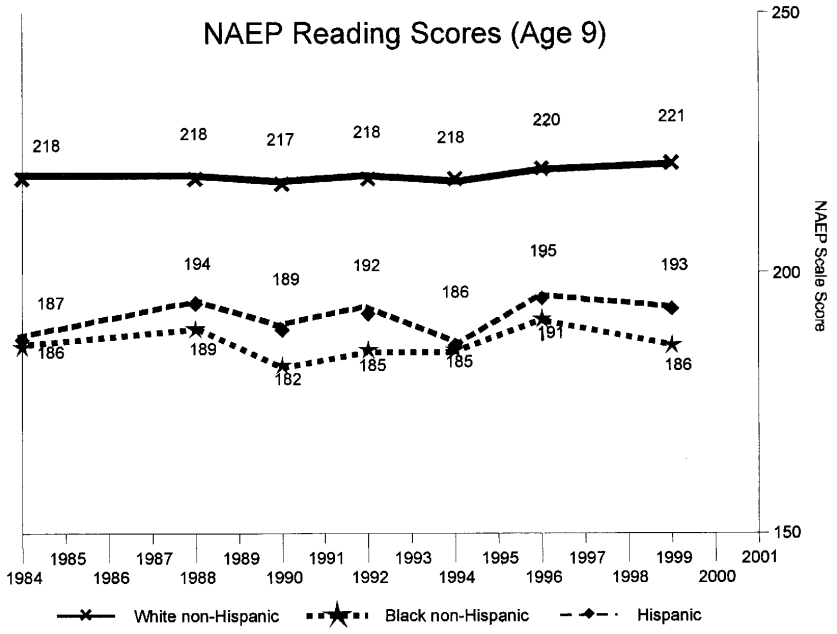
EXCELLENCE REQUIRES CHANGE

And so, the emphasis in the President's budget is about reform, about changing things. We do not think continuing on in the way we are going will accomplish this. If things do not change, they stay the same. And we know that the same is not satisfactory.

NAEP TESTING RESULTS—4TH GRADE READING SCORES

Last month I had the dubious distinction of participating in the announcement of the latest results from the National Assessment of Educational Progress in reading for our 4th grade students. And any caring person who heard those results will agree that we cannot keep doing the same. I call it dubious, because the only news

that I had to comment on after the press conference was that the average reading performance of our fourth graders had been flat. This is shown in this chart showing NAEP reading test scores for 4th graders from 1984–1999.



FLAT READING PERFORMANCE

Now, if you bear down inside that statement that the average performance is flat, you find that that result is from the better students getting better and the worst students getting worse. The net result being flat reading scores.

But if you look at it from a deeper perspective, even, the students who are doing worse are exactly the students who this bill was created to help. That is even more devastating.

So, flat performance is not good enough. And so, it requires change.

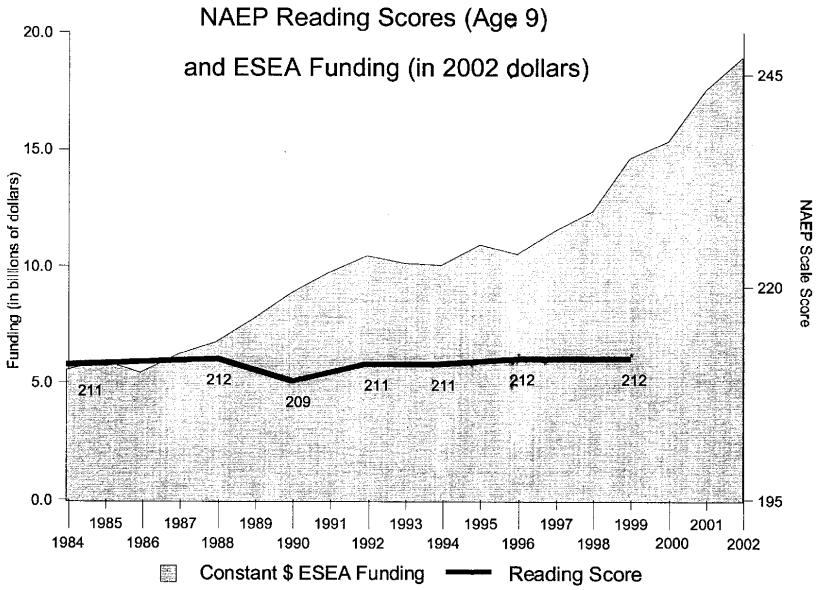
The results of that reading assessment are even more disconcerting when we look at it from the point of view of our disadvantaged students.

I am sorry to tell you that among students taking the 4th grade reading exam, ethnically, they are dividing themselves; economically, they are dividing themselves. Despite Federal programs designed to help the disadvantaged students, that is exactly the group that is doing worst.

There is a decade of historic increases in funding that supports this. We are not doing the right things or we are not doing things right.

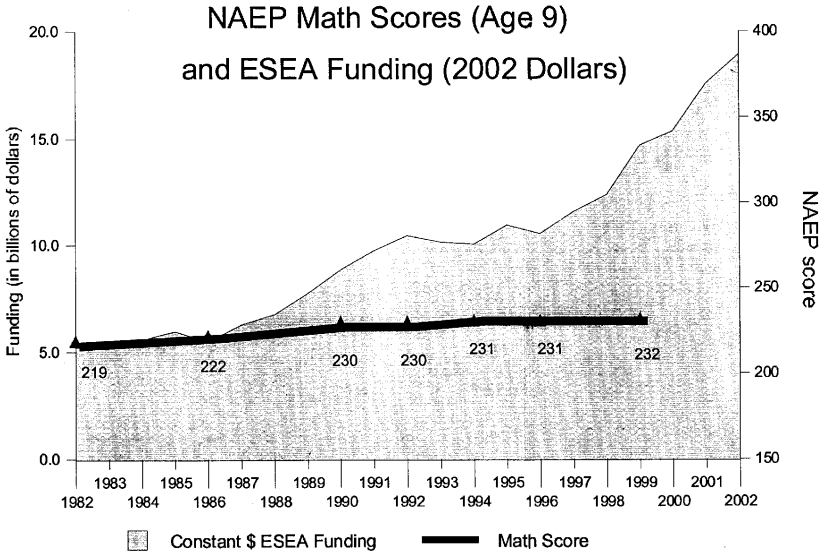
ESEA SPENDING AND 4TH GRADE READING ACHIEVEMENT

The story of our investment in education can be illustrated by this graph which shows 4th grade NAEP reading test scores for 1984–1999 and the Federal ESEA investment over the same period. It speaks for itself. Now, promoting the continuation of that seems to me to be inappropriate.



ESEA SPENDING AND 4TH GRADE MATH ACHIEVEMENT

The story of our student performance in mathematics can be illustrated by this graph.



FEDERAL ESEA INVESTMENT AND STUDENT ACHIEVEMENT

The charts make powerful arguments to stopping, to pausing. Let us stop and take a look at what kind of results we are getting and think about doing something different.

I want to say here that I know that everybody shares my passion, the Senators' passion, and all our passion about fixing these things, but I am just trying to call your attention to what is happening.

The story of our students' performance tells the story. Perhaps the most powerful one is the chart showing reading achievement for the 4th graders as measured by NAEP test scores and compared to the Federal ESEA investment. The blue is the spending. The red is the performance. The connection between those points do not seem to connect. It argues, for me, to let us take another look.

CREATING A CULTURE OF ACHIEVEMENT

I give everybody credit for wanting to do things to improve student performance. Federal funds have been forthcoming. To understand this better, I went back and read the arguments for and against the ESEA bill in 1965 and each reauthorization thereafter. I read the Congressional Records, the reports and looked at those who argued for and against various points of views. I can tell you, from that reading, that we are circling and making the same arguments and getting the same results.

While Federal funds have been forthcoming, student performance has stagnated on the average and declined among the hardest to reach students. The students who we are supposed to be reaching through Title I and other Federal programs are precisely the kids that are hurting.

Our system is a system that has allowed elementary and secondary student performance to stagnate, while in the last few years, the spending increase has averaged 17 percent. And when we spend, we think that we have conquered. When we spend, we think we have had victory. And we measure success by how much we spend.

And I am not telling you things that are new. These things have been said before. The General Accounting Office in 1998 said, and I quote, "The clearest evidence about a lack of positive effect from Federal expenditures comes from one of the largest programs, Title I. Title I of the Elementary and Secondary Education Act is the largest Federal elementary and secondary education grant program. Children in high-poverty schools began school academically behind their peers in low performance schools and could not close these gaps as they progressed through school. In addition, when assessed according to high academic standards, most Title I students failed to exhibit the reading and mathematics skills expected of their respective grade levels."

This is the goal we said we were going to accomplish in 1965. I can say that from reading the history.

Now, what should we take away from this lesson? Simply put, we know that spending more on the same thing is not the answer. We need to do things differently to adopt a culture of achieving in our schools and school systems, and to demand results from our growing investment. We also need to continue to invest in those enterprises that work.

GUIDING PRINCIPLES OF EDUCATION CHANGE

And I am proud to appear before you on behalf of the administration's budget to make the point about some principles that work. I know they work. I personally participated in them.

HOUSTON INDEPENDENT SCHOOL SYSTEM

I used them to improve the seventh largest public school system in the United States that resides in the fourth largest city in the United States that is populated by poor children. The school district that has converted itself from a district with minorities to a district of minorities; a district with 73 percent free and reduced lunch eligible students. These simple principles——

Senator REID. I did not understand that. Seventy-three percent of what?

Secretary PAIGE. Seventy-three percent of the 210,000 to 215,000 students are eligible for free and reduced priced lunches, which is a criterion or indication of being poor.

And by the way, it is probably higher than that, because we know that middle school students and high school students, traditionally, do not register for free and reduced priced lunches, even though they are eligible in many cases.

ESEA REAUTHORIZATION

You and your colleagues are in the midst of a critical debate over the reauthorization of the Elementary and Secondary Education Act and the substitute to be offered by Senator Jeffords, the Better

Education of Students and Teachers Act. That is pending before us, now.

PRINCIPLES OF EDUCATIONAL CHANGE

I will not bore you with these principles, because I know that you have heard them before. I will just briefly list them—accountability, flexibility, allowing the principals at the—the principal and the other people, not just the leader of the school—but all the people at the site to make decisions and to have control over matters, doing things that work, not funding failure.

Many people are doing the same thing over and over again. When I became superintendent of the Houston Independent School District and looked at the Title I programs, we had to call a moratorium on doing the same thing, and to say, "If you did this last year and this is your results, we are not going to allow you to do it this year."

And so the momentum of this continue-to-do-the-same-thing is so powerful, that it takes effort to stop it and put something new there. And this is not about money. It is okay to spend all the money in the world we have got, but it is about our children, who are not gaining with this principle. That is the point.

The budget is the argument, but the point is our students are not growing. And we need to figure out a way to deal with that.

Reading is a particularly difficult problem. It is the foundation of learning. And when students cannot read, the rest of it is all of no value.

Expanded parental options. We could argue politically about this. And there is no reason to beat a dead horse, but nobody has answered the question, what do you intend to do with students who are failing in a failing school? If a school has failed and failed and failed, what do you intend to do about the students?

The only answer I have heard is: Continue to fix the school. Favor the system over those kids. I argue passionately against that—I do not think any principle is more important than fixing the kids.

FAILING SCHOOLS—CUMULATIVE EFFECT OF ACHIEVEMENT GAPS

When we look at the Sanders' study, it tells us that these kinds of gaps are cumulative, which means the student who has an ineffective teacher for 1 year, and then the second year has a very effective teacher, still the gaps created by the ineffective teachers cannot be covered up. This gap is continuing. So, we go through 2, 3 years of ineffectiveness? What do we intend—what do we do with the students who are not growing in this environment? It seems to be the most important question we could ask.

You know the numbers better than I. So, I will not bore you with these numbers. I will quickly bypass them and go to the end of this presentation.

DEBATE REFORM AND PRINCIPLES OF REFORM, NOT BUDGET

I know the President has provided in his budget expanded funds. And I believe that he is amenable to increasing the spending of funds, but the question is not allowing the discussion to be

switched from reform. Reform is the issue. Funding is not the issue. If funding were the issue, we would not be arguing now. Reform is the issue. The debate is about reform, not about funding.

I am about finished. Overall, you know the numbers in the President's budget better than I, but I do want to emphasize that the President has put terrific emphasis on the critical skill of reading. And we intend to make that work.

I referred, already, to the charts that you saw before you, but I want to do so, again, because I want to underscore that if money alone were the answer to our education dilemma, we would not be here today.

You are considering this budget in the context of a debate about reform. And that will make all the difference in the world for our children. The same is not true for other Department of Education programs, other than elementary and secondary programs. Money alone will not result in a system change. And no matter how much we spend, we cannot measure success that way.

I urge you to give the President's reform proposals very careful consideration. And I will end by making this observation—and I apologize, at first, for continuing to refer to myself as a Houston public school administrator. I was drafted for that job. I did not ask for it. But once I had accepted the responsibility for the management of that system, the seventh largest public school system in the world, I was intent on making it work.

And it was disconnected from the public. By that, I mean the public had very little confidence in this system. And for 3—no, 4 straight years, we did not go back to the public, we decided not to ask the public for additional funds. So, there was no tax increase at all, although we grew, the public schools student population grew.

I want to make the point that we can reform the system without going back for additional dollars; using inside funds; redistributing these funds, and using them in a more effective way.

And after 4 years of that—each year, coming back and showing improvement as we went—when we did have to go back to the public to build buildings, we were successful in raising the funds. The public had turned down a $391 million bond issue 3 years earlier, which was the greatest lesson in my life, because if they had passed that bond issue, I would have spent 3 years building buildings.

They defeated that bond issue and I spent that next 3 years building the confidence of the public in the public school system. I spent 3 years building relationships. And I spent 3 years building productivity and efficiency inside the system.

And 3 years later, I went back to the public with a bond issue twice that size, with $678 million, the largest ever in the history of our State, and said, up front, "It will cost you 5.5 cents on the tax rate." And in Texas, you do not say "taxes." We stood out, publicly, and said it loud.

Seventy-three percent of the public voted to support that bond issue. All segments of the public; people who did not have children in our schools; from both sides of the political spectrum; from labor and from management, every segment supported it, because they had confidence in what we were doing.

HOUSTON SCHOOL SYSTEM REFORMS AND PUBLIC OPINION

Senator SPECTER. Mr. Secretary, what reforms did you initiate in the interim to lead to that change in the public attitude?

Secretary PAIGE. The first reform, Senator, was to accept responsibility for student learning. It was to hold people accountable and to administratively arrange a relationship between the leaders of our schools—the managers, the principals—and connect in that way to increase their productivity; rearranging their contracts, so each had contracts just like I had, which almost was a public service—a public sector contract, because the board could change it at any moment. They did not have the political cover of going to their board members or other people like that. That was the first one.

The second one was to set real clear, crisp standards and continue to remind them of those standards. In every school that you went to, there was a graph on the wall saying, "Here is where you are, now. And here is where you are going to be 4 years from now. And here is what annual progress means, where you will be next year."

So, we listened to the public, talking to the community groups, the business community, the faith-based community, the ethnic groups, NAACP, LULAC, all of those, getting all of these people involved.

I do not mean to imply that we licked this thing. I am just saying that we had progress and the progress was built on the common practice of listening. We stopped talking about money, started talking about productivity, and showed the results to the public.

And by the way, even when we made mistakes, we would go to the public and say, "We made this mistake." We stopped making excuses about mistakes. When something went wrong, we stood up in front of them and said, "We did this wrong. We will do it better."

We did a lot of different things, like simply taking responsibility, setting high standards, measuring results, reporting those results to the public, calling our administrators in and letting them know feedback on how they were performing.

PREPARED STATEMENT

Senator SPECTER. Mr. Secretary, your full statement has been received by the committee and has been studied and fully made a part of the record, if it is acceptable to you.

Secretary PAIGE. It is.

[The statement follows:]

PREPARED STATEMENT OF DR. RODERICK R. PAIGE

Mr. Chairman and Members of the Committee: Thank you for this opportunity to testify on behalf of President Bush's 2002 budget for the Department of Education. As you know, the President has made education his highest priority, and this priority is reflected in his 2002 budget request.

The reason for this is simple: there is nothing more important for the future of this great Nation than the education of our children. Unfortunately, our system of education is failing too many of those children. Earlier this month, the latest results of the National Assessment of Educational Progress (NAEP) showed that the average reading performance among our fourth graders has not improved since 1992. And when 37 percent of our 4th-graders—and nearly half of inner-city 4th-graders—are unable to read at even the NAEP Basic level, our education system is broken and needs repair urgently.

President Bush and I are especially concerned about the persistent gaps in achievement between poor and minority students and their more advantaged peers. For example, the NAEP results showed that in 4th grade reading, 73 percent of white students performed at or above the basic level, compared with just 42 percent of Hispanic students and only 37 percent of African American students.

This disappointing performance comes after nearly two decades of national attention on education reform and a dozen years of rapidly increasing Federal spending on elementary and secondary education. Simply spending more money in the same way is not the answer. We need to do things differently, to adopt a culture of achievement in our schools and school systems, and to demand results for our growing investment in education.

That's why I'm especially proud of the President's 2002 budget request for education. It provides a budget authority increase of $4.6 billion, or 11.5 percent—the largest increase of any cabinet-level agency—and a $2.5 billion or almost 6 percent increase over the 2001 program level. This increase is particularly impressive in the context of the President's overall effort to restore discipline to discretionary spending over the next decade while delivering an across-the-board tax cut benefiting all American families.

Even more important, these new dollars are focused on changing the culture of our education system and closing the achievement gap. Our budget reflects the principles put forward in No Child Left Behind: high standards; annual testing of all students in grades 3–8 in reading and math; increased accountability for student performance; a focus on research-based practices—particularly in teaching reading; reduced bureaucracy and greater flexibility for States, school districts, and schools; and expanded options for parents to make choices for their children's education.

CLOSING THE ACHIEVEMENT GAP

President Bush believes that the Federal government can, and must, help close the achievement gap between disadvantaged students and their peers. The primary means toward this goal is the Title I Grants to Local Educational Agencies program. We are requesting $9.1 billion for this program, an increase of $459 million, to give States and school districts financial support to turn around failing schools, improve teacher quality, and ensure that all students meet State academic standards before advancing to the next grade.

No Child Left Behind provides a new framework of accountability for ensuring that the Federal investment in Title I is well-spent and delivers the results intended when it was first authorized 36 years ago: closing the achievement gap between poor children and their more advantaged peers. The foundation of this new accountability framework is annual State assessments in reading and math for all students in grades 3–8, instead of the current law requirement for testing only twice during these critical formative years. The President's budget provides $320 million to help States develop and implement these additional assessments.

I know many in Congress have concerns about these new assessments, but I can tell you from my own experience that there is no substitute for annual information on how well students and schools are performing. Children in good schools make remarkable progress during these early grades, and we cannot afford to wait three or four years to find out that some students have fallen behind. Where there are problems, they must be discovered and addressed immediately, an approach that can only be accomplished with the information provided by annual testing.

Moreover, these tests are essential if we are to set clear goals for performance and help our schools get the job done. The alternative is to continue to rob millions of poor and disadvantaged young Americans of their futures by failing to provide them an effective education.

The important thing about testing, of course, is what we do with the results. We would start by helping teachers learn to use data effectively. Secondly, we would require schools to report assessment results for all students to parents and the public. School districts would use these results to make sure that all schools and students are making adequate yearly progress toward State content and performance standards, and that no groups of students are left behind.

Under No Child Left Behind, schools would be identified for improvement after just one year of failing to meet State standards. And unlike the current system, where about half of schools identified for improvement receive no additional assistance from their State or district, we would require States and school districts to provide these schools with technical assistance grounded in scientifically-based research. The $9.1 billion request for Title I Grants to Local Educational Agencies includes $400 million, an increase of $175 million or 78 percent, to help pay for these efforts to turn around low-performing schools.

If the school still has not improved after two years, it would be identified for corrective action and subjected to more comprehensive measures, such as implementation of a new curriculum, intensive professional development, or reconstitution as a public charter school. While such measures are underway, students would be given the option of attending another public school not identified for improvement or corrective action.

Only after all these efforts, and following three full years of poor performance—during which time a student may well have fallen behind a grade or two—would we use Federal funds to help that student find a better education at a private school. We are proposing to permit the use of Title I funds to help students transfer to a higher performing public or private school, or to obtain supplemental educational services from a public- or private-sector provider. I know there are disagreements about methods of reform, but surely everyone can agree that no child should be trapped in a persistently failing school.

Taken as a whole, these proposals reflect what I believe is a strong consensus, both within the Congress and among the American people, that States, school districts, and schools must be accountable for ensuring that all students, including disadvantaged students, meet high academic standards. At the same time, we recognize that it is unfair to demand accountability without enabling success. This is why the 2002 budget supports other proposals in No Child Left Behind that would give States, school districts, schools, teachers, and parents the tools and flexibility to help all students succeed.

For example, the President's Reading First program would help States and school districts implement comprehensive reading instruction grounded in scientifically-based reading research for children in kindergarten through third grade. The budget includes $900 million for Reading First State grants, more than triple the 2001 level for reading instruction. The request also would provide $75 million for Early Reading First, an initiative that would complement Reading First State Grants by supporting model programs to develop the academic readiness of preschool-aged children. Over 5 years, the President would invest more than $5 billion to ensure that every child in America can read by the 3rd grade.

We also are requesting $846 million for 21st Century Community Learning Centers to support a State formula program that provides high-quality extended learning opportunities after school and during the summer, particularly for children in high-poverty and low-performing schools. And a $30 million request for our Transition to Teaching proposal would help school districts recruit, prepare, and support a wide range of talented career-changing professionals as teachers, particularly in high-poverty schools and in high-need subject areas.

EMPOWERING PARENTS WITH CHOICES

President Bush and I believe that one of the best ways to improve accountability in our schools is to give parents the information and options needed to make the right choices for their children's education. This is why, for example, the accountability proposals in No Child Left Behind include school-by-school report cards and give students in failing schools the option of transferring to a better school. In addition, the 2002 budget request includes the following:

The President is proposing to increase the choices available to parents through a new $175 million Charter Schools Homestead Fund. The program dollars will be used to provide grants to leverage funds to build, lease, purchase, or renovate facilities for use by charter schools. A $200 million request for the regular Charter Schools programs, an increase of $10 million, would support approximately 1,780 new and existing charter schools that offer enhanced public school choice and have the flexibility to offer innovative educational programs in exchange for greater accountability for student achievement.

The President is also proposing a tenfold increase in the annual contribution limit for education savings accounts, from $500 to $5,000. Parents would be able to make tax-free withdrawals from these accounts to pay for elementary, secondary, college, and after-school program expenses at both public and private schools.

EXPANDING FLEXIBILITY AND REDUCING BUREAUCRACY

The Administration believes that it is possible to achieve better results by reducing regulations, paperwork, and bureaucracy and giving States and communities the flexibility to create their own innovative solutions to challenges in education.

For example, the $2.6 billion State Grants for Improving Teacher Quality proposal would combine funding from several existing education programs, including the Class Size Reduction and Eisenhower Professional Development State Grants programs, into performance-based grants. The proposal would provide a $375 million

or 17 percent increase over the antecedent programs to help States and local educational agencies (LEAs) fund their own needs and priorities in developing and supporting a high-quality teaching force.

Similarly, the $817 million Educational Technology State grants proposal would consolidate all of the Department's current educational technology programs into a single, performance-based grant program to ensure that schools use technology effectively to improve teaching and learning. And our $472 million request for Choice and Innovation State grants would combine overlapping and duplicative programs into one flexible grant program to help States and school districts implement their own innovative strategies, including school choice, for improving student achievement.

OTHER KEY ELEMENTARY AND SECONDARY PROPOSALS

The President's budget includes a $1 billion increase for the Special Education Grants to States program, for a total of $7.3 billion. This is the largest increase in this program ever requested by a President, and would provide an estimated $1,133 for each child with a disability. That is approximately 17 percent of the national average per-pupil expenditure—the highest level of Federal support ever under the Individuals with Disabilities Education Act.

We also are requesting $644 million for Safe and Drug-Free Schools State grants to provide students with more effective drug- and violence-prevention programs and to implement strategies to improve school safety. No Child Left Behind includes proposals designed to strengthen the ability of schools and teachers to prevent violence in our schools, and our budget proposal would provide flexible Federal resources to help make our schools safe and drug-free.

The President's Budget also supports a significant increase in the Impact Aid program, which provides financial assistance to school districts afffected by Federal activities. The $137 million increase for Impact Aid Construction would greatly expand support for the renovation and repair of schools that serve large proportions of military dependent students and students residing on Indian lands.

In addition to our discretionary request, the President's budget includes tax proposals that would significantly benefit elementary and secondary education. I have already mentioned our plan to expand tax-free Education Savings Accounts to increase the educational choices available to parents. Another key proposal would allow States to issue tax-exempt private activity bonds for constructing public elementary and secondary schools. Current law does not exclude from income the interest on such bonds used to finance school construction. Private entities would construct, own, and maintain the schools.

We also would allow teachers and other elementary and secondary school professionals to treat up to $400 in out-of-pocket classroom expenses as a non-itemized, above-the-line deduction beginning in 2002. Expenditures for books, supplies and equipment related to classroom instruction and for professional training programs would qualify for this deduction.

POSTSECONDARY EDUCATION

No Child Left Behind is focused on elementary and secondary education, but the 2002 request also demonstrates the President's commitment to preparing low-income and minority students for postsecondary education, strengthening financial aid programs that help students and families pay rising college costs, and building the capacity of postsecondary institutions serving large proportions of minority students.

For example, we are proposing a $1 billion increase for Pell Grants to support a maximum grant of $3,850—the highest ever—and to improve access to postsecondary education for economically disadvantaged students. Overall, the President's budget would support a total of more than $49 billion in student financial aid, an increase of $2.2 billion or 4.6 percent over the 2001 level, for an estimated 8.2 million students and parents.

To help low-income students prepare for, enroll in, and complete a college education, we are requesting a $50 million increase for TRIO outreach and support services. We also are seeking a $15 million increase for Historically Black Colleges and Universities and a $4 million increase for postsecondary institutions that serve largely Hispanic populations.

We would encourage more college students to pursue teaching careers in high-need areas by expanding loan forgiveness for math and science teachers serving low-income communities from $5,000 to a maximum of $17,500.

We also would permit tax-free distributions from Qualified State Tuition Plans (QSTPs) to pay higher education expenses, including room and board, tuition and fees, and certain expenses for books, supplies, and equipment. In addition, private

educational institutions would be permitted to establish qualified prepaid tuition plans, provided they are eligible to participate in Federal financial aid programs under Title IV of the Higher Education Act of 1965.

CONCLUSION

The President's 2002 budget request for education, in tandem with the education reform proposals contained in No Child Left Behind, support a comprehensive vision for closing the achievement gap and improving the quality of education for all Americans. I urge you to give these proposals careful consideration, and I stand ready to answer any questions you may have.

Senator SPECTER. I would like to begin, now, the round of questioning by the Senators.

Secretary PAIGE. Thank you.

Senator REID. Mr. Chairman, if the chairman yields, I would ask consent of the subcommittee that I be allowed to submit my statement for the record and questions. I am going to have to depart for other places.

Senator SPECTER. Your statement will, without objection, be made a part of the record. Are you asking to question out of turn?

Senator REID. No. I do not want to question out of turn. I will submit some questions in writing.

Senator SPECTER. Of course. Of course, Senator Reid. That will be acceptable. And I am sure the Secretary will respond in writing.

[The statement follows:]

PREPARED STATEMENT OF SENATOR HARRY REID

I want to thank Chairman Specter and our distinguished Ranking Member, Senator Harkin for holding this hearing on the Department of Education's budget.

Education is so vitally important—it impacts every aspect of our lives. There are, therefore, many issues I could discuss with you today, but I will focus on only a few.

I am troubled by the fact that the budget that President Bush sent to us—and the budget that he has asked Secretary Paige to defend—

—has nothing for school construction,

—has no increase for after school programs,

—has no targeted class size reduction funding, and

—has nothing for dropout prevention.

Senator Bingaman and I have long supported a national dropout prevention program. Last year, Congress recognized the importance for such a program and we included funding in the appropriations bill. This year, we have again introduced our bill, S. 102, the Dropout Prevention Act.

The aim of this bill is to encourage innovative thinking by the States and local school districts regarding dropout prevention, and to provide the funds if schools wish to start a similar program in their school. To help restructure the schools with the highest dropout rates in each State, this legislation would create a coordinated national dropout prevention program.

Over half a million high school students drop out each year, joining almost 4 million young Americans who lack a high school degree and are not in the process of getting one. Unemployment rates of high school dropouts are more than twice those of high school graduates.

—The probability of falling into poverty is three times higher for high school dropouts than for those who have finished high school.

—If we do not address the dropout problem in this country now, we will be faced in the future with a weak and uneducated workforce.

—By keeping kids in school, we are attacking much larger social and economic issues.

Earlier this year, I was pleased to learn from Secretary Paige that he supported a similar program when he was in Houston.

The Education bill that we have on the floor right now authorizes $250 million for the dropout prevention program. I urge the Committee to fund this program and I urge the Secretary and the President to support such funding.

Thank you.

SCHOOL CONSTRUCTION FUNDING

Senator SPECTER. Mr. Secretary, let me begin the round of questions. We do not have the lights on, which is a little difficult, because—not for you, Mr. Secretary, but for the members that cannot see when it is turning to yellow and when it turns to red. So, we will hand members slips when we come to 4 minutes and when we come to the end of the time. And as is our practice, I, as Chair, will begin the round of questioning.

And let me start with the issue of school construction, which is going to be a matter to be voted upon by the Senate. And there are differences of opinion, different gradations. And the National Center for Education and Statistics, in a 1999 study, found that $127 billion was needed for repairs, renovation, and modernization of America's schools.

Now it is true that the lion's share of responsibility is on the State and local government, but the prior administration had a program for school construction. It ended up, last year, differently from my preference. My preference was to direct the funds, about $1.3 billion, for school construction, but if the local boards met certain standards, then to have flexibility and allow the local boards to do what they chose with that money and not use it for school construction.

FEDERAL ROLE AND SCHOOL CONSTRUCTION

Now, I have a two-point question for you, Mr. Secretary, on this subject. If the Federal Government is not to take a leadership role in school construction, and knowing that the States and local governments have allowed the school buildings to deteriorate, where will we find some relief? Let me start with that question, without adding a second.

Secretary PAIGE. Mr. Chairman, I have to agree with you that the condition of our buildings across the United States is really deplorable in the main. And I guess at some point we would be benefited by a great debate about what the Federal role is in public education. I am not taking any particular position on that, now.

In fact, when President Kennedy—I mean, President Clinton proposed the legislation on school construction several years ago, as a big city superintendent I came to testify in favor of the bill, because that——

Senator SPECTER. Is that still your position?

Secretary PAIGE. No, it is not. And it was because I had a construction problem in Houston. And we had calculated that we would get somewhere in the neighborhood of $200 million, or something like that which would have been there to help us. We needed it badly. And it was my position, then, that that was something that we should do.

So, I can understand, clearly, people arguing both sides of this, but——

Senator REID. Mr. Chairman, but he is not for or against it at this stage. Is that what he said?

Senator SPECTER. He is against it. He had been for it, as superintendent of the schools of Houston, but as Secretary of Education, he is against it.

Now, why, Mr. Secretary? Because you think it is not the Federal role?

Secretary PAIGE. Well, that is—that is one thing, Mr. Chairman. I think that we need to examine to determine where the Federal role starts and ends, because I do not know if the Federal Government is capable of managing this one.

Here is my rationale. The $1.2 billion that was allocated for this purpose, under the previous administration, would not have repaired the buildings in the Houston Independent School District 3 years ago. So, today, it would cover, maybe, 75 percent of them.

Senator SPECTER. Well, how about the leadership role of the Federal Government, Mr. Secretary? If we—my idea in the current bill is to have an allocation for school construction, but if the local boards decide that they have some greater need, to give them the flexibility.

So, in effect, it is a rebuttable presumption. And it provides some continuity, even though we do not have the Clinton administration, we have the Bush administration, but to meld the two on some central ground and say, "We would like to continue this, but it is up to you, if you think you need the money somewhere else more urgently." Why not that approach, Mr. Secretary?

Secretary PAIGE. Well, Mr. Chairman, I am not prepared to debate that approach, because I think there is some thought behind that. And I think there is great merit there. However, it differs a little bit from my point of view, because my point of view is about managing the construction issue from this level. And it is going to be extremely difficult.

How do we choose among these great needs all the way across the United States?

Senator SPECTER. Well, we certainly have the—let me move to the other question, because I have got 20 seconds left, and that will be time for me to state the question and you can give the answer, but not on my time.

FLEXIBLE TEACHER FUND AND CLASS SIZE REDUCTION

Teachers. The same thing. $1.3 billion last year. Class size. Senator Murray has offered an amendment. And I have made what we call a second-degree amendment to make it presumptive, yes, for teachers, but again, if the districts decide something else, they can do as they choose.

My red light is on. I am nine seconds over. Now, we will listen to your answer, Mr. Secretary.

Secretary PAIGE. Okay. Was that last point about the teachers? Class size reduction was to increase more teachers?

Senator SPECTER. Yes.

Secretary PAIGE. Allow me, once again, to rely on my experience. Okay. When we looked at that from Houston's point of view, the first thing we found out was that we had no space to add additional classrooms for the additional teachers.

The next thing we found out was the funds would only pay salaries of first-year teachers. So, that further handicapped us. The district and the State had already reduced class sizes. So, we were handicapped in that regard.

We wanted to use those dollars to ensure improved student achievement, but the regulations were so stringent that the flexibility to do that was difficult.

Now, I will confess, now, that we got around it, but the way we got around it, I would say, was dubious. We went around by using a very crisp understanding of what the regulations said and getting ready to debate that at some point, because we thought that we might get it done that way, but the regulations tied our hands. We found a way to use the money, but the regulations tied our hands.

We would have been better off if it had come to us the way that it is packaged in the President's budget now, with $2.6 billion for teacher quality, which allows the district to make decisions about how to increase teacher quality. We should not just take the concrete, specific, limited concept that if you have more teachers, the situation is better.

It is much more complicated than that. And it is tied almost exclusively with teacher quality. Are the additional teachers better, or are they worse? Can you get better teachers?

We would like to use the money, maybe, to take the teachers we have and send them off to be trained. Or we may like to take some of the money to go to Mexico and to recruit more teachers who have dual language capabilities. You cannot know that. Only we could know that.

So, the flexibility to use those dollars, as it is packaged in the President's budget, is much preferable to all of the big city superintendents that I have talked to and all of the rural superintendents that I have talked to.

Senator SPECTER. Senator Harkin.

SCHOOL CONSTRUCTION FUNDING

Senator HARKIN. Thank you very much, Mr. Chairman.

Mr. Secretary, permit me, a little, to tarry along the construction situation.

Secretary PAIGE. Okay.

Senator HARKIN. I first started proposing this in 1991, and then in 1992, and then in 1993. And finally, in 1994, when I held the chair that Senator Specter does now, and he was ranking member, I got through $100 million in appropriations to put out a pilot program for construction. That was 1994.

In 1995, the Clinton administration rescinded it. So, there you go. You can say now you agree with the Clinton administration. He rescinded it. I was furious. Furious. It was not the Republicans that did it. It was the Clinton administration that rescinded it. You know that as well as I do.

So, I tried again, year after year, to get this thing going again. Finally, dragging, kicking and screaming, we got the administration to support it last year. And we got $1.2 billion into school construction. And I have got a list of how much has gone out to the States.

That is just a little bit of the background for you, where this is coming from.

In the meantime, after the President rescinded that in 1995, I said, "Well, I believe this will work. There is a great need, and it will work."

So, for 3 years in a row, we got money through the Appropriations Committee to go to my State of Iowa for construction grants. It went to the State Department of Education with broad guidelines. We did not give them every jot and tell them exactly how to do it.

We just said, "Here is the money. Broad guidelines. Target the poorest school districts." That is all we said. So, it went out to the Iowa State Department of Education.

LEVERAGING FEDERAL FUNDS—SCHOOL CONSTRUCTION IN IOWA

Now, Mr. Secretary, $28 million has gone out to Iowa for that. Now, hang on to your hat. That $28 million leveraged $311 million on the State and local level.

One of the things that we know about the Federal Government is, sometimes money can leverage money. And anytime you get 10 to 1 leverage on Federal dollars, something is happening out there.

What the State Department of Education said was, "We will do matching on it. And you can raise money through a bond issue, sales tax." We have local option sales tax for plant and equipment, the different things that local units of government can do in the State of Iowa.

With that little bit of money—with that little bit of money, they stepped forward and did it, and leveraged it over 10 to 1. And I have got the data to prove it.

You said two things. The Federal Government is not capable of administering this.

Secretary PAIGE. No. I mean——

Senator HARKIN. Well, I wrote it down.

Secretary PAIGE. Yes. I probably did say that, but I mean solving this problem. I did not mean administering.

Senator HARKIN. Oh, well, you said "administering." I just want you to know, we did not administer it in Iowa. We let the State Department of Education in Iowa do it.

Secretary PAIGE. Yes.

Senator HARKIN. And the legislation that we have now, the same thing; that would be our guideline. It is going to go out to the State Departments of Education in Pennsylvania and Washington and every other place. And we are just going to give them a broad guideline, target it to the poorest districts——

Secretary PAIGE. Yes.

Senator HARKIN [continuing]. And let each State do it in their own way. So, we do not have a problem of administering it. It is administered in Iowa by the Iowa Department of Education. And it has made a huge difference. Go out and ask those school districts out there what it has done in terms of leveraging that money.

So, when you talk about $1.2 billion will not repair three of your schools in Houston, when it all factors out, that is probably true, if you are talking about the totality, but think about it in terms of how much it leverages out there. If we can just get two-thirds of that leveraging nationwide, from $1.2 billion, you are talking about $7 billion, $8 billion, $9 billion. Now that makes an impact.

So, there is a history here to this. And there is some proof of concept out there that we have gone through. And that is why I hope

that your initial support of this, you would revisit, and come back again, Mr. Secretary.

Secretary PAIGE. Well, that is what I want to do, Senator, to put emphasis on our education situation.

And by the way, I would like the record to show that, if I am permitted to, I do not mean administering. I used the wrong word there. What I mean was solve it. I meant that this problem is so vast it is going to need the locals to address it, as you have indicated that they are doing.

Senator HARKIN. They do have to address it, obviously, but we are going to give them a little bit of help to move them along. That is the leveraging aspect of that money that goes out there.

IMPACT AID CONSTRUCTION

Secretary PAIGE. But there is a place where we have the direct responsibility. And I think the Federal Government has a direct responsibility for school districts that are impacted by military enrollment of our students. I think that is a primary direct responsibility of the Federal Government in terms of construction.

And when we look at the conditions of the buildings in those locales, I think that we find that we have an even greater problem there.

And the second one would be on Indian reservations. It is those areas, where I would agree that we need to have a specific Federal focus on the construction of buildings.

So, there is not that much difference here in the argument. There are places where we have direct responsibility that I think we should take care of first.

Senator HARKIN. Well, I agree that we need to do something in those areas, but—on the school districts in the military and stuff, why should that not also come out of the Defense budget? Why do we have to take that out of the Education budget? Put it in the Defense budget. That is where it ought to be done. That is my response to that.

We have got an obligation. You are right. But I think this is a military obligation that they have.

Thank you, Mr. Secretary.

Secretary PAIGE. Thank you.

Senator SPECTER. Thank you very much, Senator Harkin.

Secretary PAIGE. Thank you for your passion in this matter. I know it is important to you.

Senator HARKIN. Yours, too. Yours, too. You have got good passion, too.

Senator SPECTER. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman.

And clearly, Secretary Paige, you have a passion for making sure that all of our students get a good education. And I really commend you on that. And I have spoken to you a number times on this, both in my capacity on this committee and on the Authorizing Committee. And I appreciate your being here today and showing us, once again, your passion.

I have to just quickly add on school construction—that I am delighted to hear you say that we should be funding military impacted schools, because I have been fighting to help some impacted

schools in my State and cannot get anything from the Defense Department on this. They absolutely say it is hands-off. And I agree with Senator Harkin that this is an issue we need to deal with, but it is an issue we need to deal with for all children.

Let me go back to the issue of class size. The Chairman began this hearing with a question on this, and I heard your response about hiring only first-year teachers. The only requirements within the class size bill is that teachers hired are fully qualified, not that they are first-year teachers.

So, I am not certain where you were coming from on that, but I can certainly tell you if there is a misunderstanding with that, then we need to deal with the language. Let us not throw the program out. Let us figure out what the language needs to be.

And second, we have worked very hard with Senator Specter, Senator Harkin, and a number of people on both sides of the aisle to develop language for the very successful class size program, to assure that it is flexible; that if a school district has met their class size goals in first, second and third grade, then the money can be used for teacher training and for other purposes.

And I want to thank Senator Specter, publicly, for his interest in this. I have seen his second-degree amendment. And I hope we can work something out on this, because I think that as we see the studies that come to us, we see the progress that has been made on class size, we see that this is a way to leverage Federal taxpayer dollars to actually make a difference in students' achievement; in their math, in their science, in their reading scores.

We have seen, through various studies, that smaller classes make a difference in dropout rates and the number of students going on to college, and even teen pregnancy rates, even if it is just in those first, second and third grades, where our kids are just beginning to learn the basics, that they get the individual attention they need. And yes, it is the responsibility of the Federal Government to be a partner, to make sure that our local school districts have the ability to create smaller classes.

In fact—I have to say, I am sort of baffled by your conversion, as Secretary of Education, from where you stood on this issue were as Superintendent of Houston schools, because I know that in presentations by your advisor, Susan Sclafani, about how Houston closed the achievement gap, certainly setting out the goals and where you wanted kids to be—and telling people they had to be accountable was part of it.

But clearly, she has said that targeting assistance to low-performing schools was important—and she specifically has said, that adding teachers to lower pupil-teacher ratio was a critical part of making sure that those students achieve.

We believe that closing the achievement gap is a laudable goal, and one that many districts are struggling to reach. The class size dollars that we have put in place over the last 3 years have come back to us, triple-, quadruple-fold from results in districts where teachers and parents and students are saying what a tremendous difference smaller classes have made for them.

Because I have been on a school board, I know how hard it is to find the funds for long-term commitments like hiring more

teachers. I know how many demands there are when it comes to budget time.

The Federal class size dollars go directly to these school districts with the least amount of paperwork and the most flexibility, ensuring that students are able to get the kind of help they need. And we want to continue to leverage that. And we want to continue to build on that success. And I hope that I can work with you to make that happen, because I think it is absolutely critical to our children's success.

And I hope you can comment on that really quickly, because I do have a very important question about the chart that you have.

Secretary PAIGE. Well, Senator, you make a very powerful argument. I find very little in your comments to disagree with. My only point is the categorical nature of the way the dollars are provided for the system.

I believe the people on the scene should be able to make the decision on how those dollars are used. And we should provide them with the total flexibility to——

Senator MURRAY. I know you have said that before. And I appreciate that, but I would remind all of us that there are a number of targeted funding streams in the President's education reform proposal, including Reading First, Technology, After School Programs, and Charter Schools. This is where the Administration has said, "We do believe targeted funds make a difference."

I am passionately telling you I believe that there are other areas, as well, including class size.

Secretary PAIGE. That I think has an important role to play. We are talking about how broad or how narrow it is. And I thought that the teacher class size reduction legislation, the previous legislation, was too narrow.

I thought that it was too restrictive. And I would have preferred, as an administrator, the flexibility of using my judgment on the scene, on determining how I could improve teacher quality. But the broadness of the teacher quality is——

Senator MURRAY. We would disagree on that.

Secretary PAIGE [continuing]. What we are talking about. I think that, clearly, you know that I agree with the—that smaller is better, given just that—if you just think of that. But it is not that narrow. It is much more complicated than that.

Senator MURRAY. Well, I disagree.

Secretary PAIGE. So, I am just arguing about the narrowness of the legislation. I'm arguing for a broader teacher quality package that will allow the people on the scene to make those decisions.

Senator MURRAY. Well, I agree. Teacher quality is important, too, but so is class size.

And before I yield my time, I just want to ask you a question about the chart that you have here, because you show that between 1984 and 2002, the increase in funding has gone up significantly and the red line representing NAEP reading scores, age nine, has been level.

But is it not true that since 1984, when we had a little over 39 million students, our public schools have grown to serve 47 million students? And that chart is a little bit misleading, because we are actually educating a lot more kids in our public schools than we

were in 1984. And those demands on the school system are not considered in that chart.

Secretary PAIGE. Yes.

Senator MURRAY. I just wanted to make that clear.

Secretary PAIGE. You are correct. That is correct. What that says is our challenge is broader, our task is more difficult, but the——

Senator MURRAY. Sure.

Secretary PAIGE [continuing]. But the scores are still flat.

Senator MURRAY. But you cannot say that we have increased funding and test scores have stayed the same to make the correlation that individual students are getting more money, because we are clearly educating more students in our schools.

I understand my time is up. And I would yield back to the Chair.

Secretary PAIGE. Yes.

Senator SPECTER. Thank you very much, Senator Murray. We are sticking very close to the time. There is a Judiciary Committee meeting. And I have just been informed that they have nine Senators and need a tenth for a quorum.

So, we are going to take Solomon's approach and split the Senator down the center, so he can be in two places at one time.

Let me proceed to ask you a number of questions, Mr. Secretary, and either to have abbreviated answers, so I can cover them rapidly, or you can put them in writing. And then I am going to defer to Senator Harkin, who has one more question. And then I am going to excuse myself.

VOUCHERS AND SCHOOL CHOICE

On the question of vouchers, the President's program provides that if certain standards are not met within a third-year point, there will be vouchers issued.

As I understand it, in the past, you have opposed vouchers to private schools.

Secretary PAIGE. Well, no, I have not.

Senator SPECTER. That is not so?

Secretary PAIGE. I have been a passionate supporter of cooperating with private schools and had a very broad private school program in Houston I operated for 4 years.

Senator SPECTER. Well, there is considerable concern in the Congress about vouchers. As you know, they were defeated in the House and——

Secretary PAIGE. I am aware of that.

Senator SPECTER [continuing]. My instinct is that while it will be a close vote, it will probably not succeed. And I would like for you to submit, in writing to the committee, because it is a complicated subject——

Secretary PAIGE. Yes, it is.

Senator SPECTER [continuing]. And you cannot deal with it——

Secretary PAIGE. Right.

Senator SPECTER [continuing]. In a few minutes, your philosophical grounding. We have great respect for your views, because of your experience. Also, please deal with the question which is raised so consistently about what will happen to the public school system if vouchers do become the order of the day. And also, to

comment on the amendment to be offered by Senator Carper, vouchers for use in public schools.

Secretary PAIGE. Yes, sir.

Senator SPECTER. The program of Youth Violence was adopted by this subcommittee 2 years ago, really utilizing the same philosophy that you have approached, and that is by taking $1.45 billion from other programs and directing it to Youth Violence. And I would appreciate it if you would take a look at the program we have coordinated with the Department of Health, Human Services and Labor and Department of Justice, and give us your evaluation of that.

It is my hope to have a meeting coordinated with the President's domestic advisor. We would be interested in your evaluation there, and your further suggestions on how we deal with youth violence.

We have made this proposal without any news conferences, any public attention, but with a whole series of workshops where Senator Harkin and I personally participated for hours on end, bringing in the people who really know—the technicians in the field. And we would appreciate it if you would take a look at it——

Secretary PAIGE. I will.

Senator SPECTER [continuing]. And give us your advice.

CAMPUS CRIME

Next, there is the issue of campus crime, where legislation was enacted more than a decade ago, after a brutal rape-murder at a Pennsylvania college, and the parents, Mr. Howard and Mrs. Connie Clery, came forward.

Now, there has been a problem with respect to the Department's implementation of the Clery Act. The guidance from the Department on reporting standards has been hard to get. And when there are violations, it is difficult to secure investigation and corrective action. I had introduced that legislation and later produced amendments to toughen it up.

And this is something which is very, very important; the essence of which is to tell people what is happening on the campus, so they know what the risks are. And that has the therapeutic effect of colleges and universities not wanting to report campus crime, so acting to prevent it and a great many efforts to circumvent it by not counting the sidewalks through the university campus as part of the university or not counting university leased premises as part of the university.

So, we would appreciate your review and comment on that.

Secretary PAIGE. I thank you for that legislation, Mr. Chairman. And I will tell you, you have my commitment that we are going to have a strong look at this, because this is the right thing to do. You have our support.

BUDGET INCREASES TO BE TIED TO REFORM AND RESULTS

Senator SPECTER. Well, I appreciate that comment. I only want to ask you one question for the record. I wrote down what you said, when you said, "I think that the President is 'amenable to increasing the spending of funds.'"

By that, do you mean that if the Congress comes in somewhat higher or a little higher or reasonably higher than the President's budget, we might get him to sign the bill?

Secretary PAIGE. I meant by that, that the President appears to me, from my interaction with him, willing to fund reform. And dollars that are tied to making things work better, he seems to be more willing to support.

So, the connection would be funding reform. What he objects to is funding failure.

Senator SPECTER. Well——

Secretary PAIGE. I think he would be willing to spend whatever amount is necessary to reform the system, assuming those two things are connected.

Senator SPECTER. Well, that is a fair challenge. If we tie our spending to reform, we may then look for the President's concurrence.

Mr. Secretary, thank you very much for coming in.

Secretary PAIGE. Thank you.

Senator SPECTER. Again, I think we have covered the subject matter, although we have subverted on you to respond in writing, because of limitations of time. And I am going to turn the gavel over to Senator Harkin, who says he has one more subject matter. It is that hot newspaper article that he is indifferent to that he wants to ask you about.

Thank you, Mr. Secretary.

Secretary PAIGE. Thank you. And thank you, Mr. Chairman, for your leadership.

Senator HARKIN. Thank you. I have actually got two questions, but one basically that covers——

Senator SPECTER. You can answer only one of them. You take your source. He said he only had one question.

Senator HARKIN. Then I will adjourn it, Mr. Chairman.

Senator SPECTER. Thank you.

Senator HARKIN [presiding]. Mr. Secretary, again, back to the construction thing. Again, it is my understanding that your department has written a new guidance, alerting States that they might be able to spend school renovation grants in a way that Congress did not intend.

Under current law, 75 percent of this money had to be used for school renovation; 25 percent could be, if they wanted to, used for IDEA, Individual Disabilities—doing things that meet their needs for special education and technology for special education.

I am understanding that your new guidance is telling the States they do not have to do this, because Congress might eliminate the fund. First of all, what is the status of this guidance?

Secretary PAIGE. Mr. Chairman, let me find out more about that. I am not equipped to answer that question, but I promise this——

Senator HARKIN. Yes.

Secretary PAIGE [continuing]. Administration supports administering it so that congressional intent is carried out. So, I will look into it and get right back to you on that one.

Senator HARKIN. I would like to know that, because I just heard this, and I was just going to urge you to not issue this guidance, because——

Mr. SKELLY. Well, Senator Harkin, we have not issued the guidance, yet. We have drafted it. And we shared the content of the

guidance with some of the staff on your committee just to see what they would think about it.

PRESIDENT'S PROPOSAL AND USE OF SCHOOL CONSTRUCTION FUNDS

What it says is that although the current law does allow States considerable flexibility in using money for IDEA or technology, in addition to school renovation, the President's budget has made a proposal that would allow them even more flexibility to use that; not just 25 percent, but maybe 50 or 100 percent for special education or technology, if they chose to do that.

It is a proposal that was in the President's budget. The Congress would have to accept that proposal, pass it, and the President would have to sign it into law for that to take effect. And the guidance merely reiterates that the President's budget made that proposal.

Senator HARKIN. I understand what you are saying is that you would take the 2001 money, the money we already appropriated, and change how they could spend it, but you cannot do that on your own. You have to get us to do that.

Mr. SKELLY. That is exactly right. The guidance says——

Senator HARKIN. Well, I can tell you right now, forget it.

Mr. SKELLY. All right.

Senator HARKIN. Forget it. It is not going to happen. I cannot speak for the Chairman, but I think I can on this one. Forget it.

Mr. SKELLY. Okay.

Senator HARKIN. Because what that would do, I think, would create a lot of turmoil out there. We will fight the other battles next year and beyond, but on this one, I think it might confuse a lot of school districts out there and say, "Well, we want to apply for the money. Why apply for it, if we cannot use it and they are going to change it?"

As long as it is there, the money is—goes out July 1st. School districts, I know, all over the country, are thinking about applying for this. There are State Departments of Education. I do not think it would be fair to confuse them on it at this point.

FUNDING FOR SPECIAL EDUCATION AND IDEA REAUTHORIZATION

But what I really wanted to ask—now I am going to run out of time here—is that the administration indicated it was particularly upset by a vote last week to increase funding for schooling disabled students and lock it into the Federal budget for the next 10 years by shielding it from the annual appropriations process, which is exactly what we did.

We put it on the mandatory side. It had broad-based bipartisan support. Senator Hagel was my co-sponsor on it; Senator Jeffords, Senator Specter. I mean, broad. It passed by unanimous consent and no one objected to it. And officials described the proposal as costly and unwarranted.

Can you please respond to that, because this is very, very disturbing?

Secretary PAIGE. Well, Senator, I have not read that. This is the first time I have heard that language. I do not have anything to add to what is written there, because I have not ever seen the article.

Senator HARKIN. Okay. So, it did not come out of your shop, then.

Secretary PAIGE. I do not know.

Mr. SKELLY. That is from the Statement of Administration Policy, which is issued by the Office of Management and Budget. It was part of a longer piece. And it mentioned the IDEA amendment.

Senator HARKIN. Is that a correct quote, then, from it; that it is costly and unwarranted?

Mr. SKELLY. Those are adjectives used in the statement, yes.

Senator HARKIN. By OMB. That meeting our 40 percent obligation was costly and unwarranted.

Mr. SKELLY. I think the argument is that the—making it mandatory at this time, as a floor amendment to the ESEA, without a longer review of the IDEA—the IDEA, you know, was reauthorized in 1997. It will come up again in another 18 months.

It would be good to have a more thorough review of the IDEA, I think, is what the administration's position is, rather than making a change now as part of a floor amendment on ESEA.

Senator HARKIN. Well, okay. I can accept that as an argument. I just would point out that we are not changing any of the underlying law in IDEA. We are not—we are not changing it. We just simply are appropriating money to meet the underlying 40 percent requirement. That is all.

I do not—I cannot see any—any indication out there at all that we want to reduce that 40 percent. I think that would run into a firestorm around here.

Mr. SKELLY. I think there is one other change in the basic law that would change the fiscal relief provision from 20 percent, which was enacted in 1997, to 55 percent. In other words, of the additional funds that are made available for IDEA, Part B, State grants, some of the—if States are providing services to children with disabilities already, they could use some of that money for fiscal relief, use it for other purposes. So——

Senator HARKIN. But we can do that when we reauthorize IDEA. What we did, putting it on the mandatory side, has no effect on that. I mean, we can—we can do that. If that is the will of the Congress and the administration to do that, we can do that at that time.

Mr. SKELLY. It was in—it was just in the same amendment.

Senator HARKIN. Well, I understand, but—but I do not—reauthorizing IDEA does not have anything to do with the funding. We are just funding it. If we want to change the mix and stuff, we can do that any time we want on the reauthorization end of it, 2 years from now.

But I just think—the choice of words as being costly and unwarranted, I think, is a poor choice of words from OMB on that. And I hope that there might be some clarification put out from the administration on this.

Mr. Secretary, do you have anything else to add before I——

Secretary PAIGE. I would just like to thank you for the opportunity to come and for the stimulating discussion about that. And although we have some differences in point of view, I have great respect for your interests in improving education in America.

TESTING AND ACCOUNTABILITY

Senator HARKIN. Well, we will work together on this. I know that there are a lot of things we have got to do together. See, I want to—just for the record, make it clear, I am not opposed to what you are trying to do, in terms of testing and accountability and to try to model what you did in the Houston school system. I have no problem with that.

COST OF ANNUAL TESTING

I think there has got to be a broader approach and other things that we have got to do beyond that. And fine. I can support your proposals on that, but funding, I guess, maybe we look at it, as appropriators—the National State Boards of Education estimated that all this additional testing would cost $2.7 to $7 billion extra. Now, I cannot verify that. That is what I heard from the State Boards of Education.

Well, if we are going to require them to test, we ought to help them with some of the funding, too. I mean, I do not know if that is a proper amount of money or not. But somehow we are going to have to think about getting some additional funds out there for helping them with this testing and stuff.

Secretary PAIGE. May I just make one observation about that, Mr. Chairman? The President is proposing $320 million to help States with the development of tests. The actual implementation of tests, the cost of that varies with the effectiveness of the management of the various test implementors.

In Houston, it cost—we had to spend—for nine administered grades, 1 through 11, we implemented that at the cost of about $10 per child. And that was because it was very finely managed and carefully controlled. That cost could vary from what I think to be our very effective cost of $10 per child to $50 a child. It would depend on the effectiveness of the organization and how much the people who administer it want to save dollars there.

So, it is a figure that we really cannot get our arms around. And besides, the 1994 reauthorization required administering tests to all the students at least three times through the pipeline. And there was no argument, then, about paying for those tests that they imposed on school districts at that time.

So, what we are talking about is simply just adding tests, but we do see a need to help with the development of these tests. We know that this is going to be a process, not an event. And we will grow, in terms of learning about the costs.

CLOSING REMARKS

Senator HARKIN. Fair enough. Well, thank you very much, Mr. Secretary——

Secretary PAIGE. Thank you.

Senator HARKIN [continuing]. For your dedication to education. I am sure we will have an opportunity to meet repeatedly, between now and whenever we get our budget through and our appropriations bills through, to work out our problems on this.

Secretary PAIGE. Thank you, Senator.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

PRIVATE SCHOOL VOUCHERS

Question. Please provide your philosophical grounding for your support of vouchers and explain what you think happens to the public school system. Also, please provide your view of Senator Carper's bill and its impact on the public school system.

Answer. In the broadest sense, we believe that just as market-based competition works throughout our economy to maximize the efficient use of resources and provide high-quality goods and services at low cost, greater competition is good for our system of public education. This is why, for example, the President is such a strong supporter of charter schools, which encourage innovation that not only leads to better options for parents and students, but also brings pressure on regular public schools to improve their own educational offerings.

We also support the limited use of vouchers because we believe that parents and students alike benefit greatly from the ability to choose the school that best meets their educational needs. And when parents choose the school their child attends, they are more likely to actively support the school. I can tell you from personal experience that when parents get involved in our schools, good things happen.

More specifically, it cannot be denied that there are too many schools that are failing our children, denying them the opportunity to reach their full potential as citizens and human beings. Vouchers and other forms of choice can help ensure that no child is trapped in a failing school—one of the central goals of *No Child Left Behind*.

As for the impact of vouchers on our public schools, I have two answers. One is that for the foreseeable future the vast majority of our children will continue to attend public schools, even if in limited circumstances vouchers are available. In my view, vouchers present very little in the way of a threat to our long tradition of public education. In large part this is because of my second answer, which is that in general public schools compete very well with private schools. This was my experience in Houston, and I believe it would be the experience nationwide if voucher systems were more widely adopted.

AMENDMENT PROPOSED BY SENATOR THOMAS R. CARPER

Senator Carper's proposed amendment would authorize competitive grants to States or school districts to support the implementation of universal public school choice programs. As you know, President Bush and I support the expansion of choice and educational options for parents and students, and I believe Senator Carper's proposal would be a step in the right direction in this area. In particular, the Carper proposal would support the creation of meaningful choice by helping to pay for the cost of transporting students to the schools they choose to attend, and by helping to expand capacity at the high-quality, high-demand schools that students will want to attend.

YOUTH VIOLENCE

Question. Please look at the programs included in the youth violence prevention initiative that we have coordinated with other agencies and evaluate what has been done and provide further suggestions on how to deal with the issue of youth violence.

Answer. A number of the programs included in this initiative are demonstrating an impact on fostering youth violence prevention activities in communities across the country. For example, the Safe Schools/Healthy Students initiative the Department of Education has funded jointly with the Departments of Justice and Health and Human Services is supporting collaborations between schools, mental health providers, and law enforcement that promote healthy child and youth development and safer schools. In fiscal year 2000, some Safe Schools/Healthy Students commu-

nities reported decreases in arrests and detentions for violent acts at school. They also reported increases in the provision of mental health assessment and treatment services to students.

The Department's 21st Century Community Learning Centers program is helping to provide safe and stimulating after-school environments for students in supervised settings in which they can receive homework support, mentoring, drug and violence prevention counseling, and college preparation services. One grantee has reported a 40 percent drop in juvenile crime in the neighborhood surrounding the Learning Center's after-school program. Another has reported that the program led to a substantial drop in student use of drugs, alcohol, and tobacco.

Several States are reporting that their Character Education programs are having a positive influence on student behavior. For example, an independent evaluation of the first year of Maryland's program found that students were perceived to be more likely to solve conflicts without fighting, insults or threats; to respect others' personal rights; and to treat classmates with respect. In Utah, participating schools reported a decrease in discipline referrals, fewer student fights and confrontations, decreased vandalism, less tardiness, and an increase in positive behaviors such as interacting more kindly and respectfully with students and teachers, better attendance, improved achievement, and greater student involvement in extracurricular activities.

One of the strongest suggestions I can offer for addressing the problem of youth violence is to hold schools accountable for school safety. That is why the Administration's *No Child Left Behind* proposal would require States to develop a definition for a "persistently dangerous school" and to provide victims of serious, schoolbased crimes and students trapped in persistently dangerous schools the option to transfer to a safe alternative.

CLERY ACT IMPLEMENTATION

Question. I have some concerns about the Department of Education's implementation of the Clery Act. Please review and comment on the implementation of this Act.

Answer. The Department has made a good faith effort to implement the Clery Act. Last year, for example, the Department collected crime statistics as required by the Act. In collecting these statistics, the Department used a web-based data collection tool through which statistics were publicly available as the data were collected. This approach—combined with the Department's aggressive enforcement of the requirement—resulted in a 100 percent response rate to this data collection.

In addition to collecting the campus crime statistics, the Department has successfully investigated allegations that institutions were misrepresenting their crime statistics. Generally, we have been successful in bringing institutions into compliance with the requirements of the Act. When appropriate, the Department has imposed fines for non-compliance.

EDUCATION FUNDS FOR REFORM

Question. You stated during your oral remarks that you believe the President would be "amenable to increased funding." Please elaborate on this remark.

Answer. As I said earlier, the question is really not about funding, but reform. I believe the President is willing to fund serious reform efforts, such as those proposed in *No Child Left Behind* and included in our 2002 budget request. He is not willing to continue funding failure in our education system.

SCHOOL RENOVATION GRANTS—GUIDANCE FOR IMPLEMENTATION

Question. What is the status of the Department's guidance for implementation of the School Renovation grants program enacted in the fiscal year 2001 Labor-HHS Education appropriations conference report?

Answer. The Department distributed guidance for the School Renovation grants program to State coordinators on May 17, 2001.

Question. What statutes, rules or regulations (internal Department or government-wide) govern when and how the guidance may be issued?

Answer. The School Renovation program guidance is non-regulatory. Nonregulatory guidance is not subject to the Administrative Procedures Act, as is the case with regulations. Furthermore, other statutes or regulations do not generally govern the issuance of guidance.

The guidance for the school renovation program is designed to explain, using plain language, the provisions of the legislation to help grant recipients understand the requirements in the legislation. The Department conducts an internal review of guidance to ensure consistency with legislation before it is issued.

Question. Will the guidance package be wholly consistent with congressional intent as expressed in the fiscal year 2001 Act, and will the purpose of the program be reflected throughout the document (including cover notes, supplemental material, guidance, etc.)?

Answer. Yes, the guidance package is wholly consistent with the congressional intent expressed in the Fiscal Year 2001 Department of Education Appropriations Act.

As you know, the Administration's 2002 budget submission proposed to amend the 2001 appropriations act to provide States with additional flexibility in how they may spend their portion of the $1.2 billion in fiscal year 2001 school renovation funds. The Administration proposes to allow States to choose how much of the funds may be spent on any of the three currently allowable activities: school renovation, activities under Part B of the IDEA, and technology activities associated with school renovation.

If Congress enacted the Administration's proposal, we would communicate the enactment to the States. The Administration remains committed to securing this flexibility for the States whether congressional action occurs before or after July 1 of this year.

21ST CENTURY COMMUNITY LEARNING CENTERS

Question. The budget request proposes to consolidate the 21st Century Community Learning Centers and Safe and Drug-Free Schools programs in a formula driven State grant program so that school districts can support drug and violence prevention activities as well as after school activities. How will this help improve student safety given the findings in the Department's "Progress in Prevention" national evaluation of the Safe and Drug Free Schools program that 46 percent of districts would lose their prevention programming without its funding and more than 75 percent would reduce them to a great extent?

Answer. The Administration's fiscal year 2002 budget request does not propose to consolidate the 21st Century Community Learning Centers and Safe and Drug-Free Schools programs into a single formula grant program. The request would maintain separate funding streams for the two programs.

The Administration is requesting $644 million in fiscal year 2002, the same as 2001, for the Safe and Drug-Free Schools program. However, a greater proportion of total funds would flow to States under the President's proposal (as compared to the 2001 funding level for State Grants) to help ensure that children receive a high-quality education in a safe and drug-free environment. The President's *No Child Left Behind* proposal for reform of elementary and secondary education would hold States accountable for school safety by requiring States, as a condition of receiving a performance-based grant for safe and drug-free schools, to: (1) develop a definition for a "persistently dangerous school" and to report on school safety on a school-by-school basis; (2) provide victims of serious, school-based crimes and students trapped in persistently dangerous schools the option to transfer to a safe alternative; and (3) adopt a "zero-tolerance" policy that empowers teachers to remove violent or persistently disruptive students from the classroom.

The Administration is also requesting $845.6 million, the same as fiscal year 2001, for the 21st Century Community Learning Centers program. Program funds would be used to provide students, particularly students who attend high-poverty or low performing schools, with high-quality extended learning opportunities to help them meet challenging academic standards.

UNMET NEED AND ACCESS TO HIGHER EDUCATION

Question. "Access Denied", a report of the Advisory Committee on Student Financial Assistance was released in February 2001 and identified three interrelated factors that conspired to produce what is fast becoming an access crisis. The first is the increasing cost of higher education as a relative percentage of family income only for low-income families and the shifting focus of Federal, State, and institutional policies toward merit-based programs. Second, is the steep rise in unmet need of low-income students. On average, the very lowest income students face $3,200 of unmet need at 2-year public institutions and $3,800 at 4-year public institutions, even after factoring in loans. Third, students, motivated by rational financial considerations, make choices that lower the probability of their persistence and degree completion significantly. In addition, dramatic demographic changes will produce an increase in college enrollment of 18 to 24 year olds of 1.6 million by 2015.

Last year's final appropriation included resources to increase the maximum Pell Grant by $450. How does this budget reduce the opportunity barrier of unmet need and increase access to postsecondary education for low-income students?

Answer. The fiscal year 2002 President's Budget includes a three-pronged approach to enhancing access to postsecondary education among low-income students, which provides: (1) $1 billion in additional Pell Grant funding, increasing the maximum grant to a record $3,850 (under this proposal, the maximum grant will have grown by nearly 43 percent over the five years through 2002, significantly faster than tuition and fee increases over the same period); (2) continued support for supplemental grant assistance under the TRIO Student Support Services program, as well as increased funding for TRIO academic support and counseling services to low-income students to better prepare them for higher education; and, (3) additional funds to strengthen institutions that serve large numbers of minority and low-income students, including Historically Black Colleges and Universities and Historically Black Graduate Schools, and for Hispanic Serving Institutions.

PERSISTENCE IN COLLEGE

Question. What does this budget propose to increase persistence for students saddled with high levels of debt and significant work responsibilities while attending school on a full- or part-time basis?

Answer. Research on the relationship between persistence and work and persistence and debt on several occasions has yielded mixed results. Many analysts believe that the decision to depart from postsecondary education is related to a student's specific short- and long-term plans, the strength of the student's desire to finish, and the difficulties associated with adapting to the challenges of college life. In this area, the Department's budget includes increased assistance to institutions of higher education that serve large populations of low-income and minority students to help them meet the needs of their students, as well as to programs that directly respond to the needs of low-income and first-generation college students. For example, the budget includes additional support for Historically Black Colleges and Universities (HBCUs) under Title III and Hispanic-Serving Institutions (HSIs) under Title V to help these institutions meet the growing demand for their services. The budget also includes an increase for the TRIO programs, which help to prepare low-income students for college and help improve retention and success rates among these students once they enter college.

GROWTH IN COLLEGE POPULATION

Question. How is the Administration planning to support the increasingly diverse needs of the additional 1.6 million college students expected by 2015?

Answer. The fiscal year 2002 budget proposal addresses the short-term needs for funding for postsecondary education. The Administration's long-term strategy for supporting the diverse needs of students enrolled in postsecondary education will be developed as we prepare for the reauthorization of the Higher Education Act in 2003.

QUESTION SUBMITTED BY SENATOR LARRY E. CRAIG

TRIO PROGRAMS

Question. Mr. Secretary, in my State, I know that TRIO's Upward Bound and Talent Search programs have been very successful in serving middle and high school students. These programs are enabling students attending under-performing schools to raise their aspirations and develop the skills to achieve those goals. How are you including TRIO in your Department's overall plan to meet the educational needs of all children?

Answer. TRIO plays an important role in our overall plan by ensuring that the needs of students are met all the way through college. In particular, the Upward Bound and Talent Search programs target disadvantaged middle and high school students, providing tutoring, mentoring, counseling, and other services to adequately prepare them for success in college. The Student Support Services program provides similar services once these students are in college, helping them to achieve their higher education goals. The $50 million increase requested for the TRIO programs would significantly expand these services and increase the number of students who would benefit.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

ACCESS TO A COLLEGE EDUCATION

Question. The President's budget would increase the maximum award for Pell Grants by just $100, to $3,850. That's $355 less, in real dollars, than 25 years ago. In the meantime, college tuition costs have skyrocketed. If we really want to leave no child behind, shouldn't we do more to help our poorest high school graduates get a college education?

Answer. To help the poorest students and families pay the rising cost of attending college, the Administration is proposing an additional $1 billion in Pell Grants to increase the Pell Grant maximum award to $3,850, the highest award ever. Under this proposal, the maximum grant will have grown by nearly 43 percent over the five years through 2002, significantly faster than tuition and fee increases over the same period. The Pell Grant program is the foundation of the Federal student assistance effort and is designed to help low- and middle-income students attend college.

Helping the poorest high school graduates get a college education requires more than just providing financial assistance, however, since a disproportionate number of low-income and minority students who do enter college do so without the academic preparation needed for success. The Administration's budget would increase support for the Federal TRIO programs to help prepare low-income and minority students for postsecondary education. In addition, the Administration is proposing to increase assistance to institutions of higher education that serve large populations of low-income and minority students to help them meet the needs of these students.

ELEMENTARY SCHOOL COUNSELING DEMONSTRATION PROGRAM

Question. Most people agree that school mental health and prevention services are critical to creating a healthy and safe learning environment. But the President's budget would eliminate $30 million for the Elementary School Counseling Demonstration Program, which provides assistance for hiring school counselors, school social workers, and school psychologists. Why does the President oppose this program?

Answer. Neither the President nor I oppose the provision of counseling and mental health services for students; we just oppose the proliferation of small, categorical Federal programs with narrow purposes that limit State and local flexibility to address State and local needs. Under the President's 2002 budget request, funding for the Elementary School Counseling Demonstration program is consolidated under the $471.5 million proposed Choice and Innovation State Grants program. School districts would be permitted to use funds under this flexible grant program to hire school counselors, social workers, and psychologists if they choose. School districts may also use their Safe and Drug-Free Schools and Communities State (SDFSC) Grant funds to provide counseling and related services for students. The President's 2002 budget request includes $547.3 million for SDFSC State Grants, a $108 million increase over 2001.

SPECIAL EDUCATION TEACHER SHORTAGES

Question. There is a tremendous shortage of special education personnel throughout the country—second only to math/science. Currently there are over 35,000 individuals teaching students with disabilities who are not qualified to do so. The Department of Labor estimates that schools will need more than 200,000 new special education teachers over the next five years. Yet our colleges and universities prepare only half that number. We are even beginning to document increasing shortages of special education faculty in our Nation's universities.

In addition, with new programs, such as the President's Reading First and Early Reading First, there will be even a greater need for special education professionals with skills in communications disorders and early literacy interventions. The President's budget calls for level funding for Personnel Preparation for the Individuals with Disabilities Education Act (IDEA). This account has not received an increase in over a decade despite these critical shortages. We are working hard to fully fund Part B of IDEA, but without qualified teachers, we will not get the results we want. What is your plan to address these critical personnel shortages, and why didn't you request an increase in funding for Personnel Preparation?

Answer. We believe that if large increases in funding are provided over a short period of time for the Grants to States program under Part B of IDEA, they may not be used to achieve the improved results we all want for children with disabilities. For example, with large increases local educational agencies may have more

resources to hire special education teachers, but may be unable to do so because the supply of such teachers is relatively inelastic in the short term.

However, more gradual increases, such as the $1 billion increase proposed in the President's budget, may be used effectively to promote improved working conditions, smaller class sizes, retention incentives, inservice training, and other activities as well as increased salaries that will create greater incentives for college students to enter and remain in the field of special education. We believe that the best way to recruit and retain special education personnel is through enhancing the value of working in that field and not necessarily through providing additional funds to institutions of higher education, which is the primary activity under the Special Education Personnel Preparation program.

In addition to the funds requested for the Grants to States program, funds to address personnel needs are also provided through the Special Education State Improvement program, which was authorized by the IDEA Amendments of 1997. This program awards grants to States to help them to address their particular needs. States must use at least 75 percent of their grants under this program to address their special education personnel needs. Our fiscal year 2002 request for this program is $49.2 million, and there was a $14 million increase in funding for the program in fiscal year 2001.

We believe that the combination of increased funding provided for the Grants to States program, support for the new State Improvement program, and maintenance of support for the Personnel Preparation program will begin to effectively address our needs for special education personnel.

MATH AND SCIENCE BUDGET SUPPORT

Question. The President's budget calls for tripling the spending on reading to improve instruction and student achievement in the early grades. His education reform plan would require annual testing in reading and mathematics. Given that teacher shortages put math and science at the top of the list, why is a similar investment in the preparation and professional development of teachers in those key fields not similarly recommended in the budget for the Department of Education?

Answer. *No Child Left Behind* reflects the President's commitment to improving the quality of our teaching force in all subject areas, including mathematics and science, because teacher excellence is vital to achieving improvement in student achievement. The Administration's fiscal year 2002 budget request reflects this commitment because it includes $2.6 billion for the Department of Education for the State Grants for Improving Teacher Quality program and $200 million for the National Science Foundation for the Math-Science Partnership program.

The State Grants for Improving Teacher Quality program would combine funding from several existing education programs, including Class Size Reduction and Eisenhower Professional Development State Grants, into performance-based grants that provide sufficient flexibility for States and local educational agencies (LEAs) to meet their particular needs and to strengthen the skills and improve the knowledge of teachers and administrators. Because of the flexibility that the President is proposing for this program, States and LEAs would be able to use program funds to improve the quality of their mathematics and science teaching force, if they believe that would best address their needs.

In return for this flexibility, States and LEAs would be required to ensure that program funds are used for professional development that is grounded in scientifically based research. States would be held accountable for ensuring that all children are taught by effective teachers and improving student academic achievement. Professional development programs also would be tied to State or local standards, of sufficient intensity and duration to affect teaching performance, and directly related to the subjects taught by the teachers who are participating in the professional development.

In addition, the Math-Science Partnership program, which the President is proposing as a National Science Foundation program, would provide funds for States to join with institutions of higher education to strengthen mathematics and science K–12 education. These partnerships, which could also include LEAs, would provide highquality teacher preparation and professional development for mathematics and science teachers, help to implement high standards in mathematics and science education, and address gaps between the education of advantaged and disadvantaged students.

ASSISTIVE TECHNOLOGY ACT, TITLE I STATE GRANTS PROGRAM

Question. The State Grants program under Title I of the Assistive Technology Act is slated to sunset beginning this year. And the President's budget calls for an in-

crease of $25 million for the Title III Assistive Technology Loan program. To date, all of the grants that have been awarded under Title III have been awarded to the Title I State projects. Who will run these loan programs if the Title I projects sunset?

Answer. Under Title III of the Assistive Technology (AT) Act, the Secretary is authorized to make grants to States for the administration of alternative financing programs. In order for a State to be eligible for funding under the Title III Alternative Financing Program, the State must receive or have received Title I funding. Therefore, the AT Act clearly contemplates that when States apply for Title III funds they may no longer be participating in the Title I program. In addition, the State is required to enter into a contract with an experienced community-based organization to administer the Alternative Financing Program.

GAANN AND JAVITS FELLOWSHIPS

Question. The Department proposes level funding of the Graduate Assistance in Areas of National Need (GAANN) and Jacob Javits program at $31 million and $10 million, respectively. These programs support graduate students who will become the teachers, scholars and researchers of tomorrow. Since the stipend level for these two programs is tied by statute to the stipend level for the Graduate Research Fellowship program at the National Science Foundation (NSF), the stipend for both these programs will increase to $18,000 per student in the 2001–2002 academic year and to $20,500 in 2002–2003. Because of this, the number of new fellowships in the Javits program will decrease significantly and there will be no resources available for a GAANN competition or new awards this coming year. Knowing that an increase in funding, to keep pace with statutory obligations to increase stipends, was the only way program integrity could remain intact, why did the Administration decide to level-fund both programs?

Answer. At the time we submitted our fiscal year 2002 budget request, the approved NSF stipend level was $18,000. Unfortunately, we had no way of knowing that it would be increased for the second time in two years to $20,500 for the 2002–2003 academic year. However, knowing that it is difficult to predict the average fellow's level of need and the maximum stipend level that will be in effect at the time we make awards, our estimates were based on all fellows receiving the maximum stipend that was in effect at the time we submitted the budget. As such, our estimates reflect the minimum number of fellows that would have been supported with a maximum stipend of $18,000.

Under the Administration's request for the Javits Fellowships program, even with a stipend level of $20,500, a minimum of 60 new fellows would be supported in fiscal year 2002. The request for GAANN, even though it would not support a new competition, would maintain support for approximately 1,070 continuing fellows. A new competition would be held again in fiscal year 2003.

Question. What will the Administration do in the future to support these two small, yet vitally important programs in graduate education?

Answer. The Administration will continue to work to ensure that all low-income students have the resources necessary to complete their postsecondary education. The Javits Fellowships and GAANN programs play an important role in preparing students for scholarly careers and careers in areas of national need, which will remain a critical part of our goal to strengthen America's workforce.

VOCATIONAL EDUCATION PROGRAMS SUPPORT

Question. Career technical education funding has declined 19 percent, in real dollars, in the past decade. At a time when the Labor Department is reporting increasing unemployment, why has President Bush level funded and, in some cases, cut programs in the Carl D. Perkins Vocational Technical Education Act, a law whose sole purpose is to prepare America's students with the skills, education and training they will need to pursue employment or higher education? Please address the proposed level funding of Basic State Grants, the cut to National Programs, and the elimination of the Tech Prep Demonstration Program.

Answer. The Department's 2002 budget received the largest percentage increase of any Cabinet-level domestic agency. The budget reflects major increases for the Administration's highest priority areas, including $1 billion for Special Education Grants to States, $1 billion for Pell Grants, and substantial new funding to implement changes proposed in *No Child Left Behind*, the President's framework for reauthorization of the Elementary and Secondary Education Act. Under the proposal, many programs are eliminated or consolidated, but none of the consolidations affect the Vocational Education appropriation. The Administration recognizes the impor-

tance of the Vocational Education State Grants by maintaining level funding for the program.

The fiscal year 2002 request includes $12 million for National Programs, a reduction of $5.5 million. In past years, National Programs provided funds to assist in the implementation of new accountability requirements and other provisions of the 1998 reauthorization. Now the implementation is well underway, and many national activities have been, or will be, completed by fiscal year 2002. The request provides sufficient funding to support major national initiatives.

The Administration requests zero funding for the Tech-Prep demonstration program, which is consistent with the effort to redirect resources to high-priority areas and to eliminate small programs whose activities can be funded from other sources. Currently, States can use funds they receive from the Tech-Prep State grant program to support this kind of activity. In fact, some States are already developing and implementing Tech-Prep programs that locate secondary schools on community college campuses and that can be disseminated and adopted by other States. The Department does not believe that a separate, more prescriptively structured, program that specifically focuses on this area is needed.

QUESTION SUBMITTED BY SENATOR HARRY REID

ADDRESSING THE DROPOUT PROBLEM

Question. Secretary Paige, how do you plan to address the dropout problem our nation faces? Please provide the specific, measurable steps you plan to implement to address the problem.

Answer. Research has shown that poor academic performance is the best predictor of who will drop out of school. Students who receive low grades, perform poorly on tests, are retained in grade, or are absent frequently are more likely to drop out before completing high school than are their peers. *No Child Left Behind*, the President's framework for reforming elementary and secondary education, would apply proven strategies—high State standards, annual testing of students in grades three through eight in at least reading and mathematics, increased accountability for student performance, reduced bureaucracy and greater flexibility for States, school districts, and schools, and expanded options for parents to make choices for their children's education—to strengthen Federal support for State and local efforts to help improve student achievement.

The most effective strategy for preventing students from dropping out is to ensure that they are successful and engaged at school. The strategies proposed by the President would help ensure that all students have the opportunity to succeed in school. For example, research has shown that early intervention for students who show signs of academic difficulty or disengagement from school is very important. The President's proposal for annual testing of students in at least reading and mathematics would provide teachers with current information on a child's progress in school, including specific strengths and weaknesses, and enable teachers to arrange for the types of support and remediation that are most likely to help that child succeed academically.

In addition, research shows that students who fail to read well by the fourth grade have a greater likelihood of dropping out and a lifetime of diminished success. The Administration's proposed Reading First State Grants and Early Reading First programs will help States and school districts implement comprehensive reading instruction, grounded in scientifically based reading research, to enhance the prereading skills and school readiness of school-aged children and to ensure that all children can read well by the end of third grade.

QUESTIONS SUBMITTED BY SENATOR MARY LANDRIEU

TITLE I BUDGET REQUEST

Question. Like you, I strongly believe that the targeted investments we make through Title I Grants are key if we hope to turn around low performing schools, improve teacher quality and ensure that all students achieve high standards. Although I am extremely pleased by the fact that all of the excess dollars included under this section are to be allocated through the targeted grants formula, I still have grave concerns about how little the President's budget invests in increasing Title I.

In my own State of Louisiana last year, their overall Title I allocation was reduced by $16 million because of insufficient funds at the Federal level. This year's

increase, even if targeted, would bring only $2 million in new money for these purposes. This is in a State where over 20 percent of the school age kids are in poverty. As a Superintendent, you know accountability and reform cost money. Do you honestly believe that this amount is sufficient to help achieve the goals the President has laid out?

Answer. I agree that resources are important, but my experience as Superintendent showed that how money is spent can be just as important as how much is available, and that improving management and accountability allow more funds to be used for the instruction of students. In any case, the President's budget does include $400 million, an increase of $175 million or 78 percent, to support State and local efforts to turn around low-performing Title I schools. Your State of Louisiana will share in these funds in proportion to its overall Title I allocation.

I must point out, however, that Louisiana received a lower Title I allocation last year not because of insufficient funding—the Title I appropriation rose $660 million or more than 8 percent from 2000 to 2001—but because its child poverty rate has been declining in recent years. It is certainly true that Louisiana remains a poor State, but according to Census estimates its percentage of school-age kids in poverty fell from almost 29 percent in 1995 to a little over 24 percent in 1997. Other States experienced growing poverty rates over the same period. The Title I funding formulas are designed to target funds to States and school districts that have a growing population of poor children, so this shift in poverty rates resulted in lower allocations for Louisiana and other States with declining relative shares of poor children, and higher allocations for States with rising proportions of poor children.

TRANSITION TO TEACHING

Question. I am glad to see that the budget includes additional resources to address the teacher shortage. I am particularly interested in two of the programs you include. First, the Transition to Teaching program. Currently, this money is used to support the Troops to Teachers Program, which is a wonderful program. I understand that this budget gives you the authority to expand on that program to recruit other mid-career professionals. Can you tell me what efforts you hope to include?

Answer. For fiscal year 2002, the President is requesting $30 million for a Transition to Teaching initiative. In addition to funding the Troops to Teachers program under this initiative, the Secretary would have the authority to reserve some of these funds for a program that would be similar to the Transition to Teaching program for which Congress appropriated $31 million in fiscal year 2001. Funds could support efforts to recruit, prepare, and support a wide range of talented career-changing professionals as teachers, particularly in high-poverty schools and in high-need subject areas.

In fiscal year 2001, the appropriation for the Eisenhower National Activities program included $3 million to be transferred to the Department of Defense for the Troops to Teachers program and $31 million for Transition to Teaching activities to recruit and support mid-career professionals and recent college graduates to become teachers.

The Department has already transferred the $3 million in fiscal year 2001 funds to the Department of Defense for the Troops to Teachers program. With these funds, the Department of Defense will be able to support and expand the highly effective Troops to Teachers program by providing high-quality teachers for more students in high-poverty schools.

Also, the Department's competition for the fiscal year 2001 Transition to Teaching program is underway; applications became available in April and must be returned to the Department by June 15, 2001. The fiscal year 2001 Transition to Teaching program will provide support for recent college graduates with outstanding academic records to become licensed and successful teachers. The program would also provide assistance for mid-career professionals with work experience in high-need areas to become successful teachers.

TEACHER RETENTION AND RECRUITMENT GRANTS

Question. I am also concerned by your decision not to increase your efforts in the area of higher education for teachers. In my own State, it has been the institutions of higher education that have led the efforts to recruit and retain qualified teachers. They also are crucial in preparing teachers for the challenges they will face. The budget mentions that Title II Teacher Quality money is also available for these efforts, but that money is barely enough for professional development, recruitment and retention of existing teachers. Would you care to comment?

Answer. The Administration's budget includes $2.6 billion to support a new program, State Grants for Improving Teacher Quality, which is an increase of $375 mil-

lion over funding provided in fiscal year 2001 for consolidating programs like the Class Size Reduction and Eisenhower Professional Development State Grants. Under the President's proposal, States may choose to use these performance-based grants for the kinds of activities authorized under the Title II program, including changes to teacher certification or licensure requirements, alternative certification, tenure reform, pre-service teacher preparation, professional development, and recruitment and retention initiatives.

PELL GRANT PROGRAM COSTS

Question. In the area of higher education, this budget includes an additional $1 billion to increase the Pell Grants by $100 to a maximum of $3,850. Recent program data show that more students are applying for Pell Grants, and more of those applying are eligible for these awards, than was previously expected. Will some of this money be used to address that issue as well, and, if so, how much of the billion will be left for the increases in awards?

Answer. As you note, recent program data indicate that more students are applying for Pell Grants, and more of those applying are eligible to receive aid, than was previously forecast. This has increased the cost of funding awards for the 2001–2002 award year by $117 million; this additional prior-year need would be funded from the proposed $1 billion increase. In addition, the fiscal year 2001 appropriation used $319 million in surplus funds from prior years to fully fund the maximum award level of $3,750. In the absence of these supplemental and surplus funds, $436 million of the proposed $1 billion increase for fiscal year 2002 is needed to maintain the previous year's funding level, replacing the $117 million and $319 million used in fiscal year 2001. An additional $78 million is needed to fully fund a $3,750 maximum award in fiscal year 2002. Increasing the maximum award by $100, to $3,850, for academic year 2002–2003 requires $312 million, with the remaining $57 million of the proposed $1 billion set aside to account for possible further growth in program costs.

TRIO PROGRAMS

Question. Mr. Secretary, there are almost 9.6 million low-income students (from middle school to college) currently eligible for the TRIO programs. In the next decade, demographic trends show that this number will grow considerably as more low-income students move through the education pipeline.

Although TRIO has a demonstrated record of success, the current funding level only allows approximately 6 percent of the eligible population to be served. Understanding the importance of these programs, many members on both sides of the aisle have voiced their support of expanding TRIO so it can serve 10 percent of those eligible. Is this a goal you think the Administration will support?

Answer. The Administration does support an expansion of the Federal TRIO Programs. In fact, our fiscal year 2002 budget request would expand TRIO to serve 785,000 low-income students, approximately 8 percent of the eligible population you mention. The $50 million increase requested for TRIO would support more than 40 new projects and provide a greater intensity of services, high school work-study opportunities, and college scholarships to thousands of additional students. However, TRIO is just one of many programs in the Administration's "No Child Left Behind" proposal that reach out to low-income and minority students.

Under our budget request, Gaining Early Awareness and Readiness for Undergraduate Programs would provide academic and support services and scholarships to more than 1 million students in high-poverty middle and high schools. Additionally, substantial increases would be provided for Historically Black Colleges and Universities and Hispanic-serving Institutions that serve thousands of minority and low-income college students. The President's budget also includes an increase of $1.9 billion for the Department's elementary and secondary education programs.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

AMERICAN HISTORY INSTRUCTION SUPPORT

Question. President Bush has stated that he wishes to strengthen and reform education, and he has presented Congress and the American people with an education proposal that calls for renewed diligence in math, science, and reading. History education, however, is ignored. History, and specifically, American history, have become stealth subjects, transformed and disguised under the labels "Social Studies" or "Civics," or disregarded. Consequently, our children's knowledge of American history is shameful. What do you intend to do to address this question?

Answer. The 2002 budget request for education, in tandem with the education reform proposals contained in *No Child Left Behind*, supports the President's comprehensive vision for closing the achievement gap and improving the quality of education for all children. It is clear that Federal education policy is not accomplishing its goals, despite the investment of more than $130 billion and the creation of hundreds of categorical programs over the past three decades. The President proposes to eliminate many categorical programs to give States and communities greater flexibility to use Federal resources for their own priorities. While the Administration's proposals do not include a separate Federal program to improve history instruction, American history is clearly an important part of the overall curriculum. We believe that States and school districts are in the best position to determine how best to improve history instruction, and our proposals provide them with the flexibility to accomplish this improvement.

TEACHING AMERICAN HISTORY GRANT PROGRAM

Question. On a related subject, Congress appropriated $50 million in fiscal year 2001 to create the Teaching American History Grant program, a national program intended to help put the study of U.S. history back into the classroom. Apparently, however, the Administration intends to save millions of dollars in your Department's budget by discontinuing all one-time projects, including the Teaching American History Grant program. Is it true that the Administration intends to eliminate this program despite our education system's glaring failure to teach the history of our Nation?

Answer. The Administration's budget request supports *No Child Left Behind*, the President's framework for reform of elementary and secondary education which proposes to eliminate or consolidate many categorical programs to give States and localities greater flexibility to use Federal resources for their own priorities. As you are aware, the Department is proceeding to use the $50 million Congress appropriated in 2001 to make awards under the Teaching American History grant program. Department staff have worked with your office, the National Endowment for the Humanities, and a variety of organizations dedicated to improving the teaching of American history in order to ensure that this program is successful.

So that grantees have sufficient time and resources to implement high-quality projects, the Teaching American History Grant program will make awards for up to three years from the 2001 appropriation. Grants will support programs to raise student achievement by improving teachers' knowledge, understanding, and appreciation of American history. They will assist local educational agencies, in partnership with entities that have extensive content expertise, to develop, document, evaluate and disseminate innovative, cohesive models of professional development. These grants will offer models that can be adopted by other communities to help improve the teaching of American history in U.S. schools.

As noted in response to the previous question, the budget does not include funding to continue a separate American history program, but States and school districts would have the flexibility to use other Federal funds to continue this type of activity.

CLASS-SIZE REDUCTION FUNDING

Question. The President proposed consolidating the Eisenhower Professional Development program and the Class Size Reduction program into a new teacher quality title under the Elementary and Secondary Education Act. Accordingly, his budget provides $2.6 billion for this new title. This would be a $375 million increase over the combined fiscal year 2001 funding level of these programs. The Class Size Reduction program, which has been working to reduce kindergarten through third-grade classes nationwide from 25 to 18 students, supports the salaries of 37,000 highly qualified new teachers. If we are to stay on this program's schedule to hire an additional 13,000 new teachers in fiscal year 2002, while also fulfilling our obligation to pay the salaries of the 37,000 teachers already hired via this program, we must provide additional funding for this program alone in the amount of $700 million. This is a shortfall of $325 million. At what level does the President intend to meet the funding requirements of the Class Size Reduction program?

Answer. The fiscal year 2002 budget supports the Administration's proposal, to combine the Class Size Reduction program with the Eisenhower Professional Development State Grants program and a few other programs into a single, flexible State grant program that supports State and local efforts to improve the quality of instruction. States and districts would use their funds for such activities as high-quality professional development, reforming teacher certification or licensure requirements, and alternative certification of teachers and administrators. In addition, a

district that believes that reducing class size would be the most effective strategy for improving student achievement within the district would be free to use its funds to hire teachers to reduce class size, but no district would be compelled to use their Federal funds in a manner that is not appropriate for its students and teachers.

This proposal is one of several consolidation proposals in *No Child Left Behind*, the President's framework for reform of elementary and secondary education. The President believes that schools will work best when administrators, teachers, parents, and other interested parties, are given the latitude and support to implement the educational reforms that best meet their needs, and then are held accountable for producing results. The Administration recognizes that the same strategy is not appropriate for all communities, and that is why we are proposing to give States and districts greater flexibility in using their Federal resources.

Question. Does the President intend to fulfill the obligation of this program to hire 13,000 new teachers and to support the salaries of the 37,000 teachers previously hired via this program, or does he intend to place the burdens of these teachers' salaries on the local school districts, therefore, jeopardizing their continued employment and the Federal, State, and local efforts to reduce class sizes in grades K–3 to reasonable levels?

Answer. The Administration believes that every child in America deserves to be taught by a high-quality teacher. The $2.6 billion requested by the Administration in fiscal year 2002 for the State Grants for Improving Teacher Quality program is sufficient to enable districts to retain the teachers that were hired previously under the Class Size Reduction program and hire additional teachers to reduce class size if a district believes that reducing class size would be the most effective strategy for improving student achievement.

As I stated earlier, the Administration believes that schools will work best when administrators, teachers, parents, and other interested parties, are given the latitude and support to implement the educational reforms that best meet their needs, and then are held accountable for producing results. Under the Administration's proposal for the State Grants for Improving Teacher Quality program, Federal funds would be available to support the research-based strategy for improving the quality of instruction and student achievement that best meets the needs of the district. However, no district would be compelled to use its Federal funds in a manner that is not appropriate for its students and teachers.

QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

TITLE I "SHORTFALL"

Question. The U.S. Department of Education has concluded that the fiscal year 2001 appropriations for Title I may fall short by about $165 million, and that States' allocations will have to be reduced as a result. Do you support a supplemental fiscal year 2001 appropriations bill to cover the shortfall?

Answer. The Administration completed a budget review earlier this year that resulted in a government-wide decision to "live within our means" and oppose additional requests for funding. This is part of our overall emphasis on supporting a more sustainable rate of increase in domestic discretionary spending.

TITLE I ALLOCATIONS—USE OF UPDATED DATA

Question. Title I was created to target funds and provide supplemental services to disadvantaged, poor children, and the law requires the Department to use updated counts of poor children in an effort to ensure that funding reflects changes in the poor student population. Do you support funding for this program that is targeted to poor children by using the most recent count of poor children possible?

Answer. Yes, we do support the use of biennially updated Census poverty estimates in making allocations under the Title I Grants to Local Educational Agencies program.

TITLE I HOLD-HARMLESS

Question. Do you oppose a Title I hold-harmless provision that "freezes in" funding levels to States despite changes in the poor student population?

Answer. Yes; the President's 2002 budget request for Title I assumes the application of statutory hold-harmless provisions and not the 100-percent hold-harmless included in appropriations language in recent years.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you very much, that concludes the hearing. The subcommittee will stand in recess until 9 a.m., Wednesday, May 23, when we will meet in room SD–138 to hear from the Acting Director, National Institutes of Health, Dr. Ruth L. Kirschstein.

[Whereupon, at 10:45 a.m., Thursday, May 10, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, May 23.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

WEDNESDAY, MAY 23, 2001

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:04 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SRVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF RUTH L. KIRSCHSTEIN, M.D., ACTING DIRECTOR

ACCOMPANIED BY:

DR. RICHARD D. KLAUSNER, DIRECTOR, NATIONAL CANCER INSTITUTE
DR. CLAUDE LENFANT, DIRECTOR, NATIONAL HEART, LUNG AND BLOOD INSTITUTE
DR. AUDREY S. PENN, ACTING DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
DR. RICHARD J. HODES, DIRECTOR, NATIONAL INSTITUTE ON AGING
DR. ALLEN M. SPIEGEL, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
DR. JACK A. McLAUGHLIN, ACTING DIRECTOR, NATIONAL EYE INSTITUTE
DR. STEPHEN I. KATZ, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES
DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. The Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed. This hearing has been advanced from 9:30 to 9:00 o'clock, because of other conflicting hearings. We are scheduled to have nominees for key positions in the Justice Department and also Secretary of Treasury O'Neil will be testifying before the Foreign Operations Subcommittee. Since the scheduling was undertaken, we have been considering the tax bill, and there has been what is called the Filibuster by Amendments.

We came in at 6 a.m. o'clock expecting on Monday to complete the action on the bill fairly promptly. We had 17 votes, and adjourned shortly after midnight. Yesterday we had 27 votes, and we are scheduled to reconvene at 9:30 today, so we will not have as much time as I would like for this important session. We thought it important to proceed with this hearing, because we wanted to finish our subcommittee's agency hearings to be thorough on examining the Administrations Budget requests

Now, last year, this subcommittee tied a record going back to 1976, completing our work on June 30th, and we had the conference finished on July 27th, and in an effort to get there early when you divide up $2 trillion, it is good to be at the head of the line. One of the key reasons that I wanted to be at the head of the line was to keep the funding going for the National Institutes of Health.

All of you know what Senator Harkin and I have done in the leadership role in increasing the funding for NIH. It has been very difficult. When we appeared before the budget committee 5 years ago and asked for an extra $1 billion, we were turned down, so we got a sharp pencil out and established the priority for this unit at NIH over many, many others.

So the next year we went back to the budget committee and asked for $2 billion, since we got turned down on $1 billion. We were turned down again and we lost many votes, but finally this year we won by a very decisive margin. The administration has come forward with an increase in funding in excess of $2.7 billion, but Senator Harkin and I are targeting an increase of $3.4 billion for fiscal year 2002.

We have spent a good deal of our time on the issue of stem cells as a potential answer to a great many of the maladies, which all of you know. It has candidly been quite an experience to chair this subcommittee and to have people come in who are devastated by their illnesses or the illnesses of their family or friends. No family in the world is untouched by the maladies. This room has been overflowing, and we have consistent requests from groups to publicize their own particular problem, and to prevail on NIH to give them a larger share.

We have had Michael J. Fox coming in on Parkinson's, and we have had Jerry Lewis coming in on muscular dystrophy, and the breast cancer group, and the amyotrophic lateral sclerosis group, the Alzheimer's group and children with Juvenile diabetes.

So we have looked to this committee really almost for miracles. Prime Minister David Ben Gurion of Israel, said, "If you do not believe in miracles, you are not a realist," and I believe that the potential is unlimited for what you can do.

So that is why I am committed to staying here. It is fairly well known that I wanted to move on to another subcommittee after battling the Congress for the budget. I thought it would be easier to chair foreign operations and deal with the Israeli-Palestinian conflict than with the Conference Committee on NIH, but then, realized that people were so interested in a continued service, so here I am.

I do not want to focus on the issue of the response to the letters that I sent on May 4 on stem cells, but candidly, I am very con-

cerned about not getting the answers until yesterday. The responses totalled some 70 pages, and we hardly had time to digest them. I am even more concerned about what I understand may have been rewriting of the letters. I am going to come to that in due course, but first, I want to touch on affirmative or substantive issues, and we welcome Dr. Kirschstein here today, the Acting Director of the National Institutes of Health, having served as deputy director from July, 1993, until she took over as acting.

She had served as Director of the National Institute of General Medical Sciences, the first woman to hold the position at NIH. She came to NIH in 1956 as a medical officer in clinical pathology, with a BA magna cum laude from Long Island University, and a M.D. from Tulane University.

Let me express on a personal note to Dr. Kirschstein how appreciative I am of your work, and your cooperation, and your devotion to your job. So the floor is yours for up to 5 minutes.

SUMMARY STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman, for those very kind words. Today, I appear before the subcommittee with my colleagues, the directors of the NIH's 27 institutes and centers. As you said, the President's budget for fiscal year 2002 reflects the administration's commitment to doubling the NIH budget by fiscal year 2003, and requests $23.04 billion, an increase of $2.8 billion, or 13.5 percent above the 2002 level.

NIH is deeply gratified by the support of the American public and the Congress, and recently, of the administration. Because of this unprecedented growth in our budget, we are gaining new knowledge and translating it into new treatments, diagnostics, and prevention strategies at a remarkable pace. This is a time of extraordinary scientific opportunity.

As you know, this year we celebrated the mapping of the human genome, a remarkable accomplishment, but as we look toward next year, and on to the next decade, our work has only just begun. The greatest challenges are before us, as are the greatest rewards. Turning what we know about genes into new approaches for prevention and management of disease will require even more intense efforts, and the dedication of our best and brightest scientists, as well as the continued support of the Congress and the nation.

To this end, NIH is expanding and developing a variety of new initiatives and programs aimed at seizing these new opportunities in all aspects of biology and medicine, from animal and human molecular studies, and stem cell biology, to clinical studies. We are expanding our clinical research programs in an effort to attract new young physicians into careers in research, so we are supporting several new loan repayment programs.

We are expanding our training programs and research efforts in bioinformatics and computational biology, so that we have the expert tools and personnel to get the most out of a landslide of information emerging from genomics, proteinomics, and imaging technologies, and we are using this new technology and this new knowledge to reach out to the public and to the health-care providers to help ensure that state-of-the-art information regarding

the prevention, diagnosis, and treatment of disease is incorporated into the delivery of care.

As you know, in this regard, just last week, the National Heart, Lung, and Blood Institute issued major new practice guidelines on the prevention and management of high cholesterol levels in adults, the first major update in almost 10 years, and as reported just last Sunday in The Washington Post, the statins, originally developed to lower cholesterol levels appear to lower the risk of stroke, diabetes, and Alzheimer's Disease, as well as the rejection of certain transplants, and to affect many other disorders as well.

PREPARED STATEMENTS

Mr. Chairman, I have kept my remarks brief, but I and the Institutes directors are here to answer your questions, and to elaborate, and to assure you that the accomplishments made as a result of the research will go on in the future. Thank you.

Senator SPECTER. Thank you very much, Dr. Kirschstein.

[The statements follow:]

PREPARED STATEMENT OF DR. RUTH L. KIRSCHSTEIN

Mr. Chairman and Members of the Committee: I am Ruth Kirschstein, the Acting Director of the National Institutes of Health. I am honored to appear before the Subcommittee, representing my colleagues, the Directors of the 27 Institutes and Centers who each have presented a written statement related to the President's budget for fiscal year 2002. I shall present an overall view of the total Administration budget for NIH in fiscal year 2002.

The NIH is deeply gratified that, beginning in fiscal year 1999, the support of the American public, the Congress, and the Administration produced a commitment to double its funding by 2003. Because of that additional funding, progress in the medical sciences is advancing at a speed we only dreamed of a few years ago. This is a time of extraordinary scientific opportunity.

Last June, the International Human Genome Consortium completed a working draft of the human genome sequence. More than 30 genes for human diseases and disorders, including various cancers, deafness, and birth defects, have already been identified using this working draft, and scientists are now using the information to design better means of diagnosing and treating these disorders and of identifying other genes. New insights and knowledge in biology and new tools, including advanced imaging techniques, computing power, and robotics, allow scientists to move from studying a single gene and protein to studying entire sets of genes and proteins and understanding their interactions. In all fields of medical research, we are now ready to move even more rapidly into clinical studies, the means of bringing advances directly to the patient.

The NIH Institutes and Centers have strategically invested the increases provided since 1999 to take advantage of the enormous scientific opportunities and to address essential health needs. Although scientific accomplishments often take many years to unfold into new diagnostic tools, treatments, and ways to prevent disease before it strikes, we can already see progress stemming directly from the increased funding. I will cite a few examples that Institute and Center Directors have recorded.

A new project funded by the National Cancer Institute (NCI) supports scientists who are developing detailed profiles, at the molecular level, of tumors and cancers of the lymphatic and blood system. The scientists used microarray technology to look at how thousands of genes are expressed at once, a scale previously unimaginable. This new project, looking at approximately 1.8 million measurements of gene expression from 96 different samples, revealed that there are two distinct subtypes of a malignancy called diffuse large B-cell lymphoma (DLBCL). Before this finding, clinical researchers had been unable to account for the fact that 40 percent of patients with DLBCL respond well to current treatment, yet the remainder die of the disease. This is just the first demonstration of a technique that promises to revolutionize diagnosis and treatment for lymphoma as well as for other cancers.

The National Institute on Drug Abuse (NIDA) was able, in fiscal year 1999, to use its increased funds to jump-start the establishment of what has now become a national clinical research infrastructure for testing treatments for drug addiction.

From past research, we know that treatment of drug abuse can be effective, but these treatments had not been adequately applied in community treatment centers. The National Drug Abuse Treatment Clinical Trials Network (CTN), which was expanded in fiscal year 2000, now provides the infrastructure to bring new treatments to diverse populations of patients across the country. Since the inception of the CTN, rapidly and systematically it has grown to include 14 research centers across the country working in partnership with over 80 community treatment providers. Patients are already participating in the first seven treatment protocols, which use both medications that counter addiction and behavioral approaches. Patient brochures have been published in English and Spanish, and an additional 17 new protocol concepts have been submitted to NIDA for review.

Language impairment is a serious problem that affects about 7 percent of all school-age children in the United States. It has significant consequences for families and for society as a whole, particularly in regard to cost of education and vocational training. There has never been a good evaluation of the effectiveness of the usual interventions for language impairment. A recently developed computerized method called Fast For Word has received national attention. Scientists supported by the National Institute of Deafness and Other Communication Disorders (NIDCD) are conducting a randomized clinical study to compare this intervention, which uses acoustically modified speech with computer assistance, to computer assistance alone and to other individualized interventions. The goal is to determine which intervention leads to the greatest improvement in language, the greatest gains in being able to converse, and the greatest gains in auditory perception, as well as being the most cost effective.

These examples illustrate some of the ways the Institutes and Centers have invested the budget increases since fiscal year 1999. They not only show great progress over the short-term, but also illustrate what is required today, in terms of technology and infrastructure, to take advantage of scientific opportunity and move basic findings into the practice of medicine.

The President's fiscal year 2002 budget reflects the continuing commitment to doubling the NIH budget by fiscal year 2003, requesting $23.04 billion, an increase of $2.8 billion, or 13.5 percent more than for fiscal year 2001.

Investments have already expanded our knowledge and the practice of medicine as they have pushed back frontiers. They have also revealed new frontiers-new opportunities to understand diseases, to treat them, to prevent them, and even to cure them. As a result, the Institutes and Centers have many new research projects underway, all of which will continue well beyond 2003. And given the accelerating rate of progress and discovery, it is clear that more opportunities will present themselves. We must seize these future opportunities. To illustrate, I will present examples from four areas of research offering particular promise to yield enormous benefits in the form of new knowledge, new treatments, and new strategies for prevention of disease and disability.

GENOMICS AND GENETIC MEDICINE

Now that a draft of the human genome sequence has been completed and is available to all scientists in a public database maintained by the NIH, opportunities abound. For example, future large-scale sequencing will be aimed at developing data to help scientists interpret the human sequence. One of the most efficient ways to do this is to obtain the genetic sequences from related organisms. A comparison between the genomes of the human and other organisms such as the non-human primates, mouse, rat, fruit fly, and yeast will help identify important features which point scientists toward genes likely to cause human disease.

There are a number of disorders that are primarily due to alterations in a single gene. How that disease manifests itself is complex and varies greatly among patients. These differences, thought to be caused by other genes that influence the disease-causing genes, will be a focus of research. Studying these so-called modifier genes will help us understand variations in the rate at which disease progresses and how individuals respond to therapy. In addition, these studies will enable earlier diagnosis and more accurate prognosis, and may even provide novel targets for therapy that are more useful than the gene primarily involved in causing a disease.

Together these approaches will help us identify genes involved in, for example, heart, lung, and blood disorders; cancer; mental and developmental disorders, including Alzheimer's disease and autism; diabetes; kidney disease; the muscular dystrophies; and the causes of aging; adverse reactions to drugs; and babies born full-term but with low weight.

CLINICAL RESEARCH: TAKING BASIC DISCOVERIES INTO MEDICAL PRACTICE

The NIH will continue to expand its emphasis in fiscal year 2002 on clinical research, the means by which basic findings relating to behavior, to molecules, and to genes, can be tested and translated into medical practice and improvements in public health.

Several Institutes will begin or will expand their clinical trials networks located nation-wide, ready to evaluate new prevention strategies, drugs, and vaccines in large numbers of patients. Other initiatives in clinical research planned for fiscal year 2002 include regional centers of excellence for research on rare diseases, research on care at the end of life, and the self-management of the chronic illnesses which plague our society.

The NIH is expanding its programs aimed at building the capacity to conduct clinical research. For example, the 106th Congress authorized several new Loan Repayment Programs (LRPs), which we regard as vitally important in recruiting new clinical researchers. Two of these new programs, the Extramural Clinical Research and the Pediatric Research LRPs will be trans-NIH programs that will be supported by nearly all the Institutes and Centers in the fiscal year 2002 President's request. In addition, we will support the Clinical Research LRP for Individuals from Disadvantaged Backgrounds and the LRP for Minority Health Disparities Research. Two programs started in fiscal year 1999, the Mentored Patient-oriented Research Career Awards and the Mid-Career Investigator Awards in Patient-oriented Research, will be expanded to meet the increasing demand for clinical investigators of high quality.

Participation of patients and other volunteers in clinical research is critical to progress. The NIH's national clinical trials database, called ClinicalTrials.gov, continues to provide the public with enhanced access to new information about clinical trials. In addition to learning about NIH-supported clinical trials, the public can gain access to information about such trials for serious or life-threatening conditions sponsored by other Federal agencies as well as by industry. This expanded capacity provides an even greater array of facts about which clinical trials are being conducted and whom to contact about participating in them.

INFRASTRUCTURE AND ENABLING TECHNOLOGIES

As medical research generates more and more data, there is a pressing need for scientists with expertise in biocomputing and bioinformatics. To meet this need, the NIH will significantly expand its current program in bioinformatics and computational biology. New research initiatives will include: Centers of Excellence in Biocomputing and Bioinformatics, grants to institutions to train people in these areas of science, and a joint NIH/National Science Foundation program to support research in mathematical biology.

Rapid progress in medical research is more and more dependent upon the availability of advanced instruments and other devices that often cost well in excess of half a million dollars each. The fiscal year 2002 President's budget request provides funds so that the NIH can support high-end instrumentation for basic and clinical scientists. Such instrumentation includes very high-field NMR spectrometers, extremely sophisticated imaging systems and electron microscopes, high-resolution mass spectrometers, and high-performance supercomputers.

The fiscal year 2002 President's budget also requests $40.2 million for the newly legislated National Institute of Biomedical Imaging and Bioengineering (NIBIB), the focus of which is to develop new knowledge, create new technologies, and train researchers able to integrate fully the quantitative sciences with medical research. The programs described above are over and above the $1.2 billion the Institutes and Centers currently devote extramurally to the physical sciences, including mathematics, chemistry and other physical sciences.

ELIMINATING HEALTH DISPARITIES

We are expanding our commitment to programs focused on the health needs of minorities and the medically underserved, as well as programs designed to increase the number of minority scientists.

The new National Center on Minority Health and Health Disparities (NCMHD) was established in December 2000 and is leading NIH's efforts to plan and coordinate research focused initially on racial and ethnic disparities. The Center's mission will expand to include studies related to medically underserved populations, including people who live in rural settings remote from medical care. The President's budget for fiscal year 2002 requests a 20 percent increase to $158.4 million for the new Center over the fiscal year 2001 estimate. In addition, the budget for the Office of Research on Women's Health would increase by about $28 million, to nearly $50

million in total, to support new research and career development for women in science.

The other Institutes and Centers will continue to expand their emphasis on health disparities as well. For example, a major clinical trial involving African-Americans is designed to identify ways to slow the progression of kidney disease due to hypertension. The study compares two major classes of drugs used to treat high blood pressure—beta blockers and ACE inhibitors and, when completed, will enable the NIH to provide and disseminate information about the optimal treatment of hypertension to prevent end-stage kidney disease in this minority group. NIH will also award grants to establish formal partnerships between NIH-designated cancer centers and minority-serving institutions such as historically black, Hispanic, and tribal colleges and universities. These partnerships will support research projects and research training in the minority-serving institutions, foster long-term collaborations between scientists and faculty that examine the disproportionate incidence and mortality from cancer in minority populations, and improve the effectiveness of cancer research, education, and outreach activities.

This is, Mr. Chairman, only a small sampling of our present and future research portfolios. The fiscal year 2002 budget request enables the NIH to sustain momentum of research already in progress, to open the way to new research opportunities, and to augment both our research infrastructure and our human capital. In fiscal year 2002, the NIH will fund 36,143 research grant awards, the highest annual total ever awarded.

The budget request includes a total of $135 million for the Institutional Development Award (IDeA) program, an increase of $35 million over fiscal year 2001. This increase will bring our support to a total of $75 million for the Biomedical Research Infrastructure Network (BRIN) subcomponent of the IDeA program, which has been developed to enhance the capacity of institutions located in States that have not fully participated in medical research, and are eligible for participation in the IDeA program.

Research and development contracts increase by 20 percent. The larger increase in R&D contracts, as compared to other extramural mechanisms, includes $28 million to support the two new loan repayment programs I described earlier.

The fiscal year 2002 President's budget also includes an increase of 12.5 percent for Research Management and Support (RM&S). As the NIH research budget grows, it is important to increase activities under the RM&S, so that we can effectively manage our programs. The RM&S includes support for the NIH professional staff who guide and monitor research activities of the Institutes, for example, those who oversee protections for volunteers participating in research, and who design and conduct programs to disseminate the results of NIH research to the public and to health care professionals.

This request will provide a 10 percent stipend increase for pre-doctoral and post-doctoral trainees and will permit us to recruit and retain the best and brightest scientists in careers in medical research. In the fiscal year 2002 President's budget, Buildings and Facilities (B&F) would be funded at $306.6 million. Three projects are particularly important to our research plans: The John Edward Porter Neuroscience Research Center, the Central Vivarium/Animal Research Center, and the Building 10 Revitalization Program to repair and renovate the aging facility used for clinical studies. The budget request also includes an increase from $75 million in fiscal year 2001 to $97 million in fiscal year 2002 in programs for construction and renovation of extramural research facilities through the National Center for Research Resources.

Consistent with the Administration's initiatives to combat drug abuse, the National Institute on Drug Abuse (NIDA) received an increase of 16.2 percent in the fiscal year 2002 President's budget request. In addition, the request includes funds for the Oravax smallpox vaccine contract managed by the Centers for Disease Control and Prevention ($32 million) and for intra-governmental support for development of anthrax vaccine ($5 million) and a vaccine production facility ($5 million).

Also included in the budget request is $10 million to begin the establishment of a system of sanctuaries for chimpanzees to provide lifetime care when they are no longer needed in research supported by Federal agencies. This system of sanctuaries was authorized by law in 2000.

Mr. Chairman, this concludes my opening statement. I would be glad to respond to any questions.

PREPARED STATEMENT OF DUANE ALEXANDER, M.D., DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Mr. Chairman and Members of the Committee: I am pleased to present the fiscal year 2002 President's budget request for the National Institute of Child Health and Human Development (NICHD) of $1,096,650,000, which reflects an increase of $117,744,000 over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The mission of the NICHD extends over much of the human life span, from the time a single egg is fertilized and develops into an infant, through the childhood and teenage years, through the young adult and reproductive years, to the health concerns of mature men and women. Our research seeks to answer questions important to everyone: How can parents have children at the times they want them? How can all children be born healthy and mothers avoid the adverse consequences of pregnancy? How can every child reach adulthood free of disease and disability, able to achieve his or her full potential? How can we ease the burden of physical or mental disability to enable all individuals to participate in society as fully as possible?

Since the Institute was established almost 40 years ago, we have made enormous strides in answering these questions and improving the lives of millions of Americans. Through research, we have identified, and eliminated or reduced, many of the causes of mental retardation and as a result, far fewer children and adults have mental disabilities. Through research, we have reduced infant mortality and as a result, many more infants have grown into healthy children and adults. Through research, we have found ways to reduce the transmission of the HIV virus from mother-to-infant and as a result, AIDS in children has markedly declined in this country. And through research, we have demonstrated cost-effective methods of significantly reducing the rate of HIV transmission in developing countries.

We faced formidable scientific challenges in achieving these advances, and we face many challenges today. Yet these challenges are dwarfed by the excitement and hope of soon finding answers to questions we have wondered about for decades.

NEW TECHNOLOGY TO HELP ANSWER A FUNDAMENTAL QUESTION

For many years the answer to a critical scientific question has eluded us: what actually triggers labor in a pregnant woman, at term or at preterm? We know many things that correlate with a woman going into labor, but we have never identified the mechanism that triggers labor. This is an important question. Preterm birth is the leading cause of infant sickness and death among African American babies and the second leading cause of infant death among all races. Despite some wonderful and heartwarming stories that occasionally appear in the media about a premature infant surviving, the long-term outlook faced by very premature infants can be bleak.

Now, for the first time, the human genome project has provided us with the basis for a new technology called microarrays that will allow us to compare the active genes from pregnant women who begin labor prematurely with active genes from those who are not in labor or who deliver their babies after the full nine months. This comparison will help us to identify the gene products that are responsible for initiating labor. Armed with this knowledge, we can learn how to stop, postpone, or, if needed, induce labor. So we have within our reach the hope of addressing the single biggest cause of infant mortality, premature birth. And in the process of answering this important question, we can help eliminate the significant racial disparity in infant mortality.

NEW COLLABORATIONS TO ELIMINATE RACIAL DISPARITIES IN SIDS

As you know, we have had extraordinary success in reducing another cause of infant mortality, Sudden Infant Death Syndrome or SIDS. Since the Institute initiated the Back to Sleep campaign in 1994 to reduce the risk of SIDS, the death rate from SIDS has declined by 40 percent. Yet this decline has been less pronounced among African American infants. In fact, the SIDS rate among African American infants is greater than twice that of white infants. So in collaboration with several national African American organizations, we have initiated an outreach program to reduce the risk of SIDS among African American infants. The organizations, which include the National Black Child Development Institute, the Women of the NAACP, the

Alpha Kappa Alpha sorority, and 100 Black Women, among others, are conducting one-to-one training sessions in communities throughout the country to inform African American parents and care givers about back sleeping and other ways to reduce the risks of SIDS.

BEHAVIORAL INTERVENTIONS TO IMPROVE LEARNING

Education is a cornerstone of healthy behavior and reading provides the foundation for education. Children who have difficulty reading are at risk for failure in school, failure at work, and failure at the many activities required to navigate successfully as an adult in our society. NICHD research has demonstrated that using teaching techniques based on phonemic awareness results in most children being able to read by the end of the third grade. As you recall, in collaboration with the Department of Education, as directed by Congress, the Institute convened a National Reading Panel in 1998 to review the evidence from reading research and make recommendations for the most effective methods of teaching children to read. In the largest and most comprehensive evidence-based review of research on how children learn reading ever conducted, the Panel reviewed more than 100,000 experimental and quasi-experimental research studies. The Panel report strongly endorsed the findings and instructional approaches from NICHD's research. We are now collaborating with the National Institute for Literacy to disseminate the Panel's findings to administrators, teachers, and parents.

IMPROVING THE ENVIRONMENT FOR CHILDREN TO GROW

Compared to adults, children are at increased risk from environmental influences. Children are not just small adults. Yet their developing bodies are often exposed to the same level of contaminants as are adults. In some instances, such as ingesting lead from peeling lead-based paints, children may be exposed to greater contaminants than are adults. What happens to a child before birth and early in life will affect the child's subsequent growth, development, and well being

For this reason, the President's Task Force on Environmental Health and Safety Risks to Children recommended a longitudinal cohort study of environmental impacts on children to identify and quantify the risks that children face. Several Federal agencies, among them, the NICHD, the National Center for Environmental Health of the CDC, and the Environmental Protection Agency, are participating in planning this study. The study will enroll 100,000 children, beginning from before birth, and will gather information on environmental influences and outcomes until the children reach at least age 21. Methodological and pilot studies are planned for fiscal year 2001 to 2003 and the full study will be initiated in 2004. This planning phase will also allow us to answer key questions about the administration of the study. This is the largest such prospective study ever undertaken in this country and we look forward to working with this committee in addressing these exciting and challenging issues.

REDUCING HIV AND AIDS AMONG ADOLESCENTS

The advent of highly active antiretroviral therapy, or HAART, in the mid 1990s dramatically improved the outlook for many people living with HIV infection. But for adolescents infected with HIV, HAART posed a great promise and a greater challenge. The therapy holds the promise of converting HIV infection into a chronic but manageable condition that gives young people time to benefit from emerging therapies. The challenge is that many HIV positive adolescents have little experience with medications, therapeutic regimens, or adherence to therapy. In the absence of a strong social support system, many HIV positive adolescents on HAART do not recognize the importance of taking medications consistently, on time, every day, without fail. The stakes are high because if the drugs are taken for short bursts or erratically over long periods, the probability of drug resistance increases. To help treat HIV positive adolescents and to develop effective prevention strategies, the NICHD established the Adolescent Medicine HIV/AIDS Research Network. By providing training, reinforcement, and a strong social support system, the Network has demonstrated that adolescents can be motivated to remain on an exacting medication regimen. Moreover, the adolescents have been trained in peer counseling techniques and they are providing a strong prevention message to friends and classmates in their social network.

AUTISM RESEARCH

In our autism research, we continue to make important discoveries that help us understand this condition in the hope of finding more effective treatments. Recently

researchers funded by NICHD and other NIH Institutes identified a gene that may predispose people to developing autism. The gene, known as *HOXA1*, plays a crucial role in early brain development. This finding strongly suggests that a gene controlling early brain formation may underlie the development of autism in a large number of cases. Together with other NIH Institutes, we are also actively implementing the provision of the Children's Health Act of 2000 that calls for the establishment of the Centers of Excellence on Autism Program. As an initial step toward establishing the Centers, we are issuing Requests for Applications for Center Development grants which will allow potential Centers of Excellence to marshal the resources necessary to submit strong proposals when we request applications for the actual centers.

WOMEN'S HEALTH

Research in women's health continues to be a high priority for the Institute. We are supporting research to develop effective treatments for uterine fibroids, the number one reason for hysterectomies and a leading cause of infertility, particularly among African American women. With the Office of Research on Women's Health, we are conducting research to understand, treat, and reduce conditions such as pelvic organ prolapse and incontinence that can develop as a result of childbirth or the aging process. We are also conducting research to diagnose and treat vulvodynia, a particularly painful condition that affects the reproductive, sexual, and physical health of women. We have also initiated gender specific-research to understand how women's unique reproductive physiology influences the transmission and progression of HIV–1. This research will lay the foundation for new prevention and treatment strategies to reduce AIDS among women. And because some conditions such as uterine fibroids, ectopic pregnancies, and preterm births disproportionately affect African American women, NICHD has helped establish a collaborative partnership between reproductive scientists at minority institutions and NICHD-funded programs. The new Reproductive Science Centers at Minority Institutions are designed to increase the number of minority investigators trained to study reproductive health issues, particularly those relevant to racial and ethnic populations.

In closing Mr. Chairman, I look forward to working with you and the subcommittee and will be happy to provide answers to any questions you have.

PREPARED STATEMENT OF DR. JAMES F. BATTEY, JR. DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD) for fiscal year 2002, a sum of $336,757,000 which reflects an increase of $35,631,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The United States recently celebrated the 10th Anniversary of the signing of the Americans with Disabilities Act, a law enacted in 1990 to promote integration, equal opportunity, and inclusion of millions of Americans with a disability. Even with this legislation, individuals affected by a communication disability may still find it difficult to enter the labor force and live a productive life because of the daily challenges they face. It is often impossible for them to perform the simple acts of speaking, listening, or otherwise making their wants and needs understood. Disorders of hearing, balance, smell, taste, voice, speech, and language exact a significant economic, social, and personal cost for many individuals. The NIDCD supports and conducts research and research training in the normal processes and the disorders of human communication that affect approximately 46 million Americans. Human communication research now has more potential for productive exploration than at any time in history. With substantive investigations conducted over the past decades, the advent of exciting new research tools and new highly trained scientists, the NIDCD is pursuing a more complete understanding of the scientific mechanisms underlying normal communication and the etiology of human communication disorders. Examples of this research are highlighted in this statement for the record.

The Speed of Sound: Rapid Motor Protein of Inner Ear Identified.—Millions of Americans, especially middle-aged and older individuals, suffer from mild to moderate hearing loss. It is likely that a defect in the most sensitive cell types in the

inner ear, the hair cells, causes this type of hearing deficit. The hair cells of the inner ear are sensory receptor cells that give humans and other mammals the remarkable ability to hear. As sound travels to the ears, down the ear canal, through the bones of the middle ear and into the inner ear, the outer hair cells amplify the mechanical vibrations produced by the sound through a process known as electromotility. These electrical changes in the cell allow it to rapidly change its length and stiffness. The length changes amplify the vibrations, which are sensed by the other hair cells (inner hair cells) that send auditory information to the brain. NIDCD-supported scientists have recently identified the gene that codes for the motor protein responsible for outer hair cell electromotility as well. *Prestin* (from the musical term presto, indicating a rapid tempo) was selected as the name of the gene to emphasize one of the most interesting features in the cellular motor process, its speed in changing the length of outer hair cells. Outer hair cells can elongate and contract at rates close to 100,000 times a second! Future research on *Prestin* should lead to significant advances in understanding the auditory system, and may lead to the development of new therapeutic measures for hearing impairment.

Genes Responsible for Hereditary Hearing Impairment.—NIDCD-supported scientists continue to make impressive scientific progress in mapping and cloning genes responsible for hereditary hearing impairment. Over the past few years, the chromosomal location of over 60 genes whose mutation results in hereditary hearing impairment have been identified. In the past three years, nearly 20 genes have been identified whose mutations cause hereditary hearing impairment. The identification of these genes enables scientists or clinicians to rapidly identify individuals carrying the defective gene even if the hearing loss has a delayed onset and is not yet evident. In addition, the identification and isolation of genes responsible for hereditary hearing impairment immediately provide a powerful tool to determine how the mutation results in deafness by targeted gene mutations or deletions in an animal model. The animal model can provide information on which structures of the ear are affected, as well as the molecular and physiological defects that result in hearing impairment, and provide a system to test potential new therapies.

Gene Cloned for Syndrome That Causes Deafness and Blindness.—Usher syndrome type 1 is an inherited sensory defect involving profound deafness, balance disorders and eventual progression to blindness. It is the most common genetic cause of a syndrome leading to blindness and deafness in Americans. Studies of affected families in the U.S. and abroad indicate that there are more than six distinct genes whose mutations result in this devastating inherited disease. NIDCD-supported scientists are collaborating with researchers from France, Germany, Lebanon, and Japan to identify the defective gene responsible for one form of this disorder, USHER1C. They identified the defective *USHER1C* gene in unrelated families in the U.S., Lebanon, and Europe. The finding will allow for genetic-based diagnosis of Usher syndrome before a deaf individual begins to lose sight. Early diagnosis will permit the study of the complete progression of retinal degeneration and provide opportunities in the future for possible treatment before the retinal degeneration begins.

An Animal Model for Pendred Syndrome.—Individuals with Pendred syndrome have sensorineural deafness and goiter (enlargement of the thyroid gland). In a collaboration between National Human Genome Research Institute and NIDCD intramural scientists, genetic analysis revealed that mutations in the *Pendrin* gene occur in deaf individuals without thyroid disease, indicating that the gene is responsible for a much broader spectrum of deafness than only those individuals with Pendred syndrome. To determine the cause of this disorder, the *Pendrin* gene was deleted in mice and analysis of this mouse model was conducted. The mutant mice were found to be deaf and have a variable spectrum of balance problems similar to symptoms of individuals with the syndrome. The scientists observed swelling in parts of the developing inner ear in the mutant mouse embryos. The resulting fluid imbalance within the inner ear subsequently leads to the destruction of the sensory hair cells necessary for hearing. This mutant mouse model provides important clues about inner ear pathology associated with the human syndrome.

Otitis Media is Linked to a Strong Genetic Component. Otitis media (OM), or middle ear infection, is the most common reason why a sick child visits a physician, and is the most common reason that children receive antibiotics or undergo surgery. Previous anatomical, physiological, and epidemiological studies have raised the question of whether the likelihood of having multiple bouts of this common disease has a hereditary component. Studying twins and triplets to determine the extent to which this common disease might be due to genetic factors, NIDCD-supported scientists have determined that there is a strong genetic component to the rate of occurrence of otitis media in children. The implications of these findings are numerous for both immediate and future improvements in treatment of OM. For example, pri-

mary care physicians can follow siblings and offspring of affected children as potentially high-risk cases. These children could be monitored more closely for early detection and treatment of disease, reducing the risk of hearing loss. In addition, identification of the genetic factors that cause this disease could eventually result in genetic diagnostic tests to identify individuals with enhanced risk. Finally, studies of the molecular basis for the increased risk and frequency of otitis media could lead to new approaches for intervention and treatment of this disease.

Molecular Biology of Taste Signal Transduction.—A long history of NIDCD-supported research has shown that taste perception involves four basic taste qualities: sweet, sour, salty, and bitter. In a recent study, a fifth taste has been recognized and its taste receptor identified—umami—the taste of monosodium glutamate or the taste associated with protein-rich foods. From this finding, scientists have determined that each taste quality appears to be mediated by a distinct biochemical pathway. Salty and sour substances activate specialized ion channels in the membrane of the taste receptor cells in the taste buds in the tongue. In contrast, umami-, sweet-, and bitter-tasting substances activate another pathway involving G-protein-coupled receptors. Scientists recently characterized the diverse structure, function and expression of a large family of mammalian G-protein-coupled receptors, called T2Rs, which are selectively expressed in a subset of taste receptor cells of the tongue and palate. T2R receptors were shown to mediate bitter taste perception in humans and mice.

The Genetics of Stuttering.—Stuttering is a speech disorder in which the normal flow of speech is disrupted by frequent repetitions or prolongations of speech sounds, syllables or words. Currently, there is no cure for the 3 million Americans who stutter. The precise causes of stuttering have not been identified but there is evidence that it is genetically determined. NIDCD intramural scientists have been conducting a large study that involves individuals who stutter and their families. From this group, the scientists have recently identified a single region of the genome that may contain one or more genes involved in stuttering. Understanding the genetic causes of stuttering will eventually lead to treatment for this age-old disorder.

Language Impairment in Autism.—NIDCD-supported scientists were the first to investigate the language profiles on a large sample of children with autism. One cardinal feature of autism is the delay or absence of spoken language. In the study, the researchers found significant differences in language skills, although articulation skills (or how the sounds of the language are produced) remained normal in all the children. Different subgroups of children with autism were identified on the basis of their performance on the language measures. Some children with autism have normal language skills, while others have language skills significantly below their age expectations. The scientists also observed that the performance profile across the standardized measures for the language-impaired children with autism was similar to the profile of children with specific language impairment (SLI). These findings suggest that there may be overlapping or shared characteristics among families with SLI and autism. Future studies will need to investigate the mechanisms underlying language processing in children with SLI, autism and perhaps other disorders, in order to advance the understanding of language disorders in children.

Expanding Efforts to Identify Hearing Impairment in Newborns.—As efforts increase in many States to screen all newborn infants for hearing impairment before discharge from the hospital, more infants will be identified with hearing impairment at an early age when appropriate intervention can be started that will optimize their long-term speech and language skills. NIDCD-supported scientists have examined the importance of age at enrollment in intervention programs and subsequent language outcomes for a group of deaf and hard-of-hearing children. Significantly better language scores were associated with early enrollment, and high levels of family involvement correlated with positive language outcomes. These results provide further evidence that children will benefit when early identification of hearing loss is combined with an early intervention strategy that actively involves family participation.

Advances in the genetics of hereditary hearing impairment and in the early identification of hearing impairment have now converged, leading some clinicians to suggest genetic testing/evaluation be performed on all infants who are identified with a hearing loss at birth. In consideration of these developments, the NIDCD is planning a study to address the clinical relationship between genetic and audiologic/otologic information, as well as to assess the clinical validity, value and utility of genetic testing in the diagnosis, treatment and management of hearing impairment.

Cochlear Implants Are Cost Effective.—Over 20,000 Americans with profound hearing impairment have received cochlear implants with approximately one-half of the recipients being children. This device converts sound into electrical impulses on

an array of electrodes surgically inserted into the inner ear, bypassing the hair cells and stimulating the auditory nerve directly. NIDCD-supported studies have shown that children with cochlear implants exhibit improvements in speech perception, speech production, and better language and reading performance. In addition, a recent analysis showed that cochlear implants improve the children's quality of life, and result in a net saving to society. The cost benefit is in the form of fewer demands on special education and greater wage-earning opportunities for implant recipients.

PREPARED STATEMENT OF DR. MARVIN CASSMAN, PH.D., DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Mr. Chairman and Members of the Committee, good morning. I am pleased to present the President's budget request for the National Institute of General Medical Sciences (NIGMS) for fiscal year 2002, a sum of $1.720 billion, which reflects an increase of $180 million over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second performance report, which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The NIGMS mission is to support basic biomedical research in disciplines ranging from genetics, chemistry, and cell biology to trauma and burn research. These studies, often carried out in organisms such as yeast, fruit flies, and bacteria, yield a fundamental understanding of the biological processes that underlie all of the functions of life. Insights into the basic behavior of living systems provide the underpinning for subsequent discoveries regarding the way these processes go awry and lead to disease.

It is becoming increasingly clear that research started with the goal of understanding unknown or poorly understood processes can immediately lead to insights about the mechanisms underlying diseases. One example is a research effort focused on a rather esoteric protein that is involved in the way cells process the instructions from DNA. As part of this study, the NIGMS-supported investigators closely examined the makeup of the protein. From its somewhat unique structure, they inferred that the protein could trigger diseases that result from the body's reaction to its own materials, a process known as autoimmunity. Interestingly, this discovery was entirely incidental to the original investigations. When the scientists tested this hypothesis, they found a strong correlation between high levels of immune response to this protein and the occurrence of a disease called systemic lupus erythematosus. This suggests that the occurrence of lupus is a consequence of some aberrant event that results in the accumulation of this protein or in the body's response, or both. We anticipate that this discovery will provide a major tool to allow accurate diagnosis of lupus as well as a clue to possible cures.

Another example of the rapid conversion of a basic understanding of biology to an understanding of disease processes is found in studies being done on copper. Although copper is most often associated with pennies or the pipes used in plumbing, the metal is also an essential component of biological systems. However, when free in cells and organisms, even a small amount of copper can be very toxic. How does the body process copper in a way that does not cause irreversible damage? NIGMS grantees discovered proteins that "chaperone" copper and protect it from interacting with other cellular components until it reaches its proper destination. These proteins are called "metallochaperones." Some are specific for transporting copper, and some are specific for transporting other essential metals. There are several known hereditary diseases that are the result of defective copper metabolism, and these diseases frequently cause neurodegenerative disorders. It is important to understand just what is going wrong in individuals with these problems. Recent detailed studies on the mechanism of copper transport have shown how the chaperones that carry copper are implicated in the events leading to these diseases.

Finally, a major thrust in modern medicine is the attempt to understand individual responses to drugs based on a person's genetic make-up. For example, certain drugs used to treat cancer can have widely variable effects in patients, and many of these treatments have serious toxicities. On occasion, patients are literally poisoned because their bodies cannot get rid of, or "clear," a drug. For example, patients given the same dose of a commonly used chemotherapy drug, docetaxel, can have wide variations in the amount of time it takes to clear the medication. A solution to this problem may come from many years of basic studies on the behavior

of a drug-metabolizing protein nicknamed "CYP3A4." This protein chews up many different drugs, including docetaxel. An NIGMS grantee has developed a simple breath test to measure the activity of CYP3A4, and a small clinical study has shown that patients who exhibit low activity of the protein suffer the greatest docetaxel toxicity. Since blood tests have previously failed to predict docetaxel toxicity, the breath test may offer a promising tool to help physicians administer this drug more safely.

RECENT RESEARCH INITIATIVES

NIGMS has recently begun a number of major research initiatives, and I would like to describe our progress in three of them. The first is in the area of pharmacogenetics, an example of which is the docetaxel toxicity research I just described. The goal of this research initiative is to identify the genetic basis of individual variations in drug response, and ultimately to develop tools that will allow individual differences to be determined before drugs are prescribed. We have funded 9 research groups for a total of $12.8 million in the first year. NIGMS leads the research initiative, and five other NIH components are cofunding projects. The other NIH components are the National Heart, Lung, and Blood Institute; the National Cancer Institute; the National Human Genome Research Institute; the National Library of Medicine; and the National Institute of Environmental Health Sciences. The centerpiece of the program is the development of a database that will link gene variations to their cellular and molecular consequences, and ultimately to their physiological outcomes. Because many of these studies will initially be on defined populations we have established a Populations Advisory Group to provide advice on how to best proceed with such research. We established a second advisory group to provide a liaison to the pharmaceutical industry. Although this industry is doing a great deal of work in pharmacogenetics, much of it is proprietary. However, there are opportunities for mutually beneficial interactions, and this advisory group has been established to identify those areas.

The second major research initiative is in the area of structural genomics. The goal is to determine the three-dimensional structures of all proteins in nature, through a combination of direct experiments and theoretical analysis. Proteins are the worker molecules in every living thing. By determining the structures of proteins, we are better able to understand how each protein functions normally and how faulty protein structures can cause disease. Scientists can use the structures of disease-related proteins to help develop new medicines and diagnostic techniques.

The project was begun in September 2000 through funding nearly $30 million worth of awards to seven consortia that total 41 participating institutions. These are pilot programs to determine the most effective approaches that will result in rapid production of detailed protein structures. It is important to note that the NIGMS research initiative is part of a world-wide activity in structural genomics that also includes several industrial participants. Together with the Wellcome Trust in the United Kingdom, NIGMS organized an international structural genomics meeting that was held in England in April 2000. A second international meeting was held in the Washington, DC area in April 2001.

The third Institute research initiative provides support to "glue together" groups of investigators working on significant problems that could not be solved if the scientists worked independently. Like the other two research initiatives, it involves the formation of a network of researchers who collaborate and share their results to speed progress toward a major goal. All of these projects reflect changes in how biomedical research is done today. There is an increased emphasis on large-scale and collaborative approaches to important scientific questions. These include studies of complex systems that involve the interaction of many components, such as all of the activities that go on within a single cell and the ways that cells and organs "talk" to each other.

Studying complex systems requires the contributions of more than just biological scientists. It requires the expertise and approaches of physicists, mathematicians, computer scientists and engineers, all of whom are in a unique position to organize and analyze the vast amounts of data generated by studies of complex systems. To address this need, NIGMS has started programs to encourage these scientists to join their expertise and interests with those of biomedical researchers.

RESEARCH TRAINING

NIGMS remains committed to preparing "a cadre of versatile scientists and engineers for research and teaching careers," investing in "an educational system that creates a reservoir of flexible talent for the work force," and ensuring "opportunities for the participation of all groups in science and engineering." These goals, which

are quoted from a 1998 Office of Technology Assessment report on the objectives of Federal training programs, mirror the Institute's interests. We accomplish these goals through a variety of mechanisms, two of which I will mention. The first is our predoctoral training programs, which have been widely recognized as a means of identifying, stimulating, and rewarding quality research training. They encourage interdisciplinary training, which is a central requirement of all of our training programs. Two recent reports, one by the National Academy of Sciences and one an internal NIH study tracking the career progression of former trainees, have noted the value of these programs in generating a highly qualified group of investigators.

In order to encourage "opportunities for the participation of all groups in science and engineering," we require that our training programs make active efforts to recruit and retain underrepresented minorities. Additionally, our Minority Access to Research Careers (MARC) Program has a strong focus on research training, primarily at the undergraduate level. In fiscal year 2000, we supported 644 students at 62 institutions through this program. Although this is a program of very long standing, since 1975, we have several other programs focusing on the training of underrepresented minorities in science, a number of which have been initiated in the past few years. These programs are coupled to intensive outreach efforts that are designed to improve the capabilities of institutions to participate in Federal programs and to identify new approaches to bring underrepresented minorities into biomedical research.

HEALTH DISPARITIES

NIGMS has several special activities in the area of health disparities. One is a new collaboration with the Indian Health Service to enhance the capacity and skills of tribal organizations and Native American researchers to conduct high-quality biomedical and behavioral health research and to apply successfully for competitive research grants.

By its very nature, our pharmacogenetics research initiative will likely reveal new information linking differences in response to medicines with genes that are more common in certain population groups. Such knowledge could contribute to a reduction in health disparities by improving doctors' ability to identify and treat individuals who have these genes. Beyond these general benefits, we are planning to offer research grant supplements for studies that are specifically related to health disparities in response to medicines.

Finally, a proposed NIGMS health disparities initiative would focus on differences between various population groups in the physiological response to traumatic injury. New information about such differences could improve doctors' ability to anticipate how trauma patients are likely to fare, especially which patients are at higher risk of developing a potentially fatal complication called systemic inflammatory response syndrome.

CONCLUSION

In conclusion, NIGMS sustains and develops programs that provide the research and research personnel required to ensure the continued progress of biomedical research. Our many accomplishments attest to our success in this endeavor, and our recent research initiatives should help us make even more significant contributions to the biomedical research enterprise in the years ahead.

Thank you, Mr. Chairman. I would be pleased to answer any questions that you may have.

PREPARED STATEMENT OF DR. FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Mr. Chairman and Members of the Committee: During fiscal year 2000, Human Genome Project scientists capped the achievements of the last decade with a historic milestone—the complete initial reading of the text of our genetic instruction book. At present, roughly 93 percent of the 3.1 billion bases of the human genome are freely available in public databases. This is an awesome step toward a comprehensive view of the essential elements of human life, a perspective that inaugurates a new era in medicine where we will have a more profound understanding of the biological basis of disease and develop more effective ways to diagnose, treat, and prevent illness.

Between March 1999 and June 2000, the production of human genome sequence skyrocketed. During this time, the international collaborators in the Human Genome Project sequenced DNA at a rate of 1000 bases per second, 7 days a week,

24 hours a day. After completing the working draft of the human genome sequence in June of 2000, Human Genome Project scientists and computational experts began to scour the sequence for insights. They reported the first key discoveries in the February 15, 2001 issue of the journal Nature. Among the findings were the following:

—Humans are likely to have only 30,000 to 35,000 genes, just twice as many as a fruit fly, and far fewer than the 80,000 to 150,000 that had been widely predicted.

—Genes are unevenly distributed across the genomic landscape; they are crowded in some regions and spread out widely in others.

—Individual human genes are commonly able to produce several different proteins.

—More than 200 human genes arrived to the genome of some ancestor directly from bacteria.

—The repetitive DNA sequences that make up much of our genome, and commonly regarded as "junk," have been important for evolutionary flexibility, allowing genes to be shuffled and new ones to be created. The repetitive DNA may also perform other important functions.

FINISHING THE HUMAN GENOME SEQUENCE

Because of the enormous value of DNA sequence information to researchers around the world, in academia and industry, NHGRI has always been committed to the principle of free, rapid access to genomic information through well-organized, annotated databases. Databases housing the human genome sequence are being visited an average of more than 50,000 times a day. In fiscal year 2002, NHGRI will increase the usefulness of the human genome sequence to the world's researchers by finishing the sequencing to match the project's long-standing goals for completeness and stringent accuracy. More than a third of the draft sequence already has been finished into a highly accurate form—containing no more than 1 error per 10,000 bases. Finished sequence for the entire genome is expected by 2003. Finished sequence is already available for the entire lengths of chromosomes 21 and 22. Genes on chromosome 21 are involved in Down syndrome, Alzheimer disease, certain cancers, and manic depressive illness, while those on chromosome 22 are implicated in the workings of the immune system, in congenital heart disease, schizophrenia, mental retardation, and several cancers, including leukemia. Researchers can now study the molecular bases of the conditions linked to these chromosomes systematically and comprehensively, and the same high standard of completeness will be achieved for the other 22 human chromosomes over the next two years.

GENOME SEQUENCES OF NON-HUMAN SPECIES

In the coming year, NHGRI and its partners will sequence the genomes of important model organisms, including the mouse and rat. The Human Genome Project's goals always included the analysis of the genomes of species that have been important to laboratory research. Having genome sequence from additional species is one of the most efficient tools for interpreting the human sequence, because many of the most important elements in our genome—including genes and the regions that regulate their expression—are conserved in the genomes of other species. Genome sequences from the well-studied laboratory mouse and rat will be especially useful because, as mammals, their genomes are relatively similar to the human genome and because they have long provided insights into the molecular basis of disease.

The Mouse Sequencing Consortium formed in October 2000 and in April 2001 produced a publicly accessible draft sequence covering 95 percent of the mouse genome, a result of the collaborative efforts of three private companies, six institutes of the NIH, and a British charity, the Wellcome Trust. The Consortium will now go through the more arduous process of filling in gaps in the draft and will produce high-quality finished sequence no later than 2005. Already, the mouse data is saving researchers a great deal of time. For example, researchers at Merck recently found a mouse relative of a human gene implicated in schizophrenia by scanning the newly available mouse genome sequence. Alterations in the human gene were found in a large Scottish family where schizophrenia correlates with a chromosomal rearrangement. Researchers had searched without success for years for the related gene in mouse, but the mouse genome sequence readily revealed the corresponding mouse gene in a computer search taking only seconds. The researchers can now test the effects of inactivating the gene on the mouse brain, perhaps giving clues to the molecular basis of schizophrenia in humans.

Meanwhile, the laboratory rat, long used for a wide range of medical research, including studies on high blood pressure, cancer, and drug metabolism, is getting its

share of attention. In February, NHGRI and the National Heart, Lung and Blood Institute announced a plan for sequencing the rat genome. The institutes will fund private companies as well as academic labs; all have agreed to release data weekly into public databases.

Other model organisms' genomes are undergoing study as well. NHGRI is funding scientists at the University of California at Berkeley and the Baylor College of Medicine to close the gaps in the fruit fly genome sequence and to ensure that the finished sequence meets quality standards for finished sequence data. In fiscal year 1999, NHGRI and the National Cancer Institute, leading 15 other NIH institutes, launched the Mammalian Gene Collection, whose goals are to develop analysis tools and to produce a collection of full-length copies of genes, which can be sent to researchers on demand. So far, nearly 20,000 full-length gene copies have been identified and are slated for sequencing.

HUMAN GENETIC VARIATION

For understanding the basis of common diseases with complex origins, like heart disease, Alzheimer disease, and diabetes, it is important to catalog genetic variations and how they correlate with disease risk. Among any two people, an average of one DNA spelling variation—or SNP—exists in every 1000 bases. With a draft of the human genome sequence in hand, the pace of SNP discovery has increased dramatically. In fiscal year 1999, NHGRI organized the DNA Polymorphism Discovery Resource consisting of 450 DNA samples collected from anonymous American donors with diverse ethnic backgrounds. NHGRI has funded studies looking for SNPs in these samples. The non-profit SNP Consortium came into being in April 1999, with the goal of developing a high-quality SNP map of the human genome and of releasing the information freely. Consortium members include the Wellcome Trust, a dozen companies (mostly pharmaceutical companies), and three academic centers; they have looked for SNPs in DNA from a subset of the samples in the DNA Polymorphism Discovery Resource. In July 2000, the NHGRI and The SNP Consortium announced a collaboration that has allowed the contribution of 5 times more SNPs to the public domain than the consortium originally planned. As of March 28, the public database that serves as a central repository for SNPs has received 2,840,707 SNP submissions.

With the increased knowledge about human variation, the genetic underpinnings of various diseases, including diabetes, are being discovered. The recent discovery of a gene, calpain–10, whose disruption contributes to diabetes, resulted from studies linking diabetes with genetic variations across the whole genome and then in a specific part of chromosome 2. The newly-discovered gene suggests that a previously unknown biochemical process is involved in the regulation of blood sugar levels. Diabetes is also one of the areas of focus for intramural research at NHGRI.

Investigators from Howard University and NHGRI are engaged in a project looking for genetic risk factors for diabetes in West Africans. This is part of a wider collaboration between the two institutions to study the genetic basis of diseases that disproportionately affect African-Americans. The diabetes study focuses on West Africans since they are thought to be the population from which modern African-Americans are largely descended, and the Africans are not exposed to the same dietary risk factors as Americans. Study recruitment centers were opened in Nigeria and Ghana; in the fall of 2000, researchers met their goal of recruiting 400 pairs of siblings affected with diabetes. Genetic typing of the collected tissue samples is in progress at NHGRI's Center for Inherited Disease Research in Baltimore to search for genetic variations that increase susceptibility to diabetes.

Meanwhile, other intramural investigators are part of a consortium where researchers pool a wide range of data about the genetic factors underlying diabetes. One of the studies, called FUSION (Finnish U.S. Investigation Of Non-insulin dependent diabetes mellitus) has collected DNA samples and clinical data from 5000 Finnish people who have diabetes; many of the individuals are related. A genome-wide search among these people for genes related to diabetes risk has so far identified two areas on chromosome 20 that are likely to contain crucial genes.

GENE EXPRESSION

The new-found abundance of genomic information and technology is propelling scientists out of the pattern of studying individual genes and into studying thousands at a time. Large-scale analyses of when genes are on or off (gene expression) can be used, for example, to study the molecular changes in tumor cells. This exciting new approach combines recombinant DNA and computer chip technologies to produce microarrays or DNA chips. Classifying cancer on a molecular level offers the possibility of more accurate and precise diagnosis and treatment. Intramural re-

searchers at NHGRI have used large-scale expression studies to discover genetic signatures that can distinguish the danger from different skin cancers and that can distinguish between hereditary and sporadic forms of breast cancer.

PROTEIN STRUCTURE, FUNCTION, AND INTERACTION

With a global view of human genes now possible, scientists are eager to obtain a similarly comprehensive view of human proteins, a field called proteomics in analogy to genomics. Researchers want to know the functions of proteins and how the proteins work together in cells. Only a subset of all possible proteins are present in any given cells at any given time. To study protein function on a wide scale, various groups of researchers plan to identify the locations of proteins, their levels in different cells, their structures, the interactions among different proteins, and how they are modified. NHGRI is contributing to this field by developing technologies for efficient, large-scale analyses, particularly for determining protein interactions and measuring protein abundance in different cells.

CENTERS OF EXCELLENCE IN GENOMIC SCIENCE

In fiscal year 2001, NHGRI will award the first grants under a new program to bring cross-disciplinary teams of researchers together with shared resources and a unified goal. The Centers of Excellence in Genomic Science are designed to develop new genomic approaches for analyzing the molecules of life systematically, to integrate technical developments into biomedical research, and to expand training opportunities. Additional centers will be funded in fiscal year 2002 to develop new ways of undertaking genome-wide analyses in areas like the regulation of gene expression, protein expression and interaction, human genetic variation, and the storage and analysis of the flood of new data. These centers are expected to be a source of creative approaches addressing previously unanticipated questions. As training centers, they will give high priority to the training of people from racial or ethnic minority groups, women, and people with disabilities.

PROMISE FOR NEW TREATMENTS AND PREVENTION

Genetic testing will become increasingly important for assessing individual risk of disease and prompting programs of prevention. An example of how this may work involves the disease hereditary hemochromatosis (HH), a disorder of iron metabolism affecting about one in 200 to 400 Americans. Those with the condition accumulate too much iron in their bodies, leading to problems like heart and liver disease and diabetes. The gene causing the condition has been identified, allowing early identification of those in whom HH may develop. Once people at risk are identified, they can easily be treated by periodically removing some blood.

Genetic testing is also being used to tailor medicines to fit individual genetic profiles, since drugs that are effective in some people are less effective in others and, in some, cause severe side effects. These differences in drug response are largely genetically determined. Customizing medicine to a patient's likely response is a promising new field known as pharmacogenomics. A recent publication in the journal *Hypertension* showed how pharmacogenomics applies to high blood pressure. Researchers found a variation in a particular gene that affects how patients respond to a commonly used high blood pressure drug, hydrochlorothiazide. Other recent studies reveal that doctors should avoid using high doses of a common chemotherapy treatment (6-mercaptopurine) in a small proportion of children with leukemia. Children with a particular form of a gene (TPMT) suffer serious, sometimes fatal, side effects from the drug.

Genomics is also fueling the development of new medicines. Several drugs now showing promising results in clinical trials grew out of genomics-related studies. One example is Glivec (previously called STI571), produced by Novartis for treating chronic myelogenous leukemia (CML). In CML, an abnormal gene fusion creates an abnormally activated protein. Novartis designed a small molecule that specifically inactivates the protein. In phase I clinical trials, this drug caused favorable responses in 53 of 54 patients, while side effects were minimal no matter how high the dosage. Meanwhile, Bayer and Millennium announced the development of another cancer drug born of genomics in January 2001. GlaxoSmithKline is testing a new genomics-derived heart disease drug that targets a protein involved in fat metabolism. Johnson & Johnson is testing a drug targeting a brain receptor involved with memory and attention. Human Genome Sciences has four clinical trials in progress to test gene-based drug candidates.

ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS

From its inception, NHGRI recognized its responsibility to address the broader implications of having access to genetic information and technology. Since 1991, it has committed 5 percent of its budget to studying the ethical, legal, and social implications (ELSI) of genome research. Study of human genetic variations raises many ELSI issues. The case of hemochromatosis brings up some of these issues. Given the devastating complications from HH and the simple treatment, some have proposed widespread genetic testing to find those predisposed to HH. But considerable uncertainty remains about how strong the link is between particular gene variants and the presence and severity of HH disease. In fiscal year 2000, NHGRI and the National Heart, Lung and Blood Institute began a 5-year, $30 million epidemiological study among 100,000 adults to gauge, among other things, the prevalence and the genetic and environmental causes of HH. NHGRI is funding an examination of the ethical, legal, and social issues related to implementing a widespread screening program. Information from the study should yield insights not only for HH but also for other treatable adult-onset genetic disorders.

Many ELSI issues raise policy implications; one is how to deal with potential employment discrimination. Two years ago, a Time/CNN poll showed that 95 percent of those polled thought employers should not have access to genetic information about employees without their permission. A recent case, involving the Burlington-Northern Santa Fe railroad, shows what can happen. In March 2000, BNSF added testing for a gene (PMP22), which may be the cause of carpal tunnel syndrome in a small population of people with the disorder, to the medical evaluation of employees who file workers' compensation claims for carpal tunnel syndrome, to test whether the carpal tunnel syndrome was "work-related." Employees were not told that their blood would be submitted for a genetic test. In February, the Equal Employment Opportunity Commission and the workers' union filed suit against BNSF. The company has now stopped genetic testing and agreed to seek approval from the union before doing any genetic testing in the future. While this is a happy ending for this particular case, comprehensive public policy will be required as genetic tools become more widespread. The ELSI program at NHGRI will continue to form policy recommendations that balance the need to protect individuals with the needs of the research community and the healthcare industry.

Finally, as part of its mission of education, NHGRI produced a free educational kit, "The Human Genome Project: Exploring our Molecular Selves," that was released when the human sequence analysis was published in February. The kit includes a multimedia CD–ROM, an award-winning video documentary, and an informational brochure. The kit is designed to give science teachers and classrooms, particularly at the high school level, better access to the latest information about genome science and its implications, but it is expected to be used more broadly, by college students, voluntary health organizations, and the general public. Backing from Howard Hughes Medical Institute and Pharmaceutical Research and Manufacturers of America (PhRMA) insured that the kit, sponsored by the NIH and DOE, would be available for free. Nearly 40,000 kits have been requested in just two months.

I am pleased to present the President's budget request for the National Human Genome Research Institute (NHGRI) for fiscal year 2002, a sum of $426,739,000, which reflects an increase of $44,627,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

PREPARED STATEMENT OF DONNA J. DEAN, PH.D., ACTING DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) for fiscal year 2002, a sum of $40,206,000, which reflects an increase of $38,231,000 over the comparable fiscal year 2001 appropriation.

At the outset, I should note that the NIBIB is the newest of NIH's Institutes, having been established on December 29, 2000 by Public Law 106–580, the National Institute of Biomedical Imaging and Bioengineering Establishment Act of 2000. I am excited by the challenge afforded me to help guide the formation and early development of this newest member of the NIH family. In the past four months, we

have begun to consider the new opportunities in biomedical research that NIBIB can foster and have articulated the basic principles upon which we will build NIBIB. It is my privilege to share with you the philosophy under which the NIBIB will operate and our initial steps toward fulfilling the promises embodied in the legislation.

A MISSION OF PROMISE

The foundations of tomorrow's medicine will continue to be built on the emergence of discoveries in basic science and development of new technologies. The mission of NIBIB is to apply the principles of engineering and imaging science to biological systems. Advances in the imaging sciences could change the face of medicine, making it possible to non-invasively detect, diagnose, and guide therapy for a large variety of diseases. Bioengineering is unique in its ability to integrate principles from diverse fields, and to cross the boundaries of academia, science, medicine and industry. The focus of NIBIB will be on developing fundamental new knowledge, creating potent new technologies, and nurturing researchers to be able to fully integrate the quantitative sciences with biomedical research.

Bioengineering and the imaging sciences are rooted in physics, mathematics, chemistry, materials sciences, computer sciences and the life sciences. The application of these systematic, quantitative, and integrative ways of thinking about and approaching the solutions to problems will be important to biology and medical research. The biological scientist often seeks to answer such questions as "Why do things work the way they do?" and "How do these organisms function?" The engineer or imaging scientist may ask questions such as "How can I create something that has never existed before?" or "Can I develop a solution to this seemingly intractable problem?" The excitement of bringing together new research constituencies, perspectives and collaborations is a particular challenge and a unique opportunity for NIBIB.

In support of its mission, NIBIB will support an integrated and coordinated program of research and research training that can be applied to a broad spectrum of biological processes, disorders and diseases and across multiple organ systems. Strong coordination will be fostered with biomedical imaging and bioengineering programs of other NIH Institutes and other agencies so as to support imaging and engineering research with potential medical applications. These partnerships will facilitate the translation of fundamental discoveries into research on and applications for specific diseases, disorders, or biological processes.

Most of the revolutionary changes in biology and medicine over the past decades were rooted in fundamental discoveries in many different fields, such as the role of nuclear physics in producing radioisotopes essential for much of modern medical science. Engineering and physics were central in the development of key tools of common clinical practice today—x-rays, computed tomography (CT) scanning, fiber optic viewing, laser surgery, echocardiography and fetal sonograms. Materials science is helping to develop new joints, heart valves, and other tissue mimetics. Understanding of nuclear magnetic resonance and positron emissions was required for the imaging study of the location and timing of brain activities that accompany thought, motion, sensation, speech, or drug use. Now, as never before, the boundaries are disappearing between biology and biomedical engineering, resulting in increasing and expanding opportunities for new scientific and technological approaches and new clinical tools and devices.

IDENTIFYING PRODUCTIVE NEW RESEARCH DIRECTIONS

The creation of programs on the cutting edge of research and innovation will pose complex scientific challenges and require multidisciplinary strategies. A critical component of the Institute's inaugural year will be the formulation of a strategic plan for research in biomedical imaging and bioengineering. This activity will be undertaken in cooperation with the NIBIB Advisory Council and with broad representation from the research community. An outstanding opportunity exists to recruit scientists, engineers and physicians to new areas of biomedical research through the research programs to be developed by NIBIB.

NIH has provided important groundwork that is of invaluable aid to NIBIB as it formulates an emerging research agenda. Key areas of future research in biomedical imaging and bioengineering have been highlighted by four symposia sponsored by NIH in the last three and a half years. At these meetings, the country's leading engineers, scientists, and physician-scientists have addressed areas of opportunity in bioengineering, biomedical imaging, nanotechnology, and reparative medicine or tissue engineering.

Since one of NIH's highest priorities is the funding of medical research through research project grants, NIBIB will emphasize this mechanism to promote funda-

mental discoveries, design and development, and translation of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science, and computer sciences. The research supported by NIBIB will be multidisciplinary in nature and strongly synergistic with NIH's other research Institutes and Centers. NIBIB will expand the principles embodied in NIH's development of the Bioengineering Research Partnerships and Bioengineering Research Grants—that creation, development, and implementation of technology are worthy goals.

DEVELOPING A NEW GENERATION OF RESEARCHERS

NIBIB will meet the challenge of training a new generation of investigators with a vision transcending narrow disciplines. Training and career development programs will be central to NIBIB's approach to its mission. Increasing the pool of individuals uniquely positioned to bring innovative concepts and approaches to research in biomedicine and health will benefit the entire NIH. The changing nature of biomedical research in the future points strongly toward the need to train our young physicians and engineers to succeed in facets of biomedical research that are not yet imagined.

CONCLUSION

NIBIB's leadership in developing crosscutting research and training in biomedical imaging and bioengineering will be fostered by strong partnerships and collaborations with other Institutes and Centers of NIH, all with the ultimate goal of improvement in human health and well-being. NIBIB is poised to identify challenges in biomedical research that can benefit from bioengineering approaches, facilitate interinstitute cooperation, and promote transdisciplinary training. NIBIB will strengthen and complement, not substitute for or subtract from, the already robust research programs of NIH's other Institutes and Centers. We look forward to the challenges of the next year in creating a new and enriched focus at NIH for bioengineering and imaging sciences.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The budget request for fiscal year 2002 for the National Institute of Biomedical Imaging and Bioengineering is $40.2 million.

Mr. Chairman, I will be happy to answer your questions.

PREPARED STATEMENT OF ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Allergy and Infectious Diseases (NIAID) for fiscal year (FY) 2002. Including the estimated allocation for the acquired immunodeficiency syndrome (AIDS) of $1,192,855,000, total support requested for NIAID is $2,355,325,000, an increase of $292,317,000 over the fiscal year 2001 appropriation. The portion of the budget not related to AIDS is $1,162,470,000, which reflects an increase of $162,054,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

OVERVIEW OF NIAID

NIAID, the third largest NIH Institute, supports and conducts research to better understand, treat and prevent infectious, immunologic, and allergic diseases. The scope of the NIAID research portfolio is expanding continually in response to new challenges, such as the emergence of AIDS and other newly recognized diseases, and because of scientific opportunities facilitated by new technologies and progress in the core NIAID scientific disciplines of microbiology, immunology, and infectious diseases. Advances in these key fields, including progress in relatively new areas such as pathogen and human genomics, are driving the development of new treatments,

vaccines, diagnostic tests, and technologies that improve the health of people in the United States and around the world.

In order to meet the many health challenges of the new millennium and take advantage of unprecedented scientific opportunities, the Institute has developed a strategic research plan for the 21st century centered around four major areas: (1) Global health and emerging infectious diseases; (2) HIV/AIDS; (3) Immune-mediated diseases, including allergy and asthma; and (4) Vaccines. The complete NIAID Strategic Plan is available on the World Wide Web at *http://www.niaid.nih.gov/strategicplan2000.*

GLOBAL HEALTH AND EMERGING INFECTIOUS DISEASES

NIAID has a long history of supporting research into diseases that transcend national boundaries and hence fall under the rubric of global health. Examples of such diseases include newly recognized conditions such as AIDS and liver disease due to hepatitis C virus; diseases that have spread to new geographical settings, such as West Nile fever and dengue; and resurgent endemic diseases such as malaria and tuberculosis, which are increasingly resistant to antimicrobial drugs. In addition, we now face the specter of a new kind of emerging disease: one deliberately spread by bioterrorists. These emerging and re-emerging diseases are superimposed on other major health problems such as acute respiratory infections, diarrheal diseases, and measles, which remain leading causes of illness and death worldwide.

To mitigate the burden of these diseases, NIAID supports numerous laboratory, field-based, and clinical research projects related to global health, both domestically and abroad. Among many projects, NIAID-supported studies on malaria in Mali, pneumococcal disease in the Gambia, tropical diseases in the International Centers for Tropical Disease Research, and HIV prevention through the HIV Prevention Trials Network, have achieved important results through coordinated partnerships with local governments and other agencies and organizations. Building on NIAID's longstanding commitment in global health, the Institute this month released a new "Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis", which outlines NIAID goals and plans for fighting infectious diseases by building sustained research capability domestically and internationally and enhancing international partnerships.

Many of the challenges posed by emerging infectious diseases lend themselves to research in a relatively new field: genomics. The sequencing of the entire human genome and the anticipated assignment, over the next few years, of function to the estimated 30,000 to 60,000 human genes will have an enormous impact on all of medicine, including our understanding of the host response to microbial pathogens. In addition, the genomic sequencing of microbial pathogens will be a critical component of 21st century strategies for the development of diagnostics, therapeutics, and vaccines for infectious diseases. NIAID has funded projects to sequence the genomes of more than 50 medically important pathogens, a dozen of which have been completed. These include the bacteria that cause tuberculosis, gonorrhea, chlamydia, and cholera, as well as individual chromosomes of the malaria parasite, *Plasmodium falciparum.* Most recently, investigators have reported the complete genomic sequence of *Streptococcus pyogenes,* a bacterium that causes diseases ranging from strep throat to the flesh eating disease known as necrotizing fasciitis, as well as that of *Escherichia coli* O157:H7, a worldwide public health threat that has triggered scores of recent outbreaks of hemorrhagic colitis and numerous fatalities from kidney failure. In the interest of global scientific cooperation, NIAID-supported scientists deposit pathogen sequence data in specialized public databases such as GenBank, where investigators around the world can access it via the World Wide Web.

HIV/AIDS

AIDS, caused by the human immunodeficiency virus (HIV), has claimed 22 million lives since the disease was recognized 20 years ago. More than 36 million people are living with HIV infection, including approximately 800,000 to 900,000 individuals in the United States. In the United States and other western countries, potent combinations of anti-HIV drugs (highly active antiretroviral therapy or "HAART") have dramatically reduced the numbers of new AIDS cases and AIDS deaths. NIAID-supported investigators conducted research that was pivotal to the development of these drugs, and have helped define how best to use these medications in different clinical settings. Ongoing research promises to yield a new generation of drugs that may improve upon existing medications in terms of cost, effectiveness, and tolerability.

Until recently, expensive HAART regimens were considered to be beyond the reach of developing countries, where 95 percent of the world's HIV-infected people live. Now, with dramatic reductions in the price of antiretroviral drugs for developing nations and the commitment of world leaders to address the AIDS problem in southern Africa and other poor regions of the world, AIDS therapies will begin to reach more of the people in poor countries who could benefit from them. Building on the research infrastructure that NIAID has helped establish in Africa and elsewhere in the developing world, we intend to work with our international colleagues to link the provision of anti-HIV therapy to ongoing efforts in prevention research, with the goal of facilitating a comprehensive approach to the AIDS pandemic in poor countries. Two recently launched NIAID programs will be key to this effort: the HIV Prevention Trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN), which have research sites in the United States, Latin America, Europe, Africa, Asia and the Caribbean.

The HPTN focuses on several key areas of prevention research, including behavioral modification, interventions to prevent mother-to infant transmission of HIV, and the development of topically applied microbicides that women could use to protect themselves against HIV and other sexually transmitted pathogens. The HVTN will conduct all phases of clinical vaccine trials, from evaluating candidate vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. In pre-clinical and clinical studies, NIAID-supported investigators are testing a diverse range of vaccine strategies, several of which in recent months have shown remarkable promise in tests in non-human primates. The best candidates will be moved rapidly into HVTN trials. We remain optimistic that a safe and effective vaccine can be found that will prevent HIV infection and/or slow the progression of disease in people who are already infected with the virus.

IMMUNE-MEDIATED DISEASES

Immunologic diseases cause a considerable burden of illness and death and lead to medical costs that exceed $100 billion annually in the United States. Many immune-mediated diseases disproportionately affect women and members of minority groups. Autoimmune diseases such as type-one diabetes, rheumatoid arthritis, systemic lupus erythematosus, and multiple sclerosis collectively afflict approximately five per cent of the U.S. population. More than seven percent of American children are asthmatic, with poor children in inner city areas disproportionately affected by this serious disease. In addition, immune-mediated graft rejection remains a significant obstacle to the successful transplantation of potentially life-saving organs.

NIAID-funded research in basic and clinical immunology has led to many promising approaches for treating individuals with these and other immunologic conditions. For example, researchers are developing novel ways of selectively blocking inappropriate or destructive immune responses, while leaving protective immune responses intact. This approach, called tolerance induction, holds great promise for the treatment of many immune-mediated conditions, including autoimmune diseases and asthma and allergic diseases. The induction of tolerance to transplanted organs or tissues ultimately may allow transplant patients to forego long-term regimens of broadly immunosuppressive drugs. These drug regimens are costly and dampen not only destructive immune responses, but protective ones as well, thereby increasing a patient's risk of malignancies and infections. Among many projects in the field of immune tolerance, the Institute established the Immune Tolerance Network (ITN), an international consortium of more than 70 research groups. The ITN is implementing clinical trials in four areas: transplantation of islets (the insulin-producing cells of the pancreas), kidney transplantation, autoimmune diseases, and asthma and allergic diseases. The first ITN trial is testing a new approach to transplanting islets in diabetics who are unable to properly control their blood sugar levels. This international study builds on groundbreaking research at the University of Alberta that has resulted in long-term insulin independence for nearly 20 patients.

For more than a decade, NIAID has worked to reduce the burden of asthma, particularly among inner-city children. Investigators of NIAID's National Cooperative Inner-City Asthma Study developed a successful behavioral and educational intervention that substantially reduced asthma severity in these pediatric populations. Building on this success, NIAID and the Centers for Disease Control and Prevention (CDC) are collaborating to implement this proven intervention in a new four-year program that will reach 6,000 children in 23 inner-city health care delivery sites throughout the U.S. An ongoing NIAID intervention study, involving approximately 1,000 children nationwide, is testing the effectiveness of environmental control measures and physician education in reducing the burden of asthma. Preliminary results are showing substantial reductions in asthma symptoms and emergency

room visits. In both of these studies, recruitment has exceeded the targeted levels and retention of patients has been extraordinarily high compared to other studies of other inner-city pediatric populations. Because of these successes, NIAID-supported inner-city asthma programs are now recognized as models for conducting clinical research in the inner city and have attracted partners in the public and private sectors to collaborate with NIH-funded researchers. These collaborations promise to bring new asthma interventions to minority populations whose access to such therapies might otherwise be diminished or delayed.

VACCINE DEVELOPMENT

Vaccination has been recognized as the greatest public health achievement of the 20th century, and vaccine research has long been a cornerstone of the NIAID research portfolio. NIAID-supported research has led to the development of many new and improved vaccines now widely used, such as those against Haemophilus influenzae type b, pertussis, chickenpox, pneumococcal disease, and hepatitis A and B. The rapidly evolving science base in pathogen genomics, immunology and microbiology will facilitate further progress in developing new and improved vaccines. In particular, the availability of the genomic sequences of major microbial pathogens will facilitate the identification of a wide array of new antigens for vaccines. Because many pathogens gain entry to the body via mucosal sites, NIAID-supported scientists are developing new vaccines that target mucosal surfaces such as those in the intestine or respiratory tract. Vaccines that are easy to administer—orally, nasally, or trans-dermally—will have great utility in resource-poor setting and for mass immunization programs. In addition to the development of vaccines against classic infectious diseases, NIAID is working to develop vaccines against chronic diseases with infectious origins, as well as potential agents of bioterrorism, and autoimmune diseases and other immune-mediated conditions.

CONCLUSION

In the 21st century, NIAID is poised to exploit unprecedented scientific opportunities in immunology, microbiology and infectious diseases. As has been the case for more than 50 years, a commitment to the best possible research—basic science as well as clinical trials—will drive our efforts to improve health in this country and abroad. With a strong research base, the commitment of talented investigators, and the availability of powerful new research tools, we are confident that our initiatives will help solve seemingly intractable clinical and public health problems and improve global health in the 21st century.

PREPARED STATEMENT OF STEPHEN A. FICCA, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the Buildings and Facilities (B&F) Program for fiscal year 2002, a sum of $306,600,000, which reflects an increase of $152,810,000 over the comparable fiscal year 2001 appropriation.

ROLE IN THE RESEARCH MISSION

The annual Buildings and Facilities (B&F) Appropriation is the only means by which the public supports the crucial physical infrastructure required to carry out the in-house component of the biomedical research mission of the National Institutes of Health (NIH). As approaches to basic and clinical research evolve, the demands for, and on, research facilities change as well. Properly planned and equipped, safe, and flexible research facilities are important resources in the formula for achieving the next scientific advance or biomedical breakthrough.

The fiscal year 2002 Buildings and Facilities budget request is the product of a deliberate, corporate facilities planning process that addresses the NIH's immediate and longer range facility requirements of the entire agency. The goal of the planning process is to optimally meet the changing facility needs of the NIH research programs in the Washington, D.C., region and across the NIH field stations with a mix of owned and leased facilities.

The B&F appropriation funds a continuing, multi-year program that supports NIH facilities throughout their life-cycles. The construction program supported by the proposed fiscal year 2002 request strikes a balance among three critical facility priorities: the creation of new facilities for new and expanding scientific opportunities, the upgrading of existing facilities to keep pace with the changing requirements of ongoing NIH programs, and the responsible stewardship of the entire NIH

real estate portfolio. The specific projects included in the proposed fiscal year 2002 request are on the critical path of a larger rolling five-year plan. Thus, the investments in fiscal year 2002 are predicated on previous investments and the timely investment in the future. For example, the Building 6 modernization is the last project in a series of projects that began in the 1980's to renovate the original NIH research buildings. The upgrade of the mechanical system at the National Institute of Environmental Health Sciences is the first phase of a two-phase modernization of the mechanical and electrical systems at the Research Triangle, North Carolina, field station.

Safe, modern facilities, including the appropriate building systems and utility infrastructure, are a basic requirement to effectively carry out NIH's intramural research program, as well as stewardship of the extramural research programs. For the intramural research program, they are necessary to enable NIH's expansion into new areas of investigation, to house an expanding cadre of researchers and trainees, to attract the best and the brightest investigators, and to help retain staff who are being courted by the burgeoning biomedical industry.

The B&F request for each budget year strives to optimize the distribution of resources among the programs activities so that, year to year, the continuity of the individual projects and the B&F Program as a whole is maintained.. Within this balanced mix of new construction, essential safety and health improvements, repair and improvement projects, renovations, and equipment and system upgrades, three projects are particularly important to the NIH's research plans: the John Edward Porter Neuroscience Research Center, the Central Vivarium/Animal Research Center, and the Building 10 Revitalization Program.

The John Edward Porter Neuroscience Research Center will enable the integration of the neuroscience research community at the NIH. The Center is conceived as a place where the best and brightest scientists from many disciplines will collaborate in state-of-the-art laboratories to develop and evaluate therapies for some of the most complex problems in biomedical research. The Center will house researchers from nine institutes and multiple disciplines under one roof. It will be designed to support high priority research initiatives using innovative strategies in cell biology, neuroimaging and bio-informatics to better describe the link between biochemistry and behavior, to elucidate the nerve cell degenerative processes, and to explore other lines of inquiry that are emerging from the genetic mapping of the brain.

New facilities are needed to support this vision because nearly all of the space that houses NIH neuroscience research is substandard. Current facilities for cellular and molecular neuroscience on campus are inadequate to meet the challenges of high-quality, high-risk research projects.

The Central Vivarium/Animal Research Center is a vital part of the NIH research infrastructure. Animal models continue to be one of the most valuable means of elucidating basic biology and more complex mechanisms of disease. The multi-level facility will include state-of-the-art animal holding, receiving and quarantine areas; procedures and specialized laboratories and administrative support spaces. It will replace facilities that are crowded and only marginally suitable to the support of many of the most promising animal models with AAALAC-compliant facilities specifically designed to humanely house non-mammalian species, genetically altered rodents, chimeras, and non-human primates.

The soon to be completed Mark O. Hatfield Clinical Research Center (CRC) will be one major milestone in a continuing effort to maintain the physical research infrastructure of the Agency. It will house state-of-the-art patient-related research and laboratory research facilities for the clinical programs. The Building 10 Revitalization Program is the next phase in the renaissance of the critical infrastructure for the clinical research program at the NIH described in the 1994 Marks-Cassell report. The Building 10 Revitalization Program is a multi-phased approach that will renovate and renew the portions of the clinical program that remain in Building 10 when the CRC is occupied. The purpose of this effort when completed, is to accommodate all the research programs in the entire Clinical Center Complex in modern, safe, state-of-the-art hospital, research and support facilities. The fiscal year 2002 request for the Building 10 Revitalization Program consists of three program activities. The Building 10 Transition Program includes projects required to sustain functionality between the old and new buildings. The Building 10 Interim Renovation provides the necessary space and infrastructure reconfiguration to allow continued operation of the building during the phased renewal. Finally, the Phase I Renovation of Building 10 includes the renovation of the central core as clinical research space and the renovation and interconnections of the hospital and facilities support systems between the buildings.

FISCAL YEAR 2002 BUDGET SUMMARY

As in prior and future years, the funding request for fiscal year 2002 is a part of a long range plan. The fiscal year 2002 request for Buildings and Facilities is $306.6 million. The B&F request totals $105.1 million for new construction composed of $26 million for the continued construction of the John E. Porter Neuroscience Research Center; $10.6 million to fund the design of the second phase of the Center; $53 million to complete the design and start the construction of the Central Vivarium/Animal Research Center; $14 million to design and construct the Northwest Parking Facility; and $1.5 million to initiate the Concept Development Studies program. There is a total of $99.9 million for essential safety and health improvements composed of a combined sum of $36 million to begin the Building 10 Revitalization Program through a plan of Interim Renovations to provide temporary space, and the initiation of the Phase I Renovation; $19.7 million in funding to complete the modernization of Building 6; $10 million for the continued support of the rehabilitation of animal research facilities; $10 million for the continuing upgrade of fire and life safety deficiencies of NIH buildings; $3 million for the phased removal of asbestos from NIH buildings; $1 million to systematically remove existing barriers, to persons with disabilities, from the interior of NIH buildings; $2 million to address indoor air quality concerns and requirements at NIH facilities; $12.2 million as a second phase to improve and upgrade utilities at the NIH Animal Center; $7.2 million to replace the mechanical systems in Building 6B; $5 million to initiate a four-year program to upgrade elevators in various buildings on the Bethesda and satellite campuses; and $1 million to allow for environmental remediation activities at NIH sites. In addition, the fiscal year 2002 request includes $65 million for the continuing program of repairs, improvements, and maintenance that is the core of the B&F program. The fiscal year 2002 request also includes: $14.1 million for the Building 10 transition program; $3.6 million to upgrade mechanical systems at NIEHS; and $11.7 million to complete the construction and installation of Boiler 7 on the NIH campus in Bethesda.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF ENOCH GORDIS, M.D. DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

I am pleased to present the President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for fiscal year 2002, a sum of $381,966,000, which reflects an increase of $41,288,000 over the comparable fiscal year 2001 appropriation.

Alcohol-use disorders impose an enormous toll on society. They cost the Nation $185 billion each year, one-and-one-half times as much as all illegal drugs combined,[1] and 100,000 people die of alcohol-related causes annually.[2] These figures reflect only the toll imposed by the 14 million adult Americans who are physically dependent on alcohol or who abuse it to the point that it disrupts their lives, but who aren't dependent on it.[2] Still others add to the burden when they occasionally drink to excess and, temporarily impaired, injure or kill themselves or others, or damage property.

ALCOHOL IS UNIQUE

Among substances of abuse, alcohol is unique in a number of ways. It is a toxin that can cause damage to any tissue in the body. The resulting diseases range from certain kinds of cancer to liver and heart disease. Alcohol also is unique in the pervasiveness of its actions in the nervous system, the body's command center, through which alcohol exerts its behavioral effects. Rather than affecting only one or a few neurotransmitter systems—that is, the crucial chemical systems through which components of the nervous system communicate with each other and with the out-

[1] Updated figures from Lewin Group, 1998.
[2] IAAA epidemiology data.

side world—alcohol affects every neurotransmitter system that we have studied to date.

Alcohol also affects parts of the membrane that surrounds nerve cells, the "point of entry" for substances of abuse, that illegal drugs do not appear to affect. These factors greatly complicate the search for alcohol's sites of action in the nervous system.

Policy and legal issues—as well as social ones—also confer unique status on alcohol. For example, alcohol raises the need for laws on minimum drinking age, maximum allowable blood levels for driving, and zoning and licensing. Alcohol raises the issue of revenue, since it is associated with a tax-paying industry, an industry that promotes alcohol's use through advertising. Alcohol also raises the issue of warning labels on beverage containers.

Another of the ways in which alcohol is unique among substances of abuse is that it is a food, since it has caloric value. The brain regulates appetite for food through neuropeptides, pieces of protein. Evidence suggests that, to some extent, craving for alcohol might be driven by the same or similar biochemical pathways that drive appetite for food.

NEUROSCIENCE HOLDS THE KEY TO BEHAVIORS OF ALCOHOLISM

Some people can drink lightly and occasionally and never develop problems with alcohol, while at the opposite end of the spectrum of alcohol use, it takes over people's lives and they become physically dependent on it. Between these two scenarios lie varying degrees of use and misuse. What accounts for these differences in how people respond to alcohol, differences that may decide whether or not it destroys their lives?

Environmental factors—family and peers, for example—play a role, but variations in our nervous systems constitute the largest part of the differences in our behaviors toward alcohol. It is here that alcohol affects a multitude of biologic events that determine our propensity for drinking and our vulnerability to the biologic process of becoming dependent on alcohol. Before we have taken our first drink, the genetic and molecular make-up of our brains influences, largely, how we will respond to alcohol once we are exposed to it.

Substances ultimately stimulate the same major reward pathways of the brain. However, various substances first stimulate other, different biochemical pathways before they "light up" these major reward pathways. Thus, substances differ in the mechanisms, and in the complexity of those mechanisms, that lead to reward. The routes of alcohol's actions appear to be particularly pervasive.

Alcohol's effects on the nervous system vary throughout the life-span, from the uniquely devastating damage it causes in the fetus, to disruptions in development of the adolescent brain, to the patterns of biologic risk and damage we see in adults. Among substances of abuse, alcohol is, by far, the greatest inducer of neurologic and other birth defects.

THE ANSWERS WE SEEK

Alcohol research seeks to answer these questions: What are the genetic and molecular factors in the brain that determine these differences in how we respond to alcohol? How does alcohol change "hardwired" functions of the brain to cause physical dependence? What role do environmental factors play in alcohol dependence? Can we design interventions that disrupt these biologic and environmental pathways, to prevent alcohol's harmful effects? In each of these areas and others, we are making advances.

ADVANCES IN ALCOHOL RESEARCH

Our neuroscience research is aimed at understanding how a multitude of biologic factors combine to form neural circuits—networks of nerve cells and the thousands of biochemical activities associated with them—that mediate alcohol's actions. Our research links these biologic events with alcohol-related behaviors and the impact that environmental influences have on them.

We have made major advances. For example, we are closing in on specific regions of the nerve-cell membrane where alcohol initiates its effects. This kind of information raises possibilities for design of medications that block such sites. Among our priorities is to develop medications that will be effective in a wider range of people with alcoholism than are current medications. For example, our research on a nervous-system protein (protein kinase C_ε) has resulted in a treatment-development project by a pharmaceutical company.

Animal and clinical neuroscience findings are guiding our efforts to develop medications for alcoholism that target optimal molecular sites in the nervous system. For

example, naltrexone, approved for alcoholism treatment by the FDA in recent years, targets a specific neurotransmitter system—the opioid system—and is among the more promising pharmaceuticals currently in use.

In the genetics arena, we have found several chromosomal regions likely to contain genes that influence our susceptibility to alcoholism. Our challenge is to pinpoint their exact locations. Because alcoholism is a genetically complex disease—that is, multiple genes influence it—the search for these genes is complex. Our Collaborative Study on the Genetics of Alcoholism addresses this issue and has generated data used by other disciplines with an interest in addiction and by the scientific community.

We are conducting studies in rodents in which we either "knock out" or enhance the activities of genes, to see how this affects behaviors toward alcohol. These studies are providing us with information about biologic mechanisms that contribute to the risk of becoming alcoholic. Another genetics technology (microarray technology) is telling us which genes appear to be active under various scenarios of alcohol use. This technology enables us to scan much of the human genome for changes in gene activity that occur with physiologic states associated with alcohol; for example, alcohol dependence.

Our research is revealing mechanisms that mediate alcohol's damage to the fetus and evidence that adolescent brains are vulnerable to alcohol-induced damage. New NIAAA research also links stress-induced hormonal changes in infancy with risk of alcohol problems later in life.

Ultimately, these kinds of studies can guide us to points for pharmaceutical intervention in the biochemical pathways through which alcohol exerts its effects. We are capturing the potential of neuroscience through collaboration. Alcohol research covers the spectrum from genetics to behavior and all of the intricate molecular biology that lies between. However, so many areas of expertise now exist in neuroscience that integrating research and results relevant to alcohol investigations is difficult. To ensure that we do not miss opportunities, our Integrative Neuroscience Initiative on Alcoholism is encouraging investigators from different fields to integrate their work and their findings. We expect this major initiative to speed the translation of new findings into clinically useful data.

BEYOND BASIC SCIENCE

Our research on social and policy issues extend far beyond questions of legislation. For example, drinking among college students is a complex problem entrenched in campuses and communities. Evidence suggests that intentional and unintentional injury, including death, associated with this problem is much greater than previously suspected. Our investigators are pursuing estimates of alcohol-related death rates among this vulnerable age group, and avenues for prevention. Minority groups provide another example. Certain minority groups appear to respond differently to alcohol, physically and behaviorally, than does the general population. Our epidemiology research identifies these kinds of public-health issues, and these findings lead to basic and behavioral research that investigates root causes and potential interventions.

We bring our research findings to the public in a variety of ways. Our Research to Practice Initiative is an excellent example. In collaboration with the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, we arrange with States to meet with treatment providers and administrators. After exchanging information about our current research findings and the practitioners' obstacles to providing treatment, we place experts in temporary residencies in treatment programs that have identified specific areas of need.

We bring our findings to the public via Alcohol Screening Day, a nationwide event that enables people to receive free screening for alcohol problems and, if needed, referrals. Last year, almost 1,500 sites across the country participated, more than 370 of them college campuses. We also are dealing with the difficult issue of college drinking through our Advisory Council's Subcommittee on College Drinking. The Subcommittee, a collaboration between researchers and college presidents, has been meeting since 1998 and has commissioned major papers and panel reports to guide efforts to prevent drinking by students.

Drinking by youth is not limited to college students, and we are reaching children and adolescents through our Governors' Spouses Initiative. Spouses of governors in 28 States have joined this project to reduce drinking by young people; a crucial effort, given our findings that early initiation of drinking portends dramatically higher risk of alcoholism later in life. These efforts will be accompanied by public service announcements on underage drinking.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report, which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

PREPARED STATEMENT OF DR. PATRICIA A. GRADY, DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Nursing Research (NINR) for fiscal year 2002, a sum of $117,686,000, which reflects an increase of $12,508,000 over the comparable fiscal year 2001 appropriation.

This year, as NINR celebrates its 15th anniversary, it is encouraging to reflect on the progress made so far. Nursing research on a broad range of issues has been stimulated, developed, funded, published, and integrated into practice, where patients and the public are already reaping the benefits of improved health care. Studies include improving management of symptoms and quality of life for the increasing population of patients with longstanding chronic illnesses; smoothing the transition of advanced technologies into people's lives, such as genetic screening and telehealth; reducing health disparities among minorities and those without adequate access to the healthcare system; and improving care at the end of life. Yet nursing research is a young science. It must continue to grow to help meet urgent national health needs, expectations of our nation's people, and requirements of 2.7 million registered nurses for well-tested, effective interventions. NINR research is central in supplying empirical evidence that expands the scientific base for care affecting people's physical, psychosocial, and cultural needs.

TRANSLATING RESEARCH FINDINGS INTO PRACTICE AT THE COMMUNITY LEVEL

Let me illustrate how nursing research can influence public and private organizations at the community level—and in so doing, help eliminate health disparities. NINR study findings addressed an important health issue—low birthweight and preterm births—and supported research that promoted lower incidence while decreasing costs to the healthcare system. According to the National Center for Health Statistics, the United States is a disappointing 26th among industrialized nations in the number of babies per 1000 dying before their first birthday. The national rate is over 7 deaths per thousand. For African-Americans it is over 14 per thousand. In North Carolina, where the study took place, investigators targeted low-income African American pregnant women and Caucasian women at particular risk for low birthweight, including pregnant teens. This five-year project involved a home visit followed by low-cost, low-tech phone calls by registered nurses to monitor health and address problems of the women. Results showed that the low birthweight rate for the treatment group was 10.9 percent, compared with 14 percent for controls. For African Americans 19 years and older, the results were even more pronounced—11 percent in the treatment group versus 17 percent for controls. For this group, cost savings to the hospital were $277 per pregnancy. Extended savings also resulted from a reduction in long-term problems related to low-birthweight.

Investigators expanded the intervention to four programs that included Hispanics, African-Americans and Caucasians—three programs focusing on low-income women and one on women of all income levels nationwide. The results equaled or bettered the original study findings. All four programs are continuing today without Federal research funding—having been adopted by private sector organizations, including a national HMO.

IMPROVING DAILY LIVING FOR ALZHEIMER'S DISEASE PATIENTS

This anniversary year presents the opportunity to recognize some notable nursing science advances. For example, with respect to Alzheimer's disease patients, an important goal is preserving their functional capacity as long as possible so that they can bathe, dress and feed themselves. Researchers studied nursing home residents with Alzheimer's disease—the most disabled group in these establishments. Their disabilities were found to be caused by cognitive deficits, but also by the staff's inability to encourage independence. This can cause disability beyond what can be expected of cognitive impairment alone. The study involved nursing home staff instituting one-to-one interventions to improve the residents' abilities to bathe and dress.

First, the residents were examined to determine which skills they retained. Then the physical and social environment was restructured to reactivate those skills. Findings indicate that the intervention improved residents' bathing and particularly dressing capabilities, and disruptive behaviors were reduced. Improvements were realized within five days' time and were maintained by the end of three weeks. To achieve this, however, staff time with each resident increased. Investigators hypothesize that the amount of time can be reduced if the goal is to maintain the residents' skill levels, rather than to raise them.

END-OF-LIFE/PALLIATIVE CARE RESEARCH

Another issue predominantly affecting seniors, but also affecting people of all ages, is how to retain quality of living during life's final phase. NINR has a special interest in this area and is the Institute that coordinates end-of-life research at the NIH. A major issue is that, while capable of enhancing life, technologies and treatments can also involve burdensome procedures that may be futile and prolong discomfort and pain. The decision whether or not to withdraw life support, usually made by family members or friends on behalf of the dying patient, is a difficult decision to make. NINR researchers measured family member stress levels and found them to be twice as high as those due to other serious crises, such as construction disasters, or losing a home to fire. This study is one of the first to show that existence of an advance directive eases stress on the family when life-sustaining treatment is withdrawn. When an advance directive existed to guide decisions, the families were better able to focus on patients' quality of life and less likely to choose prolonging life at all costs.

FACTORS INFLUENCING OBESITY IN ADOLESCENTS

Obesity can decrease quality of life and shorten life span. According to the Centers for Disease Control and Prevention, 13 percent of children and 14 percent of adolescents are overweight, continuing the pattern of the past two decades. These young people are at risk for cardiovascular disease later in life. In a study of 2000 adolescents, a nurse investigator found that for both males and females, the influence on obesity of ethnicity and socioeconomic status was greater than the influence of watching TV or playing video games. African-American teens and low-income female teens were at special risk, which suggests where the emphases of prevention programs should be placed. The study also indicated that participation in high-intensity exercises, such as basketball or swimming, may protect boys against obesity. School physical education and community recreation programs that feature high-intensity physical activities could help lower the obesity rate. Further research is needed, however, before programs can be developed for girls.

NEW AND EXPANDED INITIATIVES

Turning to the immediate future, next year NINR plans an increased emphasis on chronic illness. The rise in chronic illness creates an escalating demand for strategies that enable people to live as normal lives as possible, even while they are dealing with chronic illness. Another key factor is caregiving for family members at home. This practice is increasing in importance as an essential ingredient of the Nation's healthcare system.

The chronic disease of cancer has special urgency for minorities, because it is they who bear an unequal burden for this disease. The Healthy People 2010 report states that African Americans are 34 percent more likely to die of cancer than are Caucasians. New ways must be found to reverse this disturbing trend. NINR plans to concentrate on culturally-sensitive prevention research that focuses on lifestyle factors, such as alcohol, poor diet, and exposure to environmental toxins. We will also develop and test innovative approaches to increase screening for cancers in minorities, which should help reduce disease or bring balance to the present unevenness of disease expression among populations.

Chronic pain, prevalent throughout our society, is frequently the reason people visit doctors and hospitals, and it can significantly influence recovery from illness. Imagine, however, being in severe pain but not able to tell the nurse or doctor about it. Many people are in this position, which makes pain treatment all the more difficult. Examples include those who may be cognitively impaired, or cannot speak English, or are infants unable to talk yet. Next year NINR plans a new emphasis on pain. Researchers must discover cues that indicate the presence and degree of pain so that adequate treatment can be provided for those who cannot speak for themselves. Research is also needed to address other barriers to the effective treatment of chronic pain, including under-reporting of pain and underutilization of analgesics.

Frequently accompanying chronic illness is cachexia, a condition signaled by muscle wasting and weight loss. Patients with cancer, cystic fibrosis, AIDS, and chronic lung disease are at risk for cachexia. The impact on quality of life stems from fatigue, weakness and susceptibility to other complications. Despite promising opportunities, there has been limited research attention to this condition. The urgent needs of patients with long-standing illnesses dictate that cachexia must be addressed.

Those who care for ill family members are sometimes overlooked in the overall battle against chronic illness. Yet according to the Center for Advancement of Health, nearly one in four families in our country are involved not only with physical care of their relatives, but also in dealing with behavioral or cognitive problems. Yet many caregivers must still shoulder their other responsibilities of daily life. The combination of these demands can put them at risk for poor health, caused in part by the stress of caregiving and perhaps their own advanced years. NINR plans to increase research in this area, including studies to promote learning and refining caregiving skills to benefit the patient, and strategies to safeguard caregivers' own health and quality of life.

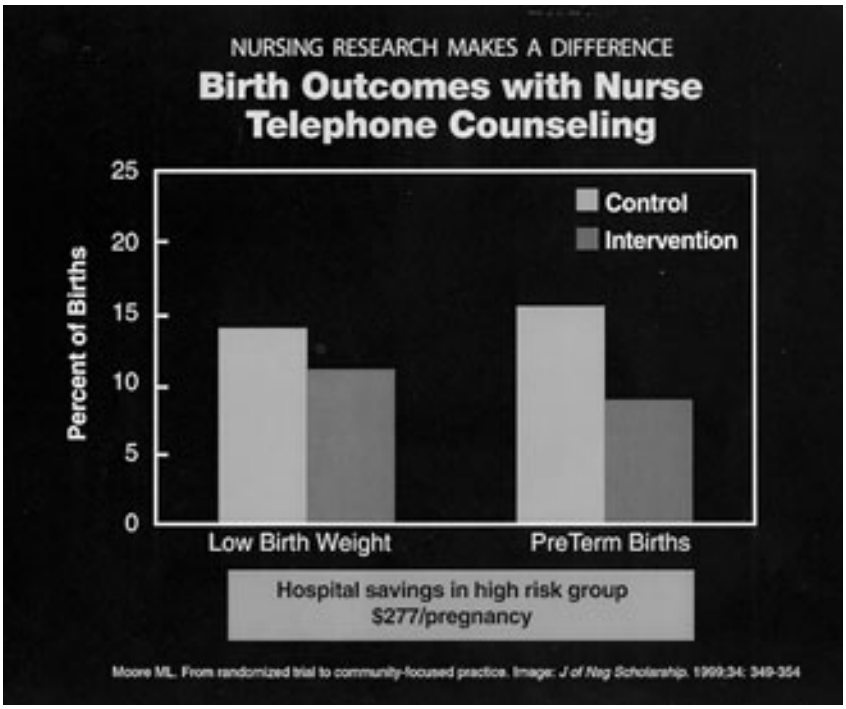
BUILDING THE CAPACITY TO DO NURSING RESEARCH

NINR must also ensure that the nation maintains a sufficient, well-prepared supply of nurse researchers to provide the empirical evidence necessary for clinical nursing practice. NINR offers a variety of NIH training opportunities, including those emphasizing patient-oriented research and research conducted by and involving minorities. We must also address the concerns of the recent report of the National Research Council on the needs for biomedical and behavioral scientists. The report recommended that NINR emphasize research training that facilitates earlier entry into research careers. To address this concern, NINR has designed several innovative programs to attract students to early research careers and to shorten the entry time into research. We also plan to continue our successful Summer Genetics Institute to fill the need for expert nurses prepared to address the many issues raised by genetic advances.

In closing, contemporary and future biomedical and behavioral research will continue to emphasize many aspects of what nurses do well—such as ethnic and culturally sensitive approaches, health promotion, and symptom management—all strong research emphases of NINR. NINR must continue to build good science in these critical areas.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compared our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

I would be pleased to answer any questions the Committee may have.



PREPARED STATEMENT OF RICHARD J. HODES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Aging (NIA) for fiscal year 2002, a sum of $879,961,000, which reflects an increase of $93,509,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

Evidence suggests that older Americans are living longer, healthier lives. Life expectancy in the United States has dramatically improved from an average of 49 years in 1900 to 76 years at the turn of the 21st century.[1] The results of several national surveys also suggest that older Americans are experiencing better health and a declining rate of disability. Despite this promising news, we know that good health is not a universal reality for all older Americans -especially for aging minority groups. Thus, the NIA is committed to supporting high quality research to address the conditions and diseases affecting the elderly population, such as Alzheimer's disease (AD), osteoporosis, cardiovascular disease, cancer, diabetes, and physical frailty.

CONQUERING ALZHEIMER'S DISEASE

AD, the most common cause of dementia among older persons, tragically affects as many as four million Americans who are predominately 65 years and older. There has been an explosion of recent findings that are yielding important clues about AD risk factors and disease pathology and, as a result, are suggesting targets for treatment and prevention.

[1] National Center for Health Statistics, National Vital Statistics Report, United States Life Tables, 1998, February 2001.

In the past year, scientists have identified a number of genetic and non-genetic AD risk factors. Separate studies concluded that a gene or genes on chromosome 10 may be risk factors for late onset AD-the most common form of AD. Prior to these findings, the apolipoprotein E (APOE) gene was the only widely recognized genetic risk factor in late onset AD. Examples of possible non-genetic risk factors uncovered recently include poor socioeconomic status, low-educational level, absence of extensive social networks, and history of serious head trauma. Evidence from these and other studies suggests that early life course events may play a role in AD development and could lead to novel interventions.

While research is ongoing to explain how AD develops, scientists are also working to translate information about risk factors and underlying disease mechanisms into effective AD treatments. The public and scientific community are particularly excited about an emerging, potentially promising AD vaccine. In a breakthrough experiment last year, which was based upon NIH-supported advances in basic research, pharmaceutical company scientists announced they had developed a vaccine that in mice appears to slow production of amyloid. Amyloid is the substance, or peptide, that forms the senile plaques in the brains of AD patients. Their research showed that repeated long-term injections of an amyloid vaccine can stimulate an immune response in test mice, nearly eliminating amyloid plaques and associated neuropathology. (Chart#1) A number of NIH-funded scientists have since confirmed and extended these observations. Other NIA-supported studies have shown that the vaccine is effective in preventing cognitive decline in mice. Human trials being conducted by pharmaceutical company researchers are now beginning to test both the safety and efficacy of these vaccines as a possible therapy for AD. The NIA is discussing potential ways in which the public and private sectors can collaborate to facilitate the success of these critical trials.

The NIA is currently supporting 17 AD clinical trials, seven of which are large-scale cognitive impairment and AD prevention trials. These trials are testing agents, such as estrogen, anti-inflammatory drugs, and anti-oxidants, for their effects on slowing progress of the disease, delaying AD's onset, or preventing the disease altogether. Other intervention trials being supported by the Institute are assessing the effects of various compounds on the behavioral symptoms (agitation, aggression and sleep disorders) in people with AD. The NIA is also supporting studies that are testing interventions for improving AD patient care delivery and alleviating caregiver burden.

REDUCING DISEASE AND DISABILITY

Besides AD, many other chronic diseases and disabling conditions can compromise the quality of life for older people. Osteoporosis, a skeletal disorder characterized by compromised bone strength, is one of the seven most common causes of disability in older people, especially older women. According to the National Institute of Arthritis and Musuloskeletal and Skin Diseases, one out of every two women (as opposed to one in eight men) over 50 will have an osteoporosis-related fracture in her lifetime. Large observational studies have determined that the use of thiazide diuretics, an inexpensive treatment for high blood pressure, is associated with higher bone density and about a 30 percent lower risk of hip fracture. To directly test the effects of low-dose hydrochlorothiazide on bone density in men and women with normal blood pressure, investigators completed a recent clinical trial. The trial found that the agent preserved bone density at the hip and spine. The modest effects observed over three years, if accumulated over 10–20 years, may explain the 30 percent reduction in hip fracture risk associated with thiazides in the earlier observational studies. The results of this trial suggest that low-dose thiazide therapy may have a role in preventing osteoporosis.

Diabetes is another one of the seven major debilitating diseases affecting older people. Adult onset diabetes, or type 2 diabetes mellitus (DM), is caused by an inability of the beta cells of the pancreas to compensate for increasing insulin demands; consequently, blood glucose levels rise. GLP–1, a glucagon-like gut peptide, can stimulate beta cells to produce more insulin even in type 2 DM; however, its biologic half-life is short and its effects quickly diminish. Exendin–4, a newly studied peptide analog of GLP–1, is long-lived and more potent than GLP–1, and has been shown to reduce blood glucose levels in rodents. A recent study with small numbers of diabetic and non-diabetic humans demonstrated Exendin–4's efficacy in inducing insulin and normalizing blood sugar, even in diabetics. (Chart#2) In the near future, an exendin-like drug possibly may become an effective treatment for type 2 DM.

Research has shown that many of the disabling conditions affecting older people could be diminished through regular exercise. The evidence was enhanced this year

by findings that found fitness affects mortality risk regardless of an individual's body fat. One study, which followed men 30–83 years of age for an average of eight years, found that within each category of body fatness,"fit" men (as measured by exercise testing) were at a lower risk of death. In addition, among fit men, obesity was not significantly related to risk of death. In another study, low fitness increased mortality risk in men approximately fivefold for cardiovascular disease and threefold for all-cause mortality. Low fitness was associated with higher mortality in all weight groups. Findings like these motivate the NIA to continue its ongoing campaign to encourage older people to exercise. Since the campaign was launched in 1998, the NIA has distributed over 350,000 copies of its exercise guide and over 15,000 copies of its companion video to the public.

BIOLOGY OF AGING

In keeping with its mission, the NIA supports research on diseases and conditions affecting the elderly as well as on the normal aging process. To understand the aging process, it is important to identify those factors that affect the overall life span of an organism. Toward this end, NIA supports and promotes research on the biochemical, genetic, and physiological mechanisms of aging and the onset of age-related disease. Experiments in a number of animal models, such as mice, fruit flies, and nematodes (roundworms), are providing valuable insights.

Understanding factors that contribute to longevity in animal models, and how these factors may apply to humans, are of major interest to the NIA. The role that oxidative stress, for example, may play in the aging process continues to be explored. In the last year, investigators announced that they had extended the average life span of nematodes via pharmacological intervention targeting oxidative stress. Using an artificial compound, EUK–134, which mimics enzymes that reduce oxidative damage, researchers extended the life span of nematodes by about 50 percent. The intervention also reversed premature aging in a nematode strain subject to elevated damage. These results strongly suggest that oxidative stress is a major factor in the rate of aging in the nematode and may be slowed by pharmacological intervention. It may be that similar compounds could lessen oxidative stress in humans and delay or reduce age-related pathology.

Caloric restriction, which entails a diet that includes all of the necessary nutrients but fewer calories, has been shown to slow the intrinsic rate of aging and to delay and reduce the onset of diseases, such as cancer. In rodents, it was demonstrated recently that caloric restriction can also increase resistance of neurons to age-related and disease-specific stresses, suggesting that it may be an effective approach for reducing neuronal damage and neurodegenerative disorders in aging. Although the effects of caloric restriction on humans have not been evaluated, this year, the NIA announced an initiative to begin studying the effects in humans of sustained caloric restriction on physiology, metabolism, body composition, risk factors for age-related pathologies, progression of age-related changes (where feasible), and its potential adverse effects. Results of these studies could be valuable in the development of better methods of preventing multiple age-related diseases.

BEHAVIORAL AND SOCIAL RESEARCH

Behavioral and lifestyle factors have a profound impact on health throughout the life span. Thus, the NIA supports behavioral and social research, including demographic research, to elicit information about the health of older people, their socioeconomic status and the social and behavioral influences that affect their lives.

Demographers reported some of the most promising news of the last decade related to the health status of older Americans. In a landmark study, researchers used the 1982 disability rates from the National Long Term Care Survey (NLTCS) for people aged 65 and older to estimate the numbers of disabled persons in each future year using census bureau projections. They then used subsequent waves of the NLTCS to determine the actual numbers of disabled persons and compared that to their estimates. Using this method, they observed 1.6 million fewer disabled older people in the U.S. in 1998 than there would have been if the disability rate had not changed since 1982.[2] (Chart #3) These decreases in disability have been confirmed using several independent databases and have been shown to benefit both men and women, and minority as well as non-minority populations. The latest preliminary findings from the 1999 NLTCS suggest that the rate of decline in chronic disability is continuing and may even be accelerating. Research is ongoing to understand the potentially significant long-term economic and social consequences of disability decline, including its effect on health care costs and the American workforce.

[2] National Long Term Care Survey 1982–1994 (Kenneth Manton, Ph.D.)

Importantly, research has also begun to identify the factors contributing to the decline so that specific interventions and behavioral changes can be designed that might sustain or accelerate trends in improved function and quality of life among older Americans.

NIA encourages research with the aim of not only extending life, but also improving the quality of life. One factor contributing to a higher quality of life in later years may be a positive outlook. A recent study demonstrated that emotional vitality is associated with decreased mortality and is correlated with slower progression of disability in disabled older women (aged 65 years and older). Using data from the Women's Health and Aging Study, a longitudinal study of disabled women, researchers found that women who were classified as emotionally vital (i.e. upbeat and positive) at the beginning of the study maintained better physical function over time than women who were not emotionally vital. Although more research is necessary to elucidate the possible role of emotions in protecting against health decline, these results suggest that helping older people maintain a high level of emotional vitality may help prevent or slow physical decline.

CONCLUSION

Many people have assumed that old age is always associated with increased disability. As little as five years ago, researchers could not conceive of an approach to preventing Alzheimer's disease (AD). However, through research advances, the nation has renewed hope that scourges, like AD, may be treated or prevented one day. Americans can also foresee the possibility of living a long, satisfying life free of major disability. To continue its trajectory of recent success, the NIA recently released its five-year strategic plans for aging research and research into health disparities. The goals are ambitious. However, these documents provide a framework that the Institute will be using to continue the tremendous progress made in the last century. By continuing and intensifying research, NIA can move forward in meeting the promise of extended life by improving the health and well-being of older people in America.

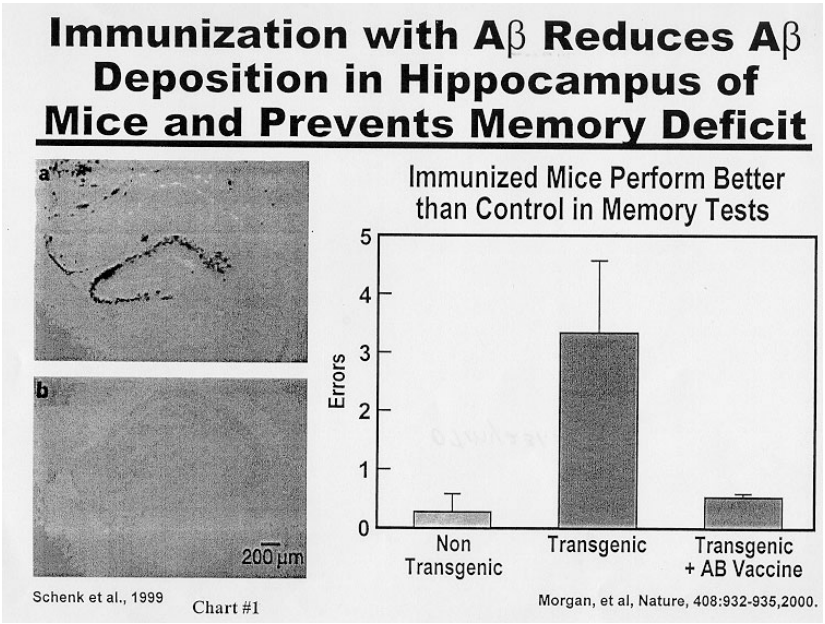
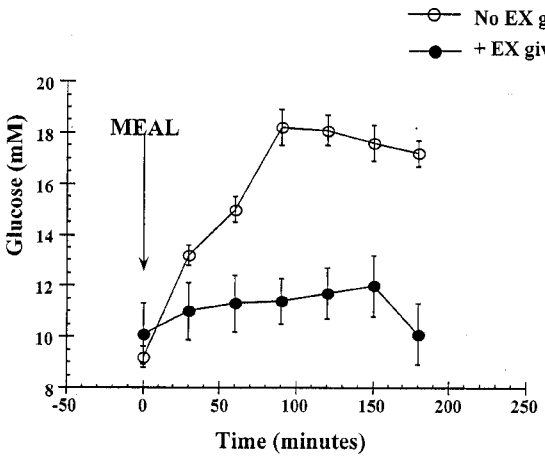


Chart #1

Effect of Exendin on the Glucose Response of Diabetic Individuals

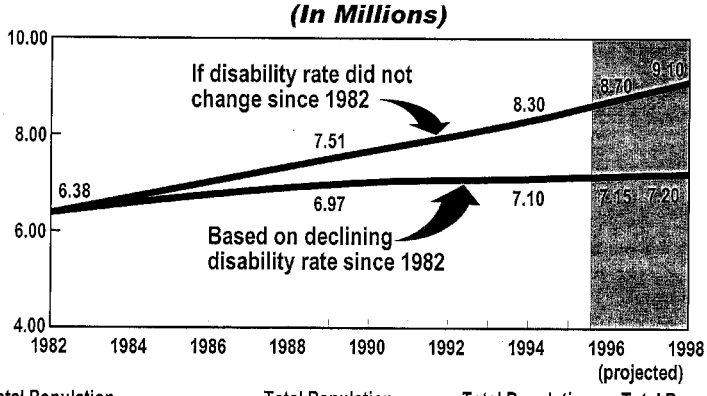


NIA, IRP, 2000

Chart #2

Number of Chronically Disabled Americans Age 65 and Over

(In Millions)



Total Population Age 65+ 26.9 Million	Total Population Age 65+ 30.8 Million	Total Population Age 65+ 33.7 Million	Total Population Age 65+ 34.8 Million

Source: National Long Term Care Survey 1982-1994 (Kenneth Manton, Ph.D.)

Sept. 2000

Chart #3

PREPARED STATEMENT OF STEVEN E. HYMAN, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

Mr. Chairman and Members of the Committee, I am pleased to present the President's budget request for the National Institute of Mental Health (NIMH) for fiscal year 2002, a sum of $1,238,305,000, which reflects an increase of $131,576,000 over the comparable fiscal year 2001 appropriation.

MENTAL DISORDERS ARE ENORMOUSLY DISABLING

Mr. Chairman, mental disorders constitute extraordinarily significant causes of disease burden in the United States and worldwide, with their greatest contribution to that burden resulting from their disproportionate impact on disability. According to the World Health Organization (WHO), major depression is the leading cause of disability in the United States and, indeed, throughout the developed world, and four mental illnesses rank among the top ten causes of disability. In recognition of this fact, the WHO has designated mental health as the topic of the World Health Assembly to be held in May in Geneva, which will be attended by Secretary Thompson and health ministers from all member nations within the U.N. In addition, mental health will be the sole topic of WHO's World Health Report for 2001, which should provide a significant platform for improved understanding worldwide. The World Health Report will complement the extremely well-received Surgeon General's Report on Mental Health issued by Surgeon General David Satcher in December 1999 in the United States. The NIMH takes great pride in having served as the critical advisor to both the United States and World reports.

CO-OCCURRING MENTAL AND GENERAL MEDICAL DISORDERS

The impact of mental illness on disability is well known. Less well known, but increasingly well documented, is the fact that mental illness can have a significant impact on the incidence and course of general medical disorders. In March, NIMH sponsored a conference in Pittsburgh that was attended by a member of this panel, Congressman Kennedy, and a member of the Senate, Senator Arlen Specter, which focused on this issue of co-occurrence, or comorbidity. Scientists presented overwhelming evidence for a physiologic role of depression in the progression of heart disease, including a contribution to heart attacks and death. Of course, depression may interfere with a person's ability to engage in rehabilitation or to adhere to diets and complex medical regimens. But that is far from the whole story. Depression causes excessive release of stress hormones, such as cortisol and adrenaline that can have negative effects on metabolism and on the heart. Depression may also make the heart more prone to abnormal rhythms, and may alter the stickiness of platelets. There is strong evidence that the fundamental pathologic processes leading to Parkinson's disease often also lead to severe depression, which, in turn, can markedly exacerbate this disabling and tragic disorder. And research points to the role of depression as a contributor to mortality in cancer and AIDS. Some treatments for general medical illnesses may also cause depression by altering brain chemistry. Treatment of cancer with high dose interferon—is often limited—indeed, often terminated—as a result of interferon-induced depression. Early treatment with antidepressant medication was shown this year to minimize depression and facilitate cancer treatment. Separation of "mind" and "body" in medicine is folly. Mental disorders are illnesses of the brain. By themselves these disorders cause enormous suffering and disability, but in addition, by altering hormone release, appetite, sleep, and other somatic systems, mental illnesses have a deleterious—and often preventable—impact on organs outside the brain.

STRATEGIC RESEARCH PLANNING TARGETS MOOD DISORDERS

The conference on depression co-occurring with other medical illnesses was held in conjunction with an exciting effort to engage the Nation's leading mood disorder researchers in our ongoing strategic planning process. The effort, entitled "Breaking Ground, Breaking Through: A Strategic Plan for Depression and Bipolar Disorder Research," will identify scientific areas that offer significant opportunities for progress or in which there are currently significant gaps. Participants analyzed the state-of-the-science in nine areas, ranging from genetics, to the neural and behavioral substrates of mood regulation, to an assessment of barriers to care for patients at all points across the lifespan and in all of our racial and ethnic minority groups. These reports will be published in a leading scientific journal later this summer, and will provide the grist for updates to our NIMH Strategic Plan. This plan, which is publicly discussed by our National Advisory Council on a regular basis, plays a critical role in our engagement with the scientific community as well as with other

stakeholders. We believe that accountability to the Congress and to the American people demands that we publicly state our goals for the advancement of diagnosis, treatment, and ultimately cure and even prevention of mental illnesses.

MOLECULAR GENETICS TOOLS BENEFIT MENTAL ILLNESS RESEARCH

In the foregoing, I have highlighted the enormous public health need created by the current realities of mental illness, and have alluded to the way in which NIMH plans to address that need. Of course the best intentions in research can go nowhere without scientific opportunities—opportunities based in a well-trained scientific community, powerful technologies, and good scientific leads. Fortunately for individuals with mental illness and their families, there are now unprecedented scientific opportunities to address these terrible disorders , and it is this conjunction of public health need with exciting and forward-looking science that truly justifies our budget request.

At NIMH, a critically important use for new funds is for research that can capitalize on the fruits of the genome project. As with most of the serious chronic illnesses that affect humanity, the major mental disorders have a substantial genetic component. For some of the most disabling disorders, including autism, schizophrenia, and bipolar disorder, the genetic aspects of risk are extremely potent, greater than those observed, for example, for most forms of coronary artery disease, type II diabetes, or hypertension. Finding the genes implicated in mental disorders is critical to accurate diagnosis, the discovery of effective new drugs, and fundamental understanding of the disease processes. Mental disorders do not result from the deterministic action of a single gene, but rather result from the interplay of multiple genes each exerting a small increment of risk, together with environmental risk factors. Prior to the human genome project it was hard to see how we would succeed in piecing these difficult puzzles together. That is all changed now. With the tools of the genome project in the offing, NIMH-funded investigators are engaged in large-scale collection of DNA samples from people with schizophrenia, bipolar disorder, autism, early-onset major depression, and other disorders. In addition, in the coming year, NIMH plans to begin to collect DNA samples from the well-characterized participants in our large-scale clinical trials. In addition to providing information about the causes of mental illness, genetics can help us to understand why some individuals respond to one treatment and not another, helping to usher in an age of individualized treatment. The result will be appropriate treatment selection for an individual to maximize efficacy and minimize unwanted side effects.

Modern molecular tools are changing not only genetics, but also brain biology. The last 3 years have seen steady progress in the development of technologies in which very dense arrays of DNA or protein samples are printed on a glass slide or other support. These functional genomic and proteomic "microarrays" permit us to ask, for example, whether a gene or protein is expressed at a higher or lower level in diseased tissue versus healthy or in a drug treated sample versus a control comparison. With a few such slides we can now look for patterns of change in thousands of genes at once. Promising research with such microarrays supported by NIMH is underway. In the past year we saw the first application of these technologies to postmortem brain tissue from individuals who had suffered with schizophrenia and other serious mental disorders. In brains from people with schizophrenia, a class of genes governing the function of synapses in the brain were expressed at clearly different levels than those observed in the comparison brains. This research, published in leading journals, has opened a new window on the causation of mental illnesses and the effects of treatment on the brain.

ANIMAL MODELS CAN PROVIDE MENTAL DISORDER PHENOTYPES

It is often not recognized that genetics creates new opportunities, not only for biologists, but for behavioral scientists. Using the tools of genetics well demands that we have a greater understanding of the symptom clusters and course of illness in people who constitute individual diagnostic groupings. At the same time, we recognize that the need to understand the precise mechanisms that cause disease require animal models. The ability to alter the mouse genome, almost at will, with the resulting production of animals with altered behavior has revealed a shortage of scientists who can analyze animal behavior and who can relate it to its neural or genetic substrates. The need for interdisciplinary scientists, individuals who bridge genetics, neuroscience, and behavioral science, was highlighted in a report released in the past year by the Institute of Medicine. Their thoughtful recommendations on training the next generation of scientists, scientists who can marshal our new technologies to solve critical problems related to mental disorders, are currently being implemented.

In the specific area of animal models aimed at understanding disease, we have collaborated with other NIH institutes that support brain research to develop centers around the country that will make novel mouse mutations and identify neural and behavioral abnormalities. An important aspect of this program is that all useful models will be shared throughout the research community. While no one expects to derive a perfect mouse model of schizophrenia or bipolar disorder, there is a great likelihood of finding mutations that model significant aspects of mental illnesses. These will be used to understand what goes wrong in the brain to produce such disorders, and most important, as screening tools to develop new treatments. These powerful approaches to biology—large-scale mouse mutagenesis, and high throughput screening for behavioral and nervous system phenotypes of interest—span the interests of multiple neuroscience-based NIH institutes.

CLINICAL TRIALS, INCLUDING CHILD MENTAL DISORDER STUDIES

We have also carried out a major expansion of our efforts in clinical trials. This expansion relates not only to the numbers of needed trials, but also to their intellectual basis. We have expanded our trials beyond their usual endpoint-answering the question of whether a medication or psychotherapy was safe and effective-to questions of whether our treatments will work for "real world" patients in diverse "real world" treatment settings such as primary care clinics and neighborhood health centers.

One important aspect of our clinical trials program is our network of Research Units in Pediatric Psychopharmacology (RUPPs). In the last month, these units have produced an important result, published in the New England Journal of Medicine, showing substantial efficacy and also safety of a selective serotonin inhibitor (SSRI) drug in the treatment of children with serious anxiety disorders who had not improved with behavioral therapy. Given the dire need to establish the safety and efficacy of treatments for children with depression, bipolar disorder, anxiety disorders, autism, and many other mental disorders, and given the initial success of these units, we are delighted that the fiscal year 2002 budget request should permit an expansion from 7 to 10 units within the network in the coming year.

The NIH Autism Coordinating Committee (ACC) will work to increase emphasis in the area of autism research, including more rapid implementation of the centers program mandated under the Children's Health Act of 2000.

Later this month, the National Advisory Mental Health Council Child Workgroup is expected to issue a report recommending that NIMH strengthen research in this area, including acceleration of interdisciplinary and multi-site research to develop new interventions—both psychosocial and pharmacologic—for child and adolescent disorders and to deploy these treatment strategies to front-line clinicians. We already are developing fiscal year 2002 initiatives that will lay the groundwork for a series of child treatment research networks designed to develop new treatments over the next decade. The expanded networks will direct resources to research on bipolar disorder, autism, depression in prepubertal children, and comorbid conditions that adversely affect child development. A parallel research network will address the critical question of how we can effectively disseminate evidence-based care within different provider practices, communities, and service systems.

JOHN EDWARD PORTER NEUROSCIENCE RESEARCH CENTER

In collaboration with the National Institute of Neurological Disorders and Stroke and seven other NIH institutes, we are moving ahead with development of a national Neuroscience Research Center (NRC) on the NIH campus, a bold initiative that is essentially dictated by the pace of progress in integrative neuroscience. The new center builds on the recognition that progress in our science demands that we overcome any balkanization that has occurred. Specialized investigators working on discrete facets of brain disease have advanced our field enormously over the past decade. Now, however, the challenge before us is to reintegrate the information we have accumulated: to look at single neurons in the context of larger neuronal ensembles, and those in the context of brain circuits and systems, all the way up to the level of the behavior of living organisms. Throughout this testimony I have described the need to build bridges across disciplines. The Neuroscience Research Center will serve as a wonderful model for such collaborations, which can capitalize rapidly on our exciting new ideas and technologies, and translate as rapidly as possible basic discoveries into the clinical arena.

Mr. Chairman, the NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan.

As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs. I will be pleased to answer any questions.

PREPARED STATEMENT OF STEPHEN I. KATZ

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases for fiscal year 2002, a sum of $443,565,000, which reflects an increase of $46,962,000 over the comparable fiscal year 2001 appropriation.

It is an honor for me to have this opportunity to share stories of progress and opportunity in the research within our mission areas. Improving daily life is the driving force for the research that we support and conduct at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Virtually every home in America is touched by diseases affecting bones, joints, muscles, and skin. We are committed to better understanding, diagnosis, treatment, and prevention of these diseases and disorders that are often chronic and disabling, many of which disproportionately affect women and minority populations.

HEALTH DISPARITIES

Research has revealed that many of the diseases within our mandate affect groups such as African Americans, Hispanic Americans, American Indians, Alaskan Natives, and Asian Americans both in increased numbers and increased severity. For example, the prevalence of lupus is higher among African Americans and Hispanic Americans, and these groups also experience more complications of lupus; African Americans also have higher rates of hip and knee osteoarthritis; scleroderma occurs with greater frequency in Choctaw American Indians; and African American people are also disproportionately affected by overgrowth of scar tissue (keloids) and by loss of pigmentation (vitiligo), both of which may be severely disfiguring.

Health Partnership Program. The health of a nation depends on the health of its communities. Recognizing this, the NIAMS is launching the first phase of its Health Partnership Program—A NIAMS Diversity Outreach Initiative, a new program to address the health disparities in joint, muscle, bone and skin diseases that exist in minority communities. The initial phase of this Program has begun as a model community-based program in the African American community in the metropolitan Washington, D.C., area, with the focus on rheumatic diseases. As a component of this partnership, plans are also underway for a new rheumatology clinic to be located in a centrally accessible area of Washington, D.C.

Recruitment to Research Careers. Specific strategies are underway and planned to increase the number of underrepresented minority investigators in the biomedical research fields related to the diseases within our mandate. The Institute, along with many other NIH Institutes, has recently issued a Request for Applications for planning grants for clinical research training in minority institutions as a first phase of this initiative. The second phase will be a five-year grant to assist in the actual development of clinical research curricula. A successful program will produce well-trained clinical researchers who can lead clinical research projects.

RESEARCH IN CHILDREN

The NIAMS has undertaken a number of programs and activities focused on children to enhance our understanding of childhood diseases and to develop improved treatments for our younger generation. For example, the NIAMS Intramural Research Program launched an exciting and promising initiative in the fall of 2000 at the NIH research hospital—the new NIH Pediatric Rheumatology Clinic. The clinic offers diagnosis, evaluation, and treatments for children with arthritis and other rheumatic diseases. The clinic will provide children with a place where they can be diagnosed and treated in a state-of-the-art facility, and researchers can learn much more about rheumatic diseases. In addition, treatment for juvenile rheumatoid arthritis has been significantly improved with the results of a recent clinical trial that showed Enbrel© (etanercept) is a safe and effective drug in the treatment of children and teenagers with juvenile rheumatoid arthritis (JRA). This clinical trial was conducted by researchers at one of the NIAMS Multipurpose Arthritis and Musculoskeletal Diseases Centers and investigators in the Pediatric Rheumatology Collaborative Study Group. The success of this clinical trial is also the culmination of many years of basic research supported by the NIAMS and other NIH components. These findings offer hope for children with juvenile rheumatoid arthritis, hope that they may live their lives as active children. In other research involving children, we now

understand that osteoporosis may actually start in childhood. Research studies in young girls revealed that minor variations in a gene for the bone protein collagen can lead to lower bone density. These minor variations in this gene, while not causing apparent disease, may define a high susceptibility group for osteoporosis later in life. Identifying and understanding genetic susceptibility to osteoporosis early in life may facilitate the targeting of interventions to those who will most profit from them.

BONE BIOLOGY AND BONE DISEASES

Bone is metabolically a very active tissue, constantly undergoing build up of new bone and resorption of old bone. Bone remodeling is a normal, but carefully balanced process. Bone diseases like osteoporosis can result from an imbalance in this process and osteogenesis imperfecta can result from the mutation of bone-producing genes, and both diseases result in low bone density, fragile bones, and increased susceptibility to fracture. Research has taught us that many factors affect bone density and strength, including genetic, nutritional, environmental, and others. Basic research has provided the foundation for our understanding of bone and has revealed some intriguing and potentially important scientific opportunities. For example, researchers found that statins, drugs that lower serum cholesterol, increase the production of a bone-enhancing molecule. This is leading to work on the development of similar drugs that can be directly delivered to the bone for maximum effect. Other studies showed us that a protein called leptin, which has an established role in controlling food intake and other aspects of behavior and physiology, seems to inhibit bone formation in animal models. Researchers will pursue this finding with the goal of designing drugs to specifically block leptin's action on bone and restore lost bone.

MUSCLE BIOLOGY AND MUSCLE DISEASES

There are many forms of muscular dystrophy, and the NIAMS has teamed with our colleagues in other components of the NIH, particularly the National Institute of Neurological Disorders and Stroke, to bring a strong focus to basic and clinical studies of muscular dystrophy. Last year we sponsored major scientific conferences in both Duchenne Muscular Dystrophy (DMD) and Facioscapulohumeral dystrophy (FSHD), issued research solicitations signaling our strong interest in the submission of high quality research applications in understanding and treating muscular dystrophy, and have funded a research registry for FSHD and myotonic dystrophy that will facilitate research by serving as a liaison between families affected by these diseases, and researchers who want to study these disorders.

SKIN BIOLOGY AND SKIN DISEASES

This has been a particular productive year in research on skin biology as well as skin diseases. Highlights of progress include: (1) ground-breaking research on impetigo, a common infection among children aged 2 to 6. The bacterium Staphylococcus aureus, cause of the common skin infection bullous impetigo, produces a toxin that attacks a protein highly specific for cell-to-cell binding in the outermost layer of the skin. Researchers have reported that breakup of this protein not only brings about the characteristic blistering, but also gives the bacterium a specific mechanism to circumvent the skin's protective barrier and spread further. (2) The gene causing Pseudoxanthoma Elasticum has been identified. Pseudoxanthoma elasticum is an inherited disorder characterized by progressive calcification of elastic fibers in the skin, eye and cardiovascular system. This disease is inherited and can have severe manifestations in these organ systems. Work is continuing to determine the function of the gene and how mutations in the gene result in the clinical disease. This discovery should allow for the eventual determination of the cause and, ultimately, allow the design of therapeutic interventions for the treatment of this disease. (3) Advances in understanding hair development and treating hair diseases have been reported. A number of skin diseases affect hair cycle resulting in various abnormal types of hair loss as well as the hair loss normally associated with aging. An understanding of the events in hair development, cycling, and the mechanism of hair loss in various diseases will allow for the development of treatments to correct these abnormalities. Knowledge of the molecular mechanisms involved in the continuously repeated cycle of resting, shedding, and regrowth means that hair biology is useful not only as a way to understand hair diseases such as alopecia areata, but also for understanding of other cycling and regenerating tissues. The research advances that have increased our understanding of the hair follicle system and the chemicals and signaling molecules involved in its cycling will allow the development of specific

interventions to treat hair diseases, both naturally occurring, such as alopecia areata, and those induced by certain cancer chemotherapeutic treatments.

CONCLUSION

The vitality of our bones, joints, muscles, and skin is key to the length and quality of our lives. Basic research has taught us much about how these components of our bodies function normally and what goes awry and causes the enormous number of diseases and disorders affecting bones, joints, muscles, and skin. Clinical research helps us to understand the nature of disease, and improves our ability to diagnose, treat, and prevent disease. Medical research supported by the NIAMS has made significant strides in improving health and quality of life, and we are committed to pursuing promising research opportunities that will continue to improve the health of the American people. We are investing in the future health of our nation, and American people of all ages and population groups will benefit from these investments.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is the NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

I will be happy to answer any questions that you may have.

PREPARED STATEMENT OF GERALD T. KEUSCH, M.D., DIRECTOR, JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the Fogarty International Center for fiscal year 2002, a sum of $56,449,000, which reflects an increase of $5,967,000 over the comparable fiscal year 2001 appropriation.

The Fogarty International Center (FIC) plays a unique role in the efforts of the United States to improve the health of the American people and of those who live in developing regions in Africa, Eastern Europe, Asia, and Latin America. The wealth of nations depends upon the health of people. A healthy world is a safer world, for our nation and for those less fortunate with whom we share this amazing and beautiful planet. Virtually all FIC research and training efforts are aimed at reducing the disparities in health that exist between the peoples of the developing world and those who live in countries that enjoy the vast advantages of prosperity.

FIC was established in 1968 to honor Congressman John E. Fogarty of Rhode Island. The Center embodies his vision that because "disease knows no boundaries, so also the benefits of medical research and indeed research itself can know no boundaries." FIC is carrying this vision into the 21st Century. Through its leadership role, program initiatives, and analysis of global science and health policy, FIC plays a central role in NIH efforts to harness the fruits of science for global health. Research advances made abroad often contribute to improvements in health in the United States. For example, research in Bangladesh establishing the physiological basis and practical use of oral rehydration therapy for cholera has led to adoption in the United States of this simple and inexpensive treatment of diarrheal disease, particularly frequent in infants and children. Research to develop diagnostic tests, new drugs, and other therapeutic strategies for HIV/AIDS, tuberculosis, and other diseases present both in the United States and abroad, is beneficial to all, no matter where it is undertaken. Adapting biomedical research advances to populations at home and elsewhere in the world requires a continuing commitment to basic science as well as rigorous clinical research by both American and foreign collaborating scientists. Success in these endeavors requires the creation of a vibrant research infrastructure and trained research staff in collaborating centers internationally. This is what FIC does best.

In carrying out its mandate, FIC supports medical investigators in over one hundred twenty U.S. institutions who collaborate with medical scientists in more than ninety nations. These efforts are multidisciplinary, embracing clinical, epidemiological, basic biomedical, and behavioral research. Although FIC acts to foster collaborative efforts in all parts of the world, it has placed special emphasis on training medical research personnel in those nations with the least resources. Such countries bear a disproportionate burden of illness and premature death, not only from communicable diseases but from non-communicable chronic diseases as well.

CHALLENGES IN GLOBAL HEALTH

FIC efforts to address the challenges in global health research are carried out through 20 research and research capacity building programs, as well as through policy and coordination efforts. With more than 35 million persons worldwide infected with HIV, AIDS is a global emergency and has been identified as a threat to our national security. In addition to individual tragedy, one person at a time, there are profound societal consequences including economic loss, social disintegration, and political instability. "Each man's death diminishes me," wrote John Donne centuries ago, "because I am involved with mankind." AIDS prevention, treatment, care, and ultimately cure are universal concerns because the people of the world are increasingly connected by trade, travel, and, unfortunately, threats to health.

To address the burgeoning pandemic, FIC launched the AIDS International Training and Research Program (AITRP), now in its 13th year. AITRP has provided research training for more scientists and health professionals from developing countries than any other program, fostering collaborative links between research institutions in the most affected areas in Africa, Asia, and South America and leaders of American medicine. AITRP trainees have been in the vanguard of the most successful efforts to reduce new infection and to keep infection rates low. Their efforts have contributed to numerous scientific discoveries and implementation of programs to reduce HIV transmission. Now that antiretroviral therapy may be within the reach of the highly stricken poor nations, a massive effort to build organizational infrastructure and train the large number of professionals required to assure the safe and appropriate use of these complex drugs is the critical bottleneck to success. Having developed extensive HIV research and training networks among U.S. Schools of Medicine and Public Health and counterparts in developing nations, FIC is in a unique position to enlarge the pool of professionals necessary to support such an effort. We cannot afford not to succeed.

Malaria, once rampant in the United States, including this capital city, has resurged and spread in endemic regions in Latin America, Africa and Asia. An added complication is that the malaria parasite has developed drug resistance. For these reasons, Americans remain at risk when they travel to endemic regions of the world, each year in increasing numbers. New strategies are needed to meet this global challenge that claims approximately 2.7 million lives annually, largely in tropical countries. FIC has implemented a new malaria research and training program to link research to control. In addition, FIC efforts to create a global coalition to address malaria have resulted in the Multilateral Initiative on Malaria (MIM), a new type of international collaboration designed to create research capacity among African scientists and to generate information in the field. As the current MIM Secretariat, FIC has overseen the enlargement of the MIM research portfolio, expanded its training activities, and increased the number of sponsoring partners. Today, MIM is the essential research counterpart for Roll Back Malaria at WHO and together these two initiatives represent the major global collaborations to combat malaria.

Well over ten million people in the United States and 2.1 billion people worldwide are infected with the tubercle bacillus. This ancient infection still results in more than 2 million deaths annually. One third of tuberculosis in the United States is attributed to infection contracted elsewhere and effective treatment is thwarted by the global emergence of TB strains with multiple drug resistance. To meet this threat, FIC started the Tuberculosis International Training and Research Program that focuses on improving clinical and laboratory practices and the training of medical research scientists. Now in its 5th year, it is an essential component of the global strategy to contain the tuberculosis epidemic and has led to important new control measures. One product of this research is a rapid, reliable, simple and inexpensive diagnostic test, which can be adapted to determine drug susceptibility.

Loss of plant and animal biodiversity is a worldwide phenomenon. The medical consequences, though less obvious, are just as serious as the effects on ecology. With the loss of plant biodiversity there is an irrevocable loss of natural products that have traditionally been the source of front line drugs such as quinine for malaria and digitalis for heart disease. The FIC-led International Cooperative Biodiversity Groups Program is a model for ethical bioprospecting in the search for new drugs while it promotes high quality science through multi-purpose partnerships between U.S. and developing country universities, major pharmaceutical companies, and non-governmental organizations. More than 6,000 species have been examined for biological activity in 13 therapeutic areas. Fifty substances of interest have been found and 15 have been selected for further research because initial studies indicate they may prove useful to treat malaria, leishmaniasis, and tuberculosis.

In response to the increasingly complex questions concerning the social and ethical dimensions of international research, FIC initiated and organized the Global Forum on Bioethics in Research, the first international effort to address critical issues related to the bioethics of conducting research in developing countries. FIC also established the first international bioethics training and research program to develop a cadre of qualified ethicists and health professionals from the developing world who can work in partnership with clinical investigators. They will shape and implement research programs and ethical research policies in their home countries to insure that human subjects receive equal protection from research risks, as do participants in research in the United States.

In collaboration with the National Science Foundation, FIC initiated a research program to study the role of ecological factors that influence the emergence of infectious diseases. This program addresses a critical need, to predict and prevent an infection from emerging rather than confront it after the problem appears. It brings together unique research teams composed of climatologists, epidemiologists, ecologists, vector biologists, entomologists, and microbiologists to develop predictive models of emerging infections. For example, the last El Nino preceded an upsurge in diarrheal disease in Latin America and malaria in Africa. To be forewarned is to be forearmed.

Under FIC leadership, innovative research is being initiated to investigate linkages between investments to improve health and economic performance in developing countries. Healthier people living better lives remains an elusive dream and the Alma Ata declaration has fallen far short of its lofty goal of "Health for All by 2000." Research results from FIC's International Studies in Health and Economic Development Program will help the U.S. and other nations working to enhance economic development in the poor countries of the world understand how best to achieve, at lowest cost, the goals of healthier, better educated people living better in politically stable nations around the world.

As we look to the future, FIC will both strengthen existing programs and respond to needs and opportunities with innovative new initiatives.

FISCAL YEAR 2002 INITIATIVES

To address the growing pandemic of tobacco-related illness and death, now shifting from the developed to the developing nations, FIC will explore how to diminish the initiation of smoking by youth and adolescents. The objective of the International Tobacco and Health Research and Capacity Building Program is to generate scientific information on biological, behavioral, and policy factors that will lead to effective control measures to reduce smoking initiation and enhance cessation. The results of these efforts will be applicable in the U.S.

New advances in clinical research are needed to translate basic research into clinical practice and to develop effective public health policy and programs. There are too few well-trained clinical researchers in low- and middle-income countries. Even fewer have policy experience to deal with research and health care. Clinical researchers are needed to address multi-dimensional medical care needs for AIDS patients, and the prudent use of antibiotics to deter the further emergence of antibiotic resistance. Travelers, refugees, and pilgrims spread resistant microbes worldwide with shocking speed. The International Clinical, Operational, and Health Services Research and Training in Communicable Diseases program will train new clinical researchers in developing countries who understand how to translate their research into practice.

Since Biblical times, those afflicted with disfiguring illnesses of body and distortions of mind have been shunned and cast aside. Such stigma is a burden both to the afflicted and the social compact. Stigma, acting through prejudice, diminishes patients' access to care and even their participation in research designed to alleviate suffering. The Stigma Research Initiative will examine the causes of and response to stigmatization of patients with such diseases as HIV, mental illness, epilepsy, drug or alcohol addiction, and physical disabilities, in the U.S. and abroad. Through epidemiological and social science studies on the roots of stigma, its expression and outcomes, new strategies can be identified and tested to relieve its effects and to enhance the well being of patients, communities, and nations.

Publication of the human genome is an extraordinary achievement that creates a wealth of opportunities to identify genetic determinants of susceptibility and resistance to disease. New discoveries to prevent and treat infectious diseases will stem from this knowledge, aided especially by new information on the genomes of microbial pathogens (most recently Strep pyogenes, the cause of "strep throat", rheumatic fever, "flesh eating" necrotizing fasciitis, and toxic shock) and insect vectors. Now for the first time, scientists can target with precision the development of

a drug or a vaccine for a specific microbe. For example, over a dozen genes have been identified that relate to the susceptibility to malaria. Efforts in malaria vaccine and drug development are now utilizing this new information.

From the very beginning of research on the human genome there has been concern about ethical issues that relate to medical applications and the protection of the individual. To permit the expansion of genetics research in developing countries, a new program, Incorporating New Genetic Tools into Global Health Strategies, will foster the development of ethically responsible international research and training in the use of modern genetic technologies. U.S. and foreign scientists will forge collaborations to define the genetic influences on conditions that affect both populations, and to discover the ways and means to improve health and reduce disparities at home and abroad.

CONCLUSION

The pursuit of health through international scientific cooperation is an inherently global enterprise and one that ultimately improves the public health of our nation. Just as trade and communications have tied the world together, advances in biology have demonstrated our social and global interdependence. "Science knows no country", said Louis Pasteur "because it is the light that illuminates the world." The genome project, the recognition that improved health is a determinant of economic development, and the impact of ecological changes on the emergence of infectious diseases all contribute to a deepening consensus that individuals and nations share common interests and responsibilities. The programs of the FIC advance this vision though their support of research and training focused on global health disparities and enabling effective collaborations between American and foreign scientists. FIC leadership and accomplishments enhance our national efforts to achieve better health for Americans and for those less fortunate in the developing world.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

Thank you Mr. Chairman. I will be pleased to answer any questions.

PREPARED STATEMENT OF RICHARD D. KLAUSNER

Mr. Chairman and Members of the Subcommittee: I am Richard Klausner, the Director of the National Cancer Institute (NCI). I am pleased to appear before you to present a brief review of some of the activities supported by the NCI and to present the President's budget proposal for fiscal year 2002. The significant budget increases over the past several years have allowed the NCI to aggressively implement its strategic plans to:

—Support a broad-based portfolio of superb research to increase our knowledge about all aspects of cancer.
—Translate basic science to transform all aspects of cancer prevention and care
—Train the next generation of cancer researchers
—Address both the quality of cancer care and the disparate burden of cancer experienced in America across the cancer continuum.

CANCER TRENDS

Four years ago, the NCI initiated an annual report to the Nation on the burden of cancer. This report is developed in collaboration with the American Cancer Society, the Centers for Disease Control and Prevention and its National Center for Health Statistics. This spring, we will report the latest cancer statistics for the country through 1998. Total cancer death rates are falling now by 1.1 percent per year with black males showing the largest drop of 2 percent per year. For breast and prostate cancer, death rates are now falling by 3.5 percent per year. Despite overall progress, incidence and/or death rates for some cancers are rising. These cancers, which include esophageal cancer, liver cancer, non-Hodgkin's lymphoma, acute myelogenous leukemia and melanoma, account for about 13 percent of the total cancer burden in the U.S. The NCI has convened task forces and directed new research to understand these trends.

The full and accurate assessment of the U.S. cancer rates is at the foundation of our ability to define the cancer burden, detect trends and pinpoint geographic and demographic variables and disparities. For 30 years, the NCI's Surveillance, Epide-

miology and End Results (SEER) Program has been the gold standard for cancer registration worldwide. This year, we announced a major expansion including California, Louisiana, Kentucky and New Jersey, and SEER now covers 26 percent of the U.S. population. We will increase the coverage of the rural population by 150 percent, of the population below the poverty line by 200 percent, of Asian Americans by 200 percent, of non-Mexican Hispanics by 70 percent and of Native Americans by 36 percent.

We have expanded and will continue to expand what we call Rapid Response Studies which allow researchers and NCI staff to rapidly respond to urgent issues that are revealed by cancer surveillance. We have greatly expanded our capacity to monitor, report and evaluate geographic differences in cancer burden. This involves a three-pronged approach. First, we are continually improving our analyses and dissemination of cancer mortality maps so that they are useful to researchers, local officials and policy makers. Second, we have provided a fund to encourage researchers to propose hypothesis-testing studies associated with geographic variations in cancer. Third, we are greatly expanding the funding for and management of Geographic Information Systems (GISs) to create computer systems that allow examination and tracking over time and space of cancer rates with any geographically defined factor that might contribute to the cancer burden. About 30 applications have been received in response to this new initiative.

EARLY DETECTION RESEARCH

New approaches, based on genomics, proteomics and other emerging technologies, are being systematically pursued to reach the goal of developing effective and reliable tests for the earliest possible detection of all cancers and even of pre-cancers. The Early Detection Research Network (EDRN) is a major new initiative of the NCI to create, for the first time, a national R&D enterprise to discover biomarkers of cancer, develop reliable tests and validate them with clinical studies. The EDRN is a partnership between NCI, other government agencies, industry and academics; in its first year, dozens of potential markers are being studied and three are moving towards validation studies. The need to develop effective early detection for lung cancer aimed at current and former smokers at risk for this deadly disease is clear. We are actively pursuing the possibility that low dose, helical Computed Tomography might provide a new method to detect early and potentially curable lung cancers. A randomized trial to compare standard screening mammography with digital mammography for the detection of breast cancer is being initiated and we continue to closely monitor the results of NCI's large randomized trial to finally determine the clinical value of PSA in prostate cancer screening. Even our most successful cancer detection tool, the Pap smear, can use improvement. A recent NCI study has addressed ways to make the test more predictive of serious findings for the large number of Pap smears that are currently read as being of uncertain significance and whose evaluation is estimated to cost as much as $1 billion per year. A DNA test looking for the virus that causes cervical cancer can successfully predict which of these Pap smears can be safely ignored and which require follow-up.

DIAGNOSIS

Two years ago, the NCI announced a major new program aimed at utilizing the emerging knowledge of the genome to create new approaches to the diagnosis of cancer, indeed to potentially change the very names and classifications being applied to human cancer. This program, called the Director's Challenge, has been responded to by a consortium of researchers from around the country who will attempt to redefine the classification of leukemia, lymphoma, lung, prostate, breast, colorectal, brain, ovarian, childhood and other cancers. Results have begun to emerge demonstrating that cancers currently lumped under one diagnosis are actually multiple molecularly distinct diseases. For at least one group of cancers called diffuse large cell lymphoma, this previously hidden heterogeneity may explain why only 50 percent of patients can be cured with current therapy. Rather, it now appears that this cancer is actually at least two different diseases, one of which is almost always cured by current therapy and the other of which is almost never cured. This program will accelerate progress towards achieving a long-held dream of being able to correctly classify human cancer.

MOLECULAR TARGETS: A NEW ERA IN THE DISCOVERY AND DEVELOPMENT OF PREVENTIVE AND THERAPEUTIC AGENTS FOR CANCER

Revealing the actual molecular machinery of cancer has long promised to bring a new, highly selective approach to both prevention and treatment. Examples of molecularly targeted therapy for cancer are beginning to emerge. For example, chronic

myelogenous leukemia (CML) is known to be the result of the breaking and recombination of two chromosomes. The fused chromosomes produce a new gene which tells the cell to produce a protein called bcr-abl whose uncontrolled activity is responsible for the growth of the leukemia cell. A new drug, called STI571, developed as a collaboration between Novartis Pharmaceuticals and NCI-funded investigators, is highly effective at turning off the activity of bcr-abl. In recently published studies, virtually every patient with the chronic phase of CML, the disease expressing the molecular target, has shown a complete correction of their blood abnormalities. This is an oral drug with apparently few and mild side effects. We now know that this same drug has activity against two other distinct molecular machines present in a variety of cancers. As a result, the NCI in collaboration with Novartis is rapidly developing numerous clinical trials to test STI571, alone or in combination with other drugs, in leukemia, gastrointestinal sarcomas (in which dramatic responses have already been seen), brain tumors, lung, prostate, breast, ovary and pediatric cancers.

To expand the discovery, validation and development of more molecular targets in cancer, the NCI has initiated a series of funding programs including:

1. Molecular Targets Drug Discovery (MTDD) grants—four new grant programs to discover and validate molecular targets for cancer for which we have received over 170 applications.

2. Interdisciplinary Research Teams for Molecular Target Assessment (IRT/MTA)—a new approach to the development of clinically useful assays to measure and monitor cancer in patients according to the actual molecular targets where treatment is directed.

3. Chemistry/Biology Centers—we have funded six centers of excellence to bring chemists and biologists together to discover chemicals that report on and can perturb the molecular machinery of cancer.

This year we hope to establish one to three large contract efforts called National Molecular Target Laboratories (MTLs). These are envisioned as genomic-scale efforts to discover molecular probes for all potential cancer relevant molecular targets.

We hope to expand the Rapid Access to Interventional Development (RAID) program, which was established two years ago to take potential therapeutics from academic or small business laboratories and turn them into drugs ready to be tested in phase I clinical trials. In its first two years, RAID is supporting 51 novel agents and we hope that 11 will reach the clinic by the end of this year.

The way scientific discovery eventually leads to advances in medical practice is through the clinical trial. Currently, the NCI is actively accruing patients (about 25,000 a year) to over 840 clinical trials including about 700 early phase trials where we can test the safety and possible effectiveness of new agents. In fiscal year 2000, 261 new trials were opened compared to 177 in fiscal year 1999. Our goal is to double the number of new agents entering such clinical testing over the next two years. Over the past year, completed clinical trials have demonstrated new treatment regimens that show a 50 percent increase in survival for resectable gastric cancer and a 40 percent increase in survival rates for metastatic renal cancer, to cite just two examples.

Over the past year, we have been implementing our strategic plan to address the pressing question of cancer disparities through our Quality of Cancer Care initiatives, our newly formed Center to Reduce Cancer Health Disparities and our Comprehensive Minority Biomedical Programs. Eighteen Special Population Networks for Cancer Awareness, Research and Training have been launched as have 12 new partnership programs between NCI-funded Cancer Centers and Minority Serving Institutions. These and other activities are aimed at increasing our understanding of cancer disparities, increasing the participation of minority and underserved communities in the cancer research enterprise and finding ways to address the disparities in cancer burden.

I am pleased to present the President's budget request for the National Cancer Institute for fiscal year 2002, a sum of $4,177,203,000, which reflects an increase of $439,275,000 over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

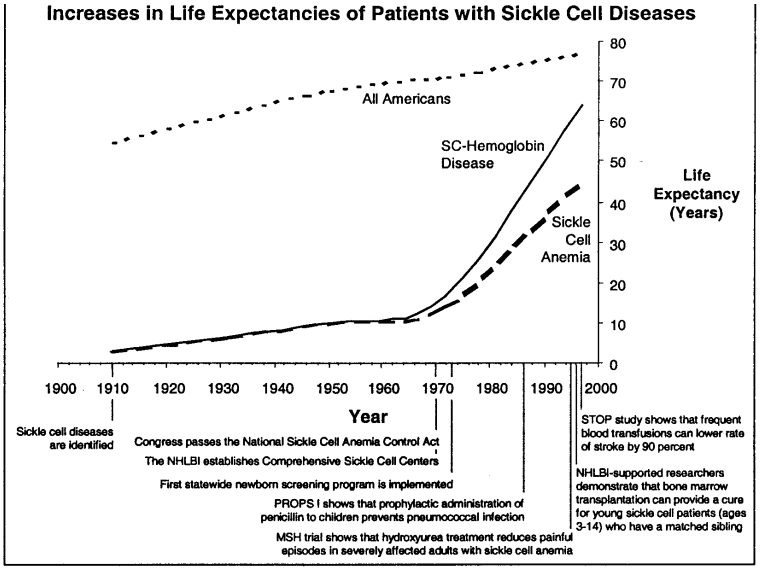
PREPARED STATEMENT OF CLAUDE LENFANT

Mr. Chairman and Members of the Committee: I am delighted to address this Committee once again on behalf of the National Heart, Lung, and Blood Institute (NHLBI). Let me begin by thanking you for your longstanding and generous support of our research programs and activities, and highlighting two examples of the benefits that have accrued to the American public.

SICKLE CELL DISEASE

As the following illustration indicates, we have made tremendous progress in our battle against sickle cell disease since our programs began about 30 years ago.

Patients with sickle cell anemia now live, on average, into their mid-forties, and average life expectancy for patients with a related condition, SC-hemoglobin disease, has climbed to the mid-sixties. These dramatic increases are highly correlated with the development and fruition of key NHLBI research programs that have provided an array of treatments and preventive regimens for the patients. Care that was once fragmented and often administered in an emergency setting is now coordinated, beginning with screening of newborns, provision of appropriate control of infections, and prevention of stroke in high-risk children through transfusion therapy.

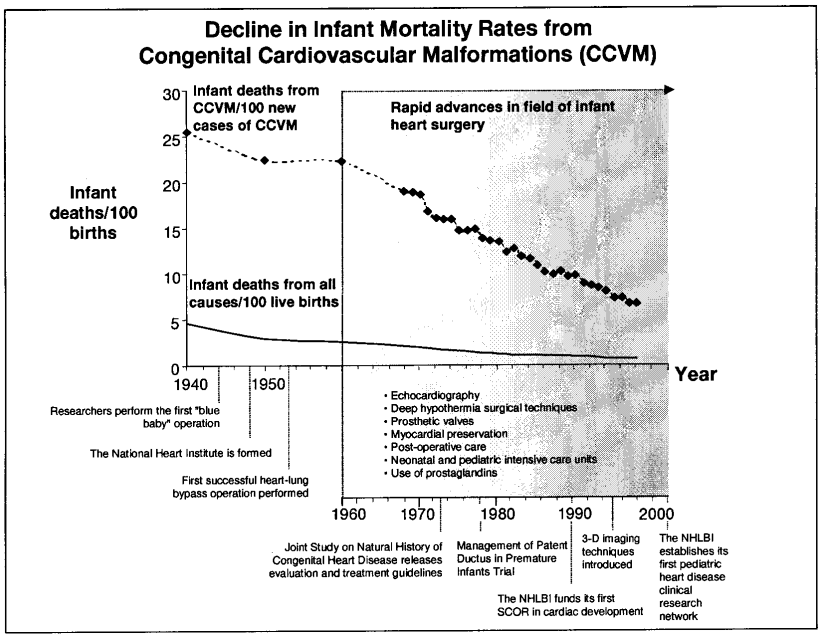


Continued progress can be expected as we capitalize on new opportunities made feasible by recent increases in the NHLBI budget. For instance, we have funded studies of bone marrow transplantation in children with sickle cell disease. At least 50 children have undergone successful transplants, leading the way for further studies of this curative process. We have expanded our studies on the drug hydroxyurea, which has been shown to decrease painful crises in adult patients by 50 percent, to determine whether this may prove safe and effective in children, as well. Additional trials are also being initiated to determine how best to manage the long-term care of children with sickle cell disease who are receiving chronic transfusions.

CONGENITAL CARDIOVASCULAR MALFORMATIONS

Congenital cardiovascular malformations are the most common birth defect in the United States, affecting nearly one of 100 newborns, or about 40,000 infants each year. While these malformations remain leading contributors to infant mortality, the chances that an affected baby will live to celebrate a first birthday are far better today than they were several decades ago. This progress, illustrated in the following chart, is testimony to the success of research that has greatly improved our ability to diagnose and treat congenital heart disease. Whereas a half-century ago, an accurate diagnosis could be made only at autopsy, nowadays many heart defects can be

diagnosed in utero. Doctors no longer sit by helplessly as babies weaken and die, because they now have an armamentarium of surgical and medical approaches, as well as reliable and effective methods for monitoring and supporting these infants.



Nonetheless, many challenges remain, and we have expanded our research programs to meet them. Although we have enjoyed much success in treating congenital cardiovascular malformations, their incidence has remained quite high and their appearance is often unexpected and unpredictable. Effective preventive strategies await a better understanding of the genetic and environmental factors that influence heart development. In that regard, we are very pleased to have been able to increase our program of Specialized Centers of Research (SCORs) in Pediatric Cardiovascular Diseases, which provides opportunities for basic and clinical scientists to collaborate in unraveling complex problems such as this. During fiscal year 1999-the initial year of the major expansion in our appropriations-we added two centers, bringing us to a total of five.

During the current fiscal year, we are establishing a Pediatric Heart Disease Clinical Research Network to facilitate development and refinement of new treatment protocols. This program will allow for rigorous evaluation of therapeutic regimens for a wide variety of cardiovascular malformations, and promote rapid dissemination of the findings to the medical community.

UNDERSTANDING HEALTH AND DISEASE

Over the years, I have emphasized the importance of a comprehensive approach that looks at health and disease from a variety of perspectives. Good (or ill) health rests on a tripod of genes, environment, and behavior. Let me provide some examples of NHLBI activities that address each of these issues.

GENETICS AND GENOMICS

The much-publicized sequencing of the human genome has brought with it tremendous excitement and opportunity. Coordinated efforts are already under way to extend the range of fully sequenced animal models so that comparative genomics can be used to identify human genes and to determine their functions. In this regard, the NHLBI has made a major investment in sequencing the genome of the rat, which has great applicability to many of the diseases under our mandate. In addition, intensive efforts are already under way to begin translating our knowledge of the structure of the genome into a working knowledge of its functions. The new

NHLBI Programs of Genomic Application, the largest Institute initiative in our history, are pursuing this goal with vigor and creativity.

The notion of using gene therapy to cure inherited diseases has long been a dream of scientists, and in some areas such as hemophilia, we have every reason to believe that it may soon become a reality. Our research in this area is gaining additional momentum with funding of new Centers of Excellence in Gene Therapy, which are designed to move these studies rapidly into the clinical arena within the context of careful and appropriate safeguards for patient safety and welfare. Although gene therapy is certain to continue to attract considerable interest, it is our belief that the biggest public health payoff of our emerging genomic knowledge may lie in the ability to understand individual differences in disease prognosis and treatment. We are already seeing exciting reports of genetic variations that account for differences in the manifestations and course of heart failure and differences in the effectiveness of asthma medications. The ability to predict, for a given patient, whether disease will be benign or severe and whether a drug will have beneficial or adverse consequences would truly revolutionize the practice of medicine.

EXTERNAL INFLUENCES

It has been said that one's genes load the gun, but the environment pulls the trigger; that is certainly true in the case of many chronic diseases. Consider, for example, chronic obstructive pulmonary disease (COPD). Some smokers develop COPD but many others do not, which suggests that genes influence individual susceptibility. However, the observation that very few nonsmokers ever develop COPD suggests that whether or not the genetic gun is loaded is irrelevant in the absence of the environmental trigger-cigarette smoke.

In the area of asthma we are looking to environmental factors as a possible explanation for the startling increases in asthma prevalence, which have occurred over too short a period of time for genetic factors to be the culprits. Research has produced some evidence that a more Westernized lifestyle that includes increased household furnishings, humidity, and temperatures; decreased ventilation; and increased time spent indoors may result in greater allergic sensitization. A number of studies have linked obesity with asthma in both adults and children, and burgeoning levels of overweight in the U.S. population are thought to be due, in part, to decreased physical activity. Still other work has advanced the somewhat counterintuitive hypothesis that modern lack of exposure to infections-because of immunization, antibiotic use, or generally improved hygiene-may adversely affect immune system development and lead to heightened susceptibility to asthma. We are avidly pursuing these and other leads in the hope of uncovering some means of stemming this rising public health problem.

BEHAVIOR

Understanding and changing health-related behaviors is critical if we are to make the most of the new discoveries of the research enterprise. Behavior is, of course, intimately connected with environmental exposure; inhaling smoke, consuming food, and taking prescription drugs are all behaviors.

Our national education programs have been quite successful in increasing public awareness and control of hypertension and high blood cholesterol, for example, but there is still considerable room for improvement, especially in certain vulnerable subsets of the population. To address this issue, the NHLBI recently established Enhanced Dissemination and Utilization Centers (EDUCs) as a means of extending the health benefits associated with current clinical guidelines and medical information. A total of 13 EDUCs have been established in communities at high risk for asthma or cardiovascular disease. They are using information generated by the Institute's education programs to inform their communities of the public health burdens of asthma and cardiovascular disease and to develop, implement, and evaluate educational strategies to reduce the burden. We believe this new approach will provide a solid foundation for our efforts to address Healthy People 2010 performance objectives of eliminating racial/ethnic and geographic disparities in underserved high-risk populations.

Our interest in this area encompasses not only the behavior of patients and the general public, but also the behavior of health care providers who dispense advice and prescribe medications. We are placing enormous emphasis on translation of new research results into clinical practice. It is of great concern that the results of definitive clinical trials indicating, for instance, the proven benefits of lipid-lowering therapy in patients with high cholesterol or beta-blocker therapy for heart attack survivors have not been widely applied to patients. We are committed to using every

avenue at our disposal to close this gap between bench and bedside and reap the greatest public health return on our research.

AMOUNT OF PRESIDENT'S REQUEST

I am pleased to present the President's budget request for the NHLBI for fiscal year 2002, a sum of $2,567,429,000, which reflects an increase of $268,329,000 over the comparable fiscal year 2001 appropriation.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

I would be pleased to respond to any questions that the Committee may have.

PREPARED STATEMENT OF DR. DONALD A. B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE

I am pleased to present the President's budget request for the National Library of Medicine (NLM) for fiscal year 2002, a sum of $275,725,000, which reflects an increase of $29,374,000 over the comparable fiscal year 2001 appropriation.

The Library is a key element in the foundation of the biomedical research enterprise. It is said that scientific research begins and ends in the library: from learning about the latest that has been published before embarking on an experiment, to publishing the results of that experiment in a journal that finds its way into an online database and onto the library shelf. In the health sciences, the institution that plays the role of information collector, organizer, and disseminator is the National Library of Medicine. The NLM not only maintains two buildings in Bethesda to house this unparalleled resource (with treasures dating to the 11th century), but the Library is the creator of immense electronic data resources that may be used, free, by anyone in the world.

There is a second aspect of the NLM's infrastructure role as creator, nurturer, and backup for national and international medical information networks. The U.S. National Network of Libraries of Medicine, created by NLM in the sixties, is an organization of 4,500 member institutions that provide vital information services to American health professionals and, increasingly, to the public. NLM is encouraging medical libraries to work closely with public libraries and other community organizations to provide the public with access to high quality health information. The NLM sponsors special programs within the network to support improving information services in areas that disproportionately affect minority groups, such as HIV/AIDS and toxicology and environmental health. There are also special outreach programs within the network for Native Americans and Spanish-speaking minorities. The Library supports an international medical information-sharing network so that it can both receive scientific information from foreign institutions and also provide their researchers and health professionals with access to NLM's electronic information resources.

Primary among these electronic resources is MEDLINE, the Library's immense database of references and abstracts to journal articles. With current usage of more than 250 million searches a year, it is the world's most-used medical literature resource. An easy-to-use Web-based program, known as PubMed, is the popular route of access. It takes only a few seconds to search through an ever-expanding collection of 11 million references and abstracts culled from more than 4,000 journals, covering the world-wide literature from 1966 to the present. The PubMed system also has links to 1800 participating publishers Web sites so that users can retrieve full text versions of articles identified in a MEDLINE search. A new feature, introduced in 2001 by the NLM and the National Center for Complementary and Alternative Medicine because of widespread public interest in the subject, is the ability to search a database limited to the literature of alternative medicine (CAM on PubMed). One unforeseen outcome of making MEDLINE available free on the Web was that the database was discovered by the general public and quickly became a favorite source of medical information. Today, the Library estimates that one third of MEDLINE searching is done by consumers.

BROADENING THE MANDATE

The enthusiasm with which the public embraced MEDLINE on the Web has altered the traditional role of the NLM, which was to serve the nation's health by providing information services through health professionals, scientists, educators, and practitioners. The Library maintains those time-honored services, but now also serves the public directly with information products created specifically for consumers. MEDLINEplus and ClinicalTrials.gov are examples of Web-based services that the public can access directly. The most broad-based of these is MEDLINEplus.

With help from members of the National Network of Libraries of Medicine across the country, the information specialists who maintain MEDLINEplus select and organize a variety of consumer health information issued by the National Institutes of Health, professional medical societies, and voluntary health agencies. MEDLINEplus not only has extensive information on more than 425 diseases and health conditions, but an extensive medical encyclopedia, detailed information about prescription drugs, directories of health professionals and hospitals, health-related articles from the daily news media, patient education modules, and links to a variety of organizations that disseminate information on various health problems. MEDLINEplus also makes it easy for the consumer to search MEDLINE for up-to-date information from the scientific literature. The Library is working with the National Institute on Aging to introduce more information related to the health of seniors, such as Alzheimer's disease, and to put the information into a format that is easily accessible by that segment of our population.

MEDLINEplus has become tremendously popular and now logs about 5 million page hits per month. The NLM has also learned that health professionals of all kinds are finding it to be an excellent source of information. Many physicians use it to keep up-to-date on medical subjects outside of their specialty. Others are referring their patients to MEDLINEplus for up-to-date and authoritative information about their health conditions.

One of the most useful features of MEDLINEplus is the ability to learn about clinical trials. The Web site ClinicalTrials.gov, developed by NLM, became publicly available in February 2000 and has already proved to be of great help to physicians, patients, and their families. ClinicalTrials.gov is a registry of more than 5,000 federally and privately funded trials of experimental treatments for serious or life-threatening diseases or conditions. It is being expanded to include more clinical trials sponsored by private companies and some performed in other countries. The database includes a statement of purpose for each clinical research study, together with the recruiting status, the criteria for patient participation in the trial, the location of the trial, and contact information. ClinicalTrials.gov is linked closely with MEDLINEplus, so that anyone looking for information about a particular disease or condition can easily tell it is the subject of any clinical trials. There is no registration for either MEDLINEplus or ClinicalTrials.gov, and complete privacy is assured to all users.

SCIENCE ADVANCES

The National Library of Medicine's involvement with the infrastructure of medicine extends far beyond its collection and the services built upon it. NLM is also a leader in providing crucial components of medical infrastructure for the 21st century. One aspect of this is ensuring that the nation's biomedical research enterprise has the trained professionals it needs in computational biology, including mathematical modeling in the life sciences, advanced imaging, and molecular biology. This role was brought into focus in the NIH report, The Biomedical Information Science and Technology Initiative (BISTI), which recommends that the NIH invest heavily in computer and information technology. As a result of BISTI, the NLM is expanding the 12 medical informatics training programs it supports at major universities to carry out research in general informatics and in Medical Genomics.

The Library also has internationally recognized program in medical genomics, organized within the National Center for Biotechnology Information (NCBI). The NCBI plays a pivotal role in coordinating, integrating, and disseminating the growing body of data currently being generated by the sequencing and mapping initiatives of the Human Genome Project. These efforts are complemented by the inclusion of individual genomic sequences, from over 75,000 organisms, submitted to NCBI from scientists worldwide, as well as the data generated through the collaborative projects aimed at sequencing the genomes of other model organisms. NCBI has also designed a novel system for linking its genomic resources to the biomedical literature, a necessary step for providing quality assurance, as well as for providing a framework for associating the most current and comprehensive biological information about a genomic sequence. Hence, NCBI's readily accessible genomic and lit-

erature databases, as well as their publicly available data analysis tools, represent a true international information infrastructure designed to facilitate and propel the biomedical research advances that will ultimately lead to better health for the American public.

Because the NLM depends to a great extent on the Internet for disseminating its many health information services, it is a supporter of the infrastructure initiative known as the Next Generation Internet. This is a cooperative effort among industry, academia, and government agencies that seeks to provide affordable, secure information delivery at rates thousands of times faster than today. Some NLM health applications, for example those involving the Visible Humans and telemedicine, require more bandwidth and more reliable service than are currently available. The Visible Human male and female data sets, consisting of MRI, CT, and photographic cryosection images, are huge, totaling some 50 gigabytes. They are being used by scientists around the world in a wide range of educational, diagnostic, treatment planning, virtual reality, artistic, mathematical, and industrial uses. Projects run the gamut from teaching anatomy to practicing endoscopic procedures to rehearsing surgery. One new project, being carried out by NLM scientists, is AnatLine, a web-based image delivery system that provides retrieval access to large anatomical image files of the Visible Human male thoracic region, including 3D images. Another is the collaborative project with other NIH Institutes to develop a super-detailed atlas of the head and neck. The Visible Human Project is an example of a program that requires both advanced computing techniques and the capability of the Next Generation Internet if it is to be maximally useful.

The Library also funds innovative medical projects that demonstrate the application and use of the capabilities of the Next Generation Internet. These projects span the spectrum of medical disciplines, geographic areas, and target audiences. One example is to evaluate the potential of telemedicine applications on the health care system in rural Alaska as a way of improving the quality of health care while at the same time containing costs. Another project, in rural Iowa, is measuring the effectiveness of video consultations for patients with special needs, including children with disabilities and persons with mental illness. In addition to supporting such advanced applications, the NLM continues its research on evaluating the performance of today's Internet pathways between and among health institutions and users. This research gives us a glimpse into what the future holds.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to our goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

PREPARED STATEMENT OF ALAN I. LESHNER, PH.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute on Drug Abuse, a sum of $907,369,000, which reflects an increase of $126,394,000 over the comparable fiscal year 2001 appropriation.

NIDA'S COMPREHENSIVE PORTFOLIO

New scientific discoveries are fundamentally changing how this Nation approaches drug abuse and addiction. As we speak, more and more diverse patient populations are receiving the best treatments that science has to offer as a result of the work of our National Drug Abuse Treatment Clinical Trials Network. Promising new medications for treating addiction to nicotine, methamphetamine, cocaine, heroin, and other drugs are being tested and developed further. And, our increasing knowledge about the health and developmental consequences of drugs of abuse, particularly emerging drugs like Ecstasy (MDMA), is allowing us to rapidly provide communities with the science-based tools to prevent and treat drug problems at the local level. It is the tremendous advances from science, fueled in part by the very generous increases in the past several budget cycles, that have allowed the National Institute on Drug Abuse (NIDA) to accomplish these momentous achievements and are providing us with renewed hope for a safe and healthy drug-free citizenry.

NIDA supports more than 85 percent of the world's research on the health aspects of drug abuse and addiction, including the impact that drugs have on other diseases such as AIDS, hepatitis C, and tuberculosis. Because NIDA is so central to the entire research enterprise, the Institute maintains a very comprehensive research

portfolio. We focus on all drugs abuse, both legal and illegal, including nicotine, with the exception of a primary focus on alcohol. NIDA also rapidly translates all of its new findings into formats that will be useful and used by a variety of audiences. I will highlight some recent accomplishments and mention a few promising directions.

NATIONAL DRUG ABUSE TREATMENT CLINICAL TRIALS NETWORK

One of the best examples of the impact that science can have on local communities is in the treatment arena. Thanks to recent treatment advances, NIDA was able in fiscal year 1999 to jump-start and then in fiscal year 2000 to greatly expand what has quickly become a national clinical research infrastructure for testing science-based drug addiction treatments in real-life community-based treatment settings. The result is that science-based treatments are now more accessible to diverse groups of patients suffering from various addictions. Patients from across the country can now participate in the 7 research protocols that are already being run through the National Drug Abuse Treatment Clinical Trials Network (CTN) with another set of trials nearing the implementation stage. Until the establishment of the CTN, researchers and treatment providers had to rely on treatment results from studies conducted in specialized settings with much restricted subject populations. Through this present network of 14 research centers and over 80 community treatment programs on the front lines of clinical practice across the country, the CTN is engaging much of the drug abuse community in a national effort against addiction and its consequences.

Additionally, the CTN provides a much needed infrastructure to more efficiently and rapidly disseminate other kinds of research findings to practitioners and patients across the country. The CTN is a major step toward achieving NIDA's millennial goal of improving the quality of drug addiction treatment in this country using science as the vehicle. The network is still not complete, however. Many areas of the country are yet to be brought into its auspices. Future plans call for the CTN to spread out geographically which will better serve the more than 5 million individuals that the Office of National Drug Control Policy reports are currently in need of treatment. The CTN will also serve as a natural vehicle to reach segments of the population that have traditionally been the least likely to access medical help, such as minority populations, disadvantaged populations, urban and rural communities, and others whose health care needs are unmet.

RESPONDING TO EVER-EMERGING NEW DRUG PROBLEMS

Unfortunately, the overall picture of drug abuse in the United States is constantly changing. As soon as we get a clear understanding of drug use patterns and gain some control over existing drug problems, new dangerous substances seem to emerge. Similar to the way a virus mutates, both regional and national drug abuse patterns are constantly reshaping and rarely remain static. Tried and true prevention and treatment approaches may not work with many of the new drugs that are emerging on the scene today. For example, newly emergent drugs like methylenedioxymethamphetamine (MDMA or "Ecstasy"), which acts as both a hallucinogen and a stimulant, require new prevention and treatment approaches, as does the unique stimulant methamphetamine. By having our pulse on these constantly changing drug trends, NIDA is poised to use the power of scientific research and its application to avert emerging drug problems before they become national epidemics. Nowhere is this proactive approach better exemplified than with the role that science continues to play as our Nation discusses and responds to menacing drugs like MDMA and methamphetamine. Because these club drugs were identified early on by NIDA as potential health problems, we were able to launch our Club Drug Research Initiative, and dissemination effort to rapidly inform communities about these drugs. The fact that over 700,000 people have visited our dedicated website on this topic *(http://www.clubdrugs.gov/)* since we launched it in late 1999 demonstrates the interest that people have in receiving science based information. Not only have we come a great distance in educating the public about these drugs, but our science has revealed some ground-breaking findings.

Research shows that "club drugs" such as MDMA are far from benign substances. MDMA has been found in animals and most recently in humans to be neurotoxic, resulting in long-lasting or possibly permanent damage to the neurons that release serotonin. MDMA has also been found to impair an individual's learning and memory abilities. Accumulating evidence shows that chronic heavy use of MDMA is associated with sleep disorders, depressed mood, anxiety, impulsiveness and hostility, and memory loss. These cognitive effects have been found to last even up to six to 12 months after abstinence from the drug. Because of the abundance of research

findings that continue to emerge on this topic, NIDA will bring leading researchers from across the globe to the NIH campus this summer to discuss the myriad of findings and determine the best future research directions to answer important remaining questions about the causes and consequences of MDMA use and how best to deal with them.

Methamphetamine, another popular club drug, has also been found to cause neuronal damage to an individual's brain cells, similar to some of the damage that occurs from stroke or Alzheimer's. Again, the abnormal brain function persists well after drug use has stopped. For example, methamphetamine abusers who were drug-free for up to eleven months still had significant memory and coordination deficiencies that were directly linked to brain changes produced by their prior drug use. These alarming results have led NIDA to expand its portfolio in all areas, with a special emphasis to look more closely at the potential health and developmental consequences that methamphetamine use by women of child-bearing years might have on the developing child.

NEUROSCIENCE PORTFOLIO SETS STAGE FOR NEW TREATMENTS

The convergence and application of powerful new tools and emerging technologies are accelerating the pace of neurobiological advances and allowing researchers to ask and answer questions that were not even imaginable five years ago. NIDA has nearly doubled the breadth and depth of its basic and clinical neuroscience portfolios. It has also allowed us to use basic research as the foundation for the entire NIDA portfolio, from prevention efforts to medications development.

One of the major new areas that NIDA will exploit in the neuroscience arena is to build on our knowledge about how specific brain circuits are affected by drugs of abuse, so that we can more precisely determine how these brain pathways are impacted by chronic exposure of drugs and how this can ultimately result in addiction. We have learned much, but still do not completely understand what causes an individual to make the critical transition from being able to voluntarily use and then abstain from drugs to the uncontrollable compulsive drug-seeking State that has become the hallmark of addiction. An array of new technologies, such as microarrays, which can simultaneously analyze the activity of thousands of genes, is allowing us to better elucidate the molecular and cellular mechanisms by which voluntary drug use can evolve over time into addiction. We will be better able to determine what genes are being turned on and off by drug exposure and to identify patterns of gene expression that make some individuals more vulnerable to addiction than others. For example, researchers found that individuals with a genetic deficiency in an enzyme that metabolizes nicotine (CYP2A6) are less likely to start smoking, and smoke less if they do start, than individuals with normal CYP2A6 activity. Building on this knowledge, researchers tested more than 200 compounds to decrease CYP2A6 activity and found that one compound (methoxsalen) commonly used to treat skin disorders may be helpful to people who want to quit smoking. This is just one example of the role that genetic research can play in helping us to develop even more novel therapeutic approaches to prevention and treatment of tobacco smoking.

Developing new approaches for treating addiction to nicotine is an important research endeavor for NIDA. NIDA will work both independently and collaboratively to bring more pharmacological and behavioral therapies for nicotine addiction to fruition. NIDA is especially interested in developing treatments that are specifically tailored to adolescent populations. At our Teen Tobacco Treatment Research Center in Baltimore, for example, over 60 adolescent patients are participating in a 3-month outpatient study that is helping to determine the most effective methods for treating tobacco dependence in this population. These findings will be used to improve treatment for teens across the country.

SCIENCE-BASED PRINCIPLES FOR DRUG ABUSE PREVENTION

Just as NIDA has declared as our millennial goal to improve the quality of drug abuse treatment nationwide using science as the vehicle, we are working to do the same in the prevention arena. To ensure that science-based prevention principles and protocols can be effectively used by a wide variety of populations across the country NIDA plans to launch a *National Drug Abuse Prevention Trials System* in fiscal year 2002. Leading prevention researchers will be brought together at NIDA's 2nd National Conference on Drug Abuse to discuss the latest prevention findings and to help NIDA prioritize the most promising prevention programs that should be initially tested in the new System.

BLENDING PUBLIC HEALTH AND PUBLIC SAFETY APPROACHES

In the same way that we have developed and sent to the field general principles that define effective prevention and treatment strategies, we are working to lay out standardized principles about duration, setting, and detailed protocols that should be used to more effectively treat individuals while they are under criminal justice control. Given the fact that untreated addicted criminal offenders have extremely high rates of post-release recidivism both to drug use and to criminality, NIDA's research can play a pivotal role in helping to address this public health and public safety issue. As we continue to learn about how to improve treatment outcomes and how to reduce the risk of relapse for patients undergoing treatment, NIDA will use this knowledge to work with the Department of Justice and others to improve the treatment of addicted criminals, particularly those with co-occurring mental disorders.

SCIENCE LEADS OUR NATIONAL DISCOURSE

Scientific advances continue to come at a tremendous pace and are not only improving the health and quality of life for our citizens, but are changing how we as a Nation view and approach addiction. Understanding initial drug use as a voluntary, and thus preventable, behavior; and understanding addiction to be a treatable, often chronic and relapsing disease of the brain, forces us as a Nation to adopt an even more sophisticated approach to dealing with this nation's drug problems. Having science set the stage for our course of action, including furthering the blending of public health and public safety approaches, is clearly the best way to reduce the enormous financial and social burden of drugs on our society. There are indicators at all levels, Federal, State and local, that this is in fact occurring. NIDA will continue to provide the latest science-based information to ensure the national discourse on this topic proceeds. We will also continue to ensure that new findings rapidly reach local communities. Science brings us all renewed hope and confidence for a healthy and prosperous future. It is NIDA's role to ensure that this hope for the future is fully realized.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

NIH Budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

PREPARED STATEMENT OF DR. YVONNE T. MADDOX, ACTING DEPUTY DIRECTOR, OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, Members of the Committee: I am pleased to present the President's budget request for the Office of the Director (OD) for fiscal year 2002, a sum of $232,098,000, which reflects an increase of $44,552,000 over the comparable fiscal year 2001 appropriation. The OD provides leadership and coordination for the research activities of NIH, both extramural and intramural. The OD also is responsible for a number of special programs and for management of centralized support services essential to the operation of the entire NIH.

The OD guides and supports research by setting priorities; allocating funding among these priorities; developing policies based on scientific opportunities and ethical and legal considerations; maintaining peer review processes; providing oversight of grant and contract award functions and of intramural research; communicating health information to the public; facilitating the transfer of technology to the private sector; and providing fundamental management and administrative services such as budget and financial accounting, and personnel, property, and procurement management, administration of equal employment practices, and plant management services, including environmental and public safety regulations of facilities. The principal OD offices providing these activities include the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Offices of: Science Policy; Communications and Public Liaison; Legislative Policy and Analysis; Equal Opportunity; Budget; and Management. This request contains funds to support the functions of these Offices.

The OD also maintains several trans-NIH offices and programs to foster and encourage research on specific, important health needs; I will now discuss the budget requests for each of these trans-NIH offices in greater detail.

THE OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) plans, coordinates and evaluates the NIH HIV/AIDS research activities; serves as the focal point for AIDS policy and budget development; and coordinates NIH involvement in international AIDS research activities.

OAR develops an annual comprehensive AIDS research plan and budget for all NIH sponsored AIDS research, based on the most compelling scientific priorities that will lead to better therapies and prevention of HIV infection and AIDS. These priorities are determined through a unique and collaborative process involving the NIH Institutes and non-government experts from academia and industry, with the full participation of AIDS community representatives.

The OAR also administers a discretionary fund and supports the Intramural AIDS Targeted Antiviral Program (IATAP) and the AIDS Research Loan Repayment Program (LRP). The budget request includes $53.5 million for OAR activities in fiscal year 2002.

THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) is the focal point for women's health research at NIH and strives to ensure that research supported by NIH addresses the health concerns of women, that women are appropriately included as subjects in research protocols and clinical trials, and that women are encouraged to pursue careers in medical research. The science-based activities of ORWH are determined by the Agenda for Research on Women's Health for the 21st Century, an agenda developed following public hearings and scientific workshops involving some 1,500 representatives dedicated to improving the health of women. In fiscal year 2002, the OD budget request includes an increase of $28 million for ORWH to pursue the recommendations within this agenda including research on chronic diseases in women, support for reproductive health research, research to aid in the prevention and detection of cervical cancer and ovarian cancer, studies to develop gender-based treatments for diabetes and kidney disease, and studies that address prevention and elimination of lung cancer in women. In addition, the ORWH, with NIH Institutes and the Agency for Health Research and Quality (AHRQ), will support career development programs that encourage the pursuit of interdisciplinary research careers relevant to women's health and encourage patient-oriented or population-based clinical research careers. Finally, ORWH will continue to monitor compliance with established policies for the inclusion of women and minorities in clinical research.

THE OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

As NIH continues its efforts to improve health outcomes, there is increasing awareness that many of our most serious health concerns are related to individual behaviors and social context. The Office of Behavioral and Social Sciences Research (OBSSR) furthers the mission of NIH by emphasizing the role that behavioral and social factors play in health. The fiscal year 2002 OD budget includes $23.7 million for OBSSR, an increase of $3 million, or 15.7 percent, over fiscal year 2000. OBSSR works to integrate a psychological and social perspective across all research programs at NIH and to increase the support for behavioral and social science research and training.

One strategy that OBSSR uses to increase support for behavioral and social sciences research is the development of broad trans-NIH initiatives that address issues relevant to many Institutes and Centers (ICs). OBSSR has addressed one of the Nation's most troubling health concerns—youth violence. A special panel of experts found that there is a need for interventions to prevent and treat youth violence, as well as for studies that would improve service delivery and maintain behavioral change. OBSSR, with four Institutes, initiated a Request for Applications (RFA) entitled, "Research on the Development of Interventions for Youth Violence," to focus on these needed areas of research.

Child neglect is one of the most critical areas of research when focusing on the well-being of children, and a topic about which little is known. OBSSR authored both a RFA and a Program Announcement (PA) for this activity along with six NIH Institutes; the Agency for Children, Youth, and Families (ACYF); The Department of Justice (DOJ), and the Department of Education. Both the RFA and the PA encourage research to enhance understanding of the causes, extent, treatment, management, and prevention of child neglect.

Enhancing opportunities to collaborate and form partnerships is an important component of the OBSSR strategic plan. OBSSR is currently collaborating with the

Association of American Medical Colleges (AAMC) to explore the development of a curriculum for behavioral and social sciences relevant for medical schools. The OBSSR, with several ICs, also supports centers to investigate aspects of the interactions between mind and body in health and disease. In addition, OBSSR has joined with 12 Institutes to address the problem of inadequate adherence to prescribed medications and therapies.

THE OFFICE OF DISEASE PREVENTION

The Office of Disease Prevention (ODP) has several specific programs/offices that strive to place new emphasis on the prevention and treatment of disease:

—In fiscal year 2002, the Office of Dietary Supplements (ODS) will continue to promote the scientific study of the use of dietary supplements. The Office will continue to support investigator-initiated research through the Research Enhancement Awards Program (REAP) and through PAs with other ICs at NIH. The Office will also stimulate research through conduct of conferences, workshops, and presentations at national and international meetings.

—In continuing efforts to inform the public about the benefits and risks of dietary supplements, the ODS expanded the International Bibliographic Information on Dietary Supplements (IBIDS) database to include a consumer-oriented search strategy.

—ODS is nearing completion of public-oriented information pages (Fact Sheets) about specific vitamin and mineral dietary supplements for wide dissemination in print and on the Internet. These are to be followed by a series of Fact Sheets for botanical and herbal supplements which are being developed in conjunction with the National Center for Complementary and Alternative Medicine (NCCAM).

—To determine the effects and safety of dietary supplements containing ephedra, ODS, with other Federal partners, will conduct an evidence-based review of ephedra efficacy and safety; and will nominate ephedra for study by the National Toxicology Program of the National Institute of Environmental Health Sciences.

Another component of ODP, the Office of Rare Diseases (ORD), supports research activities on rare diseases and conditions, develops and disseminates information to health care providers and patient support groups, and forges links among investigators with ongoing research activities in this area. The ORD continues to support workshops and symposia to stimulate research and to identify research opportunities related to rare diseases.

The ORD, with the National Human Genome Research Institute (NHGRI), plans to release a Request for Proposals (RFP) to establish an information center to respond to requests received by the NIH for information about rare and genetic disorders.

The ORD is also planning to respond to the critical needs of patients with rare, life-threatening diseases by establishing a diagnostic center of excellence for patients whose previous diagnoses have been elusive despite extensive prior efforts to determine the exact nature of their illnesses. The center would foster research on rare diseases, develop facilities designed specifically for rare diseases research, and would eventually support investigator training focusing on rare diseases.

OTHER OD ACTIVITIES

The OD also supports a number of additional NIH programs that promote research and enhance research career development:

—The NIH, through the OIR maintains intramural loan repayment and scholarship programs as important instruments for recruiting high quality candidates in basic and clinical research positions. The request contains funds for the NIH Clinical Research Loan Repayment Program and the Undergraduate Scholarship Program, both for individuals from disadvantaged backgrounds, and for the General Research Loan Repayment Program. Each program provides for the payment of educational costs in return for specific commitments of service in NIH's intramural research facilities. The request also contains funds for the implementation and administration of two new NIH clinical loan repayment programs, the Extramural Clinical Research Loan Repayment Program and the Pediatric Research Loan Repayment Program.

—The Office of Science Policy (OSP) has a role in addressing science policy issues on behalf of NIH and in coordinating NIH's approach to the Government Performance and Results Act (GPRA). In addition, the OSP has developed, with the ICs, curriculum supplements to complement existing science curricula in grades

K–12 that benefit both students and teachers and encourage students to consider careers in research.

—The request also reflects several functional transfers, including the transfer of funding for bioengineering and bioimaging activities to the National Institute of Biomedical Imaging and Bioengineering (NIBIB); funding for the Extramural Loan Repayment Program transferred to the National Center for Minority Health and Health Disparities (NCMHD); funding for the Extramural Associates Program (EAP) and the Extramural Associates Research Development Award (EARDA) Program to the National Institute of Child Health and Human Development (NICHD); and the transfer of the Academic Research Enhancement Award (AREA) funding to the several ICs supporting these awards.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

Thank you for giving me the opportunity to present this statement; I will be pleased to answer questions.

PREPARED STATEMENT OF DR. JACK A. MCLAUGHLIN

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request of the National Eye Institute (NEI) for fiscal year 2002, a sum of $571.1 million, which reflects an increase of $60.5 million over the comparable fiscal year 2001 appropriation.

Diseases of the eye and disorders of vision can have a profound affect on the quality of our lives. Many of them are chronic, disabling diseases and conditions that may ultimately lead to visual impairment or blindness. The National Eye Institute and the scientists it supports are committed to improving the visual health of our citizens. The research that they perform in this pursuit touches upon every area of scientific endeavor and every facet of the visual system.

RETINAL DISEASE RESEARCH

The retina is the transparent, light-sensitive tissue that lines the back of the eye. Diseases and disorders of the retina and its blood supply account for much of the blindness and visual disability in this country. The most important of these include macular degeneration, diabetic retinopathy, retinitis pigmentosa and related disorders, retinal detachment, uveitis, and cancer (choroidal melanoma and retinoblastoma).

NEI-sponsored scientists are actively pursuing laboratory and clinical studies on the development, molecular and cell biology, molecular genetics, and metabolism of the photoreceptor cells that capture light; the initial neural processing of information that is transmitted to the visual centers of the brain; the pathogenesis of diabetic retinopathy; the fundamental causes of and etiologic factors responsible for uveitis; the identification of the genes and neurodegenerative mechanisms for macular degeneration, retinitis pigmentosa, and related disorders; and the cellular and molecular events that accompany retinal detachment. The ultimate goal of these studies is to develop effective therapeutic or preventive measures where none currently exist or to improve those treatments that are currently available.

CORNEAL DISEASE RESEARCH

The cornea is the transparent tissue at the front of the eye that plays an important role in refracting or bending light to focus visual images sharply on the retina. Because the cornea is the most exposed surface of the eye, it is especially vulnerable to damage from injury or infection. The leading causes of corneal blindness are herpes and other infections, corneal opacification or clouding, and inherited and degenerative diseases. The NEI supports laboratory and clinical studies on a wide range of research topics, including: the regulation of genes that express proteins unique to corneal tissue; the characterization of specific proteins and cell surface receptors that interact with corneal cells, pathogens, and blood-borne cells; the mechanisms that maintain corneal hydration and transparency; the physiologic basis for immune privilege in the cornea; corneal wound healing; the cellular and molecular mechanisms by which corneal transplants are rejected; and the role of specific viral genes in the establishment and reactivation of corneal herpetic infections. These studies

should ultimately improve our ability to limit or prevent damage to corneal clarity caused by injury, infection, or other disease processes.

CATARACT RESEARCH

A cataract is an opacity of the eye's normally clear lens that interferes with vision. Cataract may develop at any time during life, although it is most often associated with advancing age. In addition to aging, cataract may be a consequence of diabetes and other metabolic disorders, trauma, exposure to ionizing radiation, or it may be inherited or congenital in nature. Cataract treatment in this country is one of the most successful of all surgical procedures. At this time, surgery to remove the opaque lens is the only effective way of treating cataract.

The NEI-sponsored research includes: studies of the development and aging of the normal lens of the eye; the identification, at the cellular and molecular level, of those components that maintain the transparency and proper shape of the lens; the control of lens cell division and differentiation; the delineation of the structural and regulatory sequences of crystallin and noncrystallin lens genes; and the impact of continual oxidative insult on the lens. The aim of this research is to develop the means to delay or prevent cataract formation.

GLAUCOMA RESEARCH

Glaucoma is a group of disorders that share a distinct type of optic nerve damage that can lead to blindness. Glaucoma is often associated with increased pressure within the eye caused by inadequate drainage of aqueous humor, the fluid within the eye that nourishes the cornea and lens. Researchers once thought that glaucoma resulted solely from increased pressure, but they now know that the elevation in the pressure within the eye is only one of the risk factors for the disease. Although glaucoma is primarily a chronic disease of aging, it may occur at any age. It can occur as a primary disorder or it can be secondary to other ocular or systemic conditions. Because glaucoma is a major health problem and the number one cause of blindness in African-Americans, it is a primary focus for NEI's research on health disparities. Approximately three million Americans have glaucoma, with about half of these unaware that they have the disease. As many as 120,000 are blind from this disease.

The NEI supports clinical trials that assess the role of medical and surgical therapy in the treatment of the disease. One study, the Ocular Hypertension Treatment Study, is attempting to determine the benefit of treating people with elevated pressure in their eyes who are at moderate risk for developing glaucoma with pressure lowering medications to prevent or delay sight-threatening damage to the eye from glaucoma. The NEI also supports studies on the identification and characterization of genes that are involved in the development of glaucoma and the basic mechanisms that control fluid secretion and outflow and the design of methods to control these processes and to protect the optic nerve from damage.

STRABISMUS, AMBLYOPIA, AND VISUAL PROCESSING RESEARCH

Research on strabismus and amblyopia encompasses a broad range of clinical and laboratory studies on the structure and function of the neural pathways from the retina to the brain, the central processing of visual information, visual perception, the control of ocular muscles, and refraction. A large number of congenital, developmental, and degenerative abnormalities affect the visual sensorimotor system, but three disorders are of primary concern: strabismus or the misalignment of the eyes; amblyopia, or lazy eye, in which one eye has reduced vision due to misalignment or unequal refraction; and refractive errors, especially myopia (nearsightedness), hyperopia (farsightedness), and presbyopia (difficulty focusing on near objects with advancing age).

As a means of improving the visual health of those afflicted with these conditions, the NEI supports a broad range of laboratory, therapeutic, and preventative studies that are concerned with the development and function of the neural pathways from the eye to the brain; the central processing of visual information; visual perception; optical properties of the eye; oculomotor function; functioning of the pupil; and control of the ocular muscles. Additional emphasis is on research on optic neuropathies, eye movement disorders, and the development of myopia.

VISUAL IMPAIRMENT AND ITS REHABILITATION

Each of the chronic diseases and disorders previously described can cause blindness and lesser degrees of visual impairment that may also be disabling. As a means of addressing the special needs of those with uncorrectable visual impair-

ment or low vision, the NEI supports a program of research on visual impairment and its rehabilitation. Some individuals require simple optical or mechanical aids to perform daily functions adequately, while others may need more specialized devices or modifications to their environment. Many face depression as they deal with their loss of vision and potentially their loss of independence.

The NEI supports research to understand the origins of visual impairment and assist in the rehabilitation of those who have such disabilities. The NEI supports projects aimed at improving the methods of specifying, measuring, and categorizing loss of visual function; devising strategies to help visually impaired people maximize the use of their residual vision; systematically evaluating new and existing visual aids; developing an adequate epidemiological base to understand the causes of blindness, partial loss of sight, and visual anomalies; and studying the optical, electronic, and other rehabilitative needs of people with visual impairments.

HEALTH EDUCATION AND COMMUNICATION

The NEI's National Eye Health Education Program (NEHEP) was developed to increase awareness among health care professionals and the public of scientifically based health information that can be applied to preserving sight and preventing blindness. Working through its partnership of over 50 professional and voluntary organizations, which includes some of the other NIH Institutes, the NEHEP attempts to reach select target audiences, informing them of the importance of early detection and treatment of eye diseases, particularly glaucoma and diabetic retinopathy, and persuading them to make an appropriate change in behavior.

To increase awareness of low vision and its impact on quality of life, NEHEP developed the Low Vision Education Program. This program is directed toward people with low vision, their families and friends, and the health care and service professionals who care for them. It takes particular note of the growing population of people over age 65 and other high risk populations, including Hispanics and African Americans who are likely to develop low vision at an earlier age. As part of this education effort, the NEI has developed a public service campaign and a mobile exhibit on low vision that is currently traveling to shopping malls and centers throughout the United States. The exhibit consists of five colorful kiosks designed to attract a cross section of the population. It contains an interactive multimedia touchscreen program; provides information on low vision services and resources; and displays aids and devices that help people with low vision, all available in Spanish as well as English. The exhibit and touchscreen program explain the causes of low vision; offer personal accounts of people living with low vision; and provide a self-assessment to help people determine if they or someone they know may have low vision.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

Mr. Chairman that concludes my prepared statement. I would be pleased to respond to any questions you or other members of the committee may have.

PREPARED STATEMENT OF KENNETH OLDEN, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Environmental Health Sciences (NIEHS) for fiscal year 2002, a sum of $561,750,000, which reflects an increase of $58,668,000 over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

GENES AND THE ENVIRONMENT

Over the past 100 years, advances in biomedical research have led to remarkable improvements in the prevention, diagnosis, and treatment of human illness. Life expectancy has increased from an average age of 49 years at the turn of the century to the current average of 76. Continued improvements in quality of life and longevity will require a better understanding of the development and progression of common diseases. Identification of the major determinants of human health is one of the major challenges of the 2lst century.

Scientists in biomedicine, environmental health, and public health are working to understand and prevent human diseases. Most chronic diseases in humans arise from a complex array of factors which could include several genes, environmental conditions or exposures, the age, nutritional status or stage of development of a person, and other predisposing factors. The relationship between genes and the environment can be compared to a loaded gun and its trigger. A loaded gun by itself causes no harm; it is only when the trigger is pulled that the potential for harm is released. Genetic susceptibility creates an analogous situation where the loaded gun is one or a combination of susceptibility genes and the trigger is an environmental exposure. One can inherit a predisposition to have a disease, but never have the disease unless exposed to the environmental trigger. Therefore, most chronic diseases will not be fully understood until both the genetic and environmental contributions to their etiology are elucidated. Unfortunately, the relationship between genes and the environment is neither well understood nor extensively studied at the present time. Until recently, limited and inadequate knowledge of human genetics had hampered progress in this area and had limited scientists to relatively simplistic models-models that assume that diseases are caused by mutations in a single gene or by exposure to a single environmental agent. Interactions between multiple genes, or between genes and several environmental agents, have only been rarely considered as the cause of human illness. So our knowledge has many information gaps.

To develop the framework that will allow us to accurately assess environmental threats to human health-threats that affect us from conception to death-we need to fill in the missing information in at least three areas. We need:

—information relating to toxicity for environmentally significant compounds from well-characterized animal models tested at biologically relevant doses;

—a comprehensive catalogue of human gene variation that can influence susceptibility to environmental exposures;

—extensive epidemiological and other population-based studies that can definitely link human disease to environmental exposure.

ASSESSMENT OF TOXICITY/CARCINOGENICITY

Estimates are that 70–75 percent of the high-volume, high-use chemicals (15,000) in commercial use in the United States have not been assessed for human toxicity or carcinogenicity (National Academy of Sciences, 1980; Environmental Defense Fund, 1993). While many, if not most, of these may not require testing since they are very similar to chemicals already tested, several do need testing. But, given the sheer magnitude of the problem, we can never satisfy this testing requirement using traditional technologies. For example, the National Toxicology Program only recently celebrated the completion of carcinogenicity assessments of 500 chemicals after 30 years of operation. The time-honored way of determining which of the thousands of environmental agents are toxic to humans is to expose hundreds of animals to the suspected product and observe them for adverse health outcomes (e.g., cancer or developmental anomalies). These studies take years to complete, cost millions of dollars, use hundreds of animals, and are not sufficiently informative.

Now, however, we have new tools generated by advancements in the science of genomics; that is, the study of our genes and what they do. These tools offer unprecedented ways to understand biological and disease processes at the molecular level. The NIEHS is merging the field of toxicology with genomics, creating a science of toxicogenomics that identifies toxicant activity at the genetic and molecular level. Last November, the NIEHS developed a National Center for Toxicogenomics to promote a genomics-based approach for assessing the toxic or carcinogenic potential of environmental agents. Using this approach, one can survey the entire human genome in just a few days to determine the response of various tissues or organ systems to specific environmental exposures. Rather than using pathology to identify illness, the toxicogenomics approach relies on gene expression profiles or signature patterns to determine which agents are toxic or carcinogenic. Current experience with this rapidly evolving technology has validated its potential usefulness in that

various classes of toxic agents give rise to unique signature patterns (i.e., gene expression profiles) characteristic of specific disease pathways.

To promote the development and validation of the gene expression profiling approach, the NIEHS has established five university-based regional centers with the NIEHS intramural program serving as a data repository and coordinating center.

SEARCH FOR ENVIRONMENTAL SUSCEPTIBILITY GENES

Organisms and species are exposed to hazardous agents in the environment on a continual basis. As a result, sophisticated metabolic pathways have evolved that can minimize the biological consequences of hazardous environmental agents. These pathways constitute the so-called "environmental response machinery." All human genes, including those that encode components of the environmental response machinery, are subject to genetic variability, which can be associated with altered efficiency of a biological pathway. So a person's risk for developing an illness as a result of an environmental exposure might be dependent on the efficiency of his or her own unique set of environmental response genes. These genes, for example, might determine how a person responds to and metabolizes drugs or carcinogenic compounds after exposure.

The Environmental Genome Project was initiated in 1997 to stimulate population-based and other research into the role of genetic variation in response to environmental exposure. The key objective is to identify all the genes in the human genome that confer susceptibility to environmental agents. The NIEHS is supporting five university-based centers to resequence suspected or candidate environmental susceptibility genes to identify genetic variations responsible for differences in response to environmental agents leading to specific diseases.

Presently, environmental health regulatory agencies craft rules as if "one-size-fits-all." However, we know that individuals can vary by more than two-thousand fold in their capacity to repair or prevent damage following exposure to toxic agents in the environment. For example, several people died after members of the Aum Shinrikya cult released potent nerve gas called sarin in a Tokyo subway station about six years ago; not all those exposed, however, died. We now know that some humans are much more vulnerable to sarin poisoning than others. Circulating in the blood of 25 percent of Asians and 10 percent of Caucasians is a version of an enzyme called paraoxonase that converts sarin to a less toxic chemical about 10 times more quickly than the enzyme found in most people. The gene that produces paraoxonase is one of dozens that toxicologists think make some individuals more or less susceptible to the effects of pollutants and other environmental chemicals (e.g., organophosphate pesticides), contributing to adverse health outcomes such as cancer, asthma, birth defects, diabetes, cardiovascular disease, Parkinson's and Alzheimer's. So, scoring for variations in a person's genetic code can help determine the likelihood that an individual will have an adverse response from exposure to sarin or other environmental agents. Knowledge of the prevalence of susceptibility genes would take much of the guesswork out of environmental health decision-making.

GENETIC VARIABILITY, EXPOSURE, AND DISEASE ASSOCIATION

To study the functional implications of genetic polymorphism or variation relative to specific environmental exposures and disease development, better exposure data will be required. Exposure monitoring is a "right-to-know" issue for citizens who are involuntarily exposed to environmental pollutants. However, little is known about actual human exposure and body burdens of environmental pollutants. This knowledge gap hampers regulatory decision making and introduces uncertainties in setting exposure limits. It also limits our understanding of dose-response relationships and capacity to develop effective prevention strategies. Exposure is typically estimated using indirect surrogates of environmental quality, such as toxic release and production inventories and environmental monitoring. Actual exposure is highly variable for individuals and subpopulations. It is really a function of individual uptake, metabolism, excretion and behavior. So the assumption that all men, women and children living in the same geographic area have similar exposure is seriously flawed. What we need are direct measures of exposure based on tissue analysis or deposition. The NIEHS is spearheading an interagency effort to intensify exposure assessment research. We have been working with Centers for Disease Control and Prevention to expand the types of toxicants measured in samples collected thru National Health and Nutrition Examination Survey (NHANES) such as those recently reported in the National Report on Human Exposure to Environmental Chemicals. These and future efforts are expected to strengthen what is often viewed as the weakest link in the risk assessment process.

The effects of exposure are not just limited to individual chemicals. Typically, toxicity and carcinogenicity are assessed in animals one chemical at a time, and the risk for each chemical in the mixture is added up to get a total risk. Implicit in summing up the risks is the assumption of independent, not interactive but additive, effects. This assumption is controversial. Also, this contrasts with the "real world" where humans are exposed to multiple agents-chemical, physical and biological-at any given time in the form of mixtures. We are aware of situations where current assumptions do not hold in that components of mixtures behave synergistically. We now have the capacity to develop technology to assess the toxicity of mixtures. One promising technology being developed with the NIEHS support is the DNA microarray gene expression profiling approach described above.

SUMMARY

Much of 20th century medicine focused on managing endstage diseases rather than preventing them at the outset. Yet prevention is the most cost-effective and life-enhancing means we have to protect human health at every life stage. In the past, the environmental health sciences, where prevention is the goal, lacked the necessary tools to identify important disease triggers. Now, however, the Nation's long-term investment in the basic sciences has put us in the position to fill the knowledge gaps. We are poised to more efficiently and more precisely identify the environmental components that set the stage for disease initiation and progression.

PREPARED STATEMENT OF AUDREY S. PENN

Mr. Chairman and Members of the Committee: I am Audrey Penn, Acting Director of the National Institute of Neurological Disorders and Stroke. I am pleased to present the President's budget request for NINDS for fiscal year 2002, a sum of $1,316,448,000, which reflects an increase of $139,428,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The mission of NINDS is to reduce the burden of neurological disorders. Today I will speak briefly about that burden. I will also say a few words about the progress so far in treating these diseases and the remarkable opportunities presented by recent scientific advances. However, I will spend most of my limited time telling you what NINDS is doing to ensure that science is translated as quickly as possible into help for people with neurological disorders.

THE BURDEN OF NEUROLOGICAL DISORDERS

Disorders that affect the brain, spinal cord, nerves of the body, muscles and their control impose an enormous toll on society. Neurological disorders can compromise the complex thinking and emotions that make us human, the routine perception and movement that we take for granted, and even the control of bodily systems that are normally beneath our conscious awareness. Trauma, infections, toxic exposure, birth defects, degenerative diseases, tumors, gene mutations, systemic illness, vascular events, nutritional deficiencies, and adverse effects of essential treatments for diseases like AIDS and cancer can all disrupt the functions of the nervous system.

We often think first of neurological disorders that afflict older Americans-stroke, Alzheimer's, Parkinson's. But problems like multiple sclerosis, brain and spinal trauma usually strike young adults, and the list of childhood disorders is enormous-autism, cerebral palsy, Duchenne muscular dystrophy, Batten disease, Canavan disease, to name just a few. Disorders like epilepsy and brain tumors, which can strike at any age, also occur frequently.

Some neurological disorders are very common. NINDS and American Heart Association studies show that more than 700,000 Americans suffer strokes each year. The Centers for Disease Control and Prevention estimates that head trauma kills more than 50,000 people each year and more than five million survivors suffer disabilities. Physicians tell us that pain is the most common symptom that brings people to a doctor. A recent journal from the American Academy of Neurology, for example, suggests that migraine headaches affect about twenty percent of women. Diabetic neuropathy commonly accompanies diabetes. Epilepsy, autism, cerebral palsy,

dystonia, the neurological aspects of AIDS and several other disorders also affect many people.

Collectively the hundreds of rare disorders of the nervous system also affect many people and their families. The history of medicine teaches us that studying rare diseases often has wide repercussions. Creutzfeldt-Jakob disease (CJD) is a terrible disorder that strikes about one in a million people. The long tradition of NINDS research on this formerly obscure disease is now coming to the forefront because of the public health concerns raised by the related bovine spongiform encephalopathy (BSE or "mad cow disease"). In the last year NINDS initiated a contract program to develop tests needed for confronting the public health and economic threats from BSE. Rare disorders often provide clues to more common diseases, and CJD is a good example here too. Abnormal aggregation of proteins called prions are at the crux of CJD. Abnormal clumps of other proteins have also been implicated in common diseases such as Parkinson's, Huntington's, and Alzheimer's.

PROGRESS AND PROMISE IN NEUROLOGICAL DISEASES

Perhaps because the brain is so complex and inaccessible, neurological disorders have always been among the most difficult to treat of all medical problems, but we are making progress. The American Heart Association estimates that the death rate from stroke went down by 14 percent from 1987 to 1997. NIH is continuing prevention trials that have contributed to that decline. In the 1990's NINDS clinical trials demonstrated the first acute treatment that improves outcome from stroke, the drug t-PA, and the first emergency drug treatment that can reduce the disability from spinal cord injury, high dose methyprednisolone. Neurosurgeons have developed guidelines that can improve outcome from head trauma. The first treatments that reduce symptoms and even slow progression of multiple sclerosis have emerged from studies of the nervous and immune systems. Several new drugs for epilepsy are now available, partly through efforts of the NINDS drug development programs. New surgical treatments, such as chronic deep brain stimulation, show promise for Parkinson's and other disorders. We have new genetic tests that help diagnose inherited neurological disorders. Clearly we are making progress, and much of that progress rests on the stream of advances from basic neuroscientists which is continuing. But each example represents only the first steps toward adequate treatments and prevention. We have a long way to go.

What is most encouraging is the range of new therapeutic strategies on the horizon. It may seem peculiar, but one important step in learning how to prevent or cure a disease is to first learn how to cause it. The striking progress in understanding the nervous system and its diseases at the level of genes, proteins, cells and brain circuits, is bringing us long sought after animal models of human disorders. Animal models enable scientists to follow the course of disease progression, refine understanding of causes, and develop therapies. Discovery of the genes responsible for inherited disorders such as Batten disease, ataxias, spinal muscular atrophy, and muscular dystrophy often leads to animal models of these disorders. Finding the genes responsible for uncommon inherited forms of Alzheimer's, Parkinson's and amyotrophic lateral sclerosis (ALS) has led to animal models that will foster progress against the more common non-inherited versions of these disorders. Genes are not the only route to developing animal models. This year brought new models for neurodegeneration in Parkinson's disease through use of a pesticide, rotenone, as well as through manipulation of genes; surgical techniques have always been important for developing animal models of stroke and trauma; and immunological approaches are important in diseases such as multiple sclerosis.

Using animal models, researchers are exploring the potential of cell transplantation, gene transfer, natural biochemicals, electrical stimulation, and new approaches to drug therapy for treating neurological disorders. Researchers using gene transfer vectors to deliver the natural neurotrophic (growth and survival) chemical GDNF were able to counter some Parkinson's-like effects in animals. Gene transfer also has shown promise in mice with the same gene defect as boys with Duchenne muscular dystrophy, and strategies to repair defective genes also now appear plausible for this disease. Cell transplantation in animals has helped repair damage from spinal cord injury, restore the myelin insulation of nerve fibers that is lost in multiple sclerosis, provide missing enzymes in inherited disorders like Tay-Sachs disease, and replenish the chemical dopamine in Parkinson's disease. Study of the steps in "cell suicide" that occurs as the simple nervous system of the worm develops led to the recognition that similar cell death mechanisms play out in several neurological disorders. Blocking steps in this cell death program has shown benefits in animal models of stroke, trauma, Huntington's disease and ALS. This is only a

sampling, but shows that not far over the horizon are possibilities for treating many neurological disorders.

WHAT IS NINDS DOING TO MOVE TOWARD CURES?

The genius of the NIH system is its power to engage the collective wisdom and ingenuity of the nation's scientific community. We must continue to nourish those ongoing efforts and position ourselves prudently to continue to support that base upon which all our efforts rest. At the same time, the scientific progress compels us to target efforts toward translating the scientific potential into real help for people as quickly as possible, and the recent funding increases empower us to do so. The key is again to rely upon the distributed insight of the medical and scientific community.

NINDS has a multi-tiered planning process to harness that collective wisdom to meet our mission. The planning process brings together scientists, physicians, the advocacy community, industry, and NIH staff in several complementary ways. We began, about two years ago, by convening more than 100 leaders from the scientific community, together with patient-advocates and NINDS staff, to assess needs, opportunities and priorities in several cross-cutting areas, each relevant to progress against many disorders. Seven panels focused on Neurogenetics; Neurodegeneration; Channels, Synapses, and Circuits; Cognition and Behavior; Neurodevelopment; Plasticity and Repair; the Neural Environment; and Experimental Therapeutics and Clinical Trials. NINDS posted draft panel reports on the internet and solicited comments from more than 250 patient advocacy groups and professional scientific organizations. This input helped shape the NINDS strategic plan "Neuroscience at the New Millenium." which serves as a foundation for all our planning efforts.

Building on the strategic goals, we have begun a series of disease specific planning efforts, beginning with Parkinson's disease. A January 2000 workshop brought together intramural, extramural, and industry scientists, Parkinson's disease advocates, and ethicists, forming the basis for the "NIH Parkinson's Disease Research Agenda," submitted to Congress in March of last year. NIH is vigorously implementing the Agenda. We held several workshops focused on specific aspects of Parkinson's disease research, such as drug therapies, gene therapies, cognitive and emotional aspects, and environmental influences. Including solicitations issued shortly prior to the Agenda or nearing release, NIH has developed more than a dozen requests for grants or contracts that target specific Agenda priorities. Targets of opportunity include deep brain stimulation, clinical trials for neuroprotective drugs, and proteins implicated in the disease. We have supplemented existing grants to expedite work on high throughput drug screening, bringing new investigators to the field, and genetics of Parkinson's in minority ethnic groups. Working groups or consortia have formed in critical areas, such as deep brain stimulation. NINDS is also continuing to support the eleven Udall Parkinson's disease research centers. The Institute will soon launch a website that will set the standard for informing the public about progress in implementing a disease specific research plan, and also serve as a resource for researchers and caregivers.

Several other disease specific planning efforts are also underway. As a joint undertaking NCI and NINDS brought together a Progress Review Group on Brain Tumors. More than 100 experts in several scientific and medical disciplines with a bearing on brain tumors presented assessments of current understanding and future needs in 14 critical areas. NINDS and NCI are working to implement these recommendations. A Progress Review Group in Stroke is following a similar process. Last spring's landmark conference "Curing Epilepsy: Focus on the Future" launched efforts that developed "benchmarks" for epilepsy research which are the first step towards a research agenda. This spring the Institute of Medicine of the National Academy of Sciences released an assessment of current status of research on multiple sclerosis with recommendations for future research. This effort, which included NIH researchers, will inform future efforts on this disease. Disease specific planning efforts dovetail with the NINDS strategic plan, revealing elements in common for many diseases and those unique to each disorder.

Health disparities has also been a focus of specific planning efforts at NINDS. Since fiscal year 1999 NINDS, working together with NCRR, the ORMH and other Institutes, has expanded its original center at Morehouse School of Medicine to eight specialized neuroscience research programs at minority institutions and a network of research consortia at 28 leading neuroscience research programs. NINDS is expanding activities of this program with a parallel development of other research as an integral part of the Institute plan for addressing health disparities.

Another aspect of NINDS planning efforts is an active agenda of scientific workshops, often held in cooperation with private groups and with other components of

NIH, such as the Office of Rare Diseases. NINDS holds about 40 of these meetings each year. Some focus on specific therapeutic strategies or technologies, such as neural prostheses, gene therapy, optical imaging, computational neuroscience and high throughput drug screening. Others target specific diseases. Recent workshops focused on Duchenne muscular dystrophy, facioscapulohumeral muscular dystrophy, hereditary spastic paraplegias, spinal cord injury, ALS and spinal muscular atrophy, channelopathies, neurofibromatosis, and pediatric stroke. At these workshops, in addition to the scientific discussions, NINDS solicits advice on how to eliminate bottlenecks and encourage progress.

I could describe many other planned and ongoing activities, and certainly more exciting science, but I want to conclude with a simple message. Because NINDS has an "acting" director does not mean the Institute will be less active until a permanent director is appointed. Given the burden of neurological disorders, the scientific opportunities, and the favorable funding environment, it would be unconscionable for the Institute to become passive. I assure you we are doing everything we can to move aggressively toward better ways to treat and prevent neurological disorders.

Thank you. I would be happy to answer questions.

PREPARED STATEMENT OF JOHN RUFFIN, PH.D., DIRECTOR, NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES

Mr. Chairman and Members of the Committee: I am honored to appear before you as the new Director of the National Center on Minority Health and Health Disparities (NCMHD) to present the President's budget request for fiscal year 2002, a sum of $158.425 million, which reflects an increase of $26.356 million over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The Secretary for Health and Human Services approved the NCMHD on January 16, 2001, as called for in Public Law 106–525. Within the National Institutes of Health, the NCMHD serves as the focal point for planning and coordinating minority health and other health disparities research. The Center coordinates the development of a comprehensive health disparity research agenda that identifies and establishes priorities, budgets, and policy that govern the conduct and support of all NIH-sponsored minority health and other health disparities research and training activities. Significant progress has been made since the establishment of the Center; however, considerable work remains to be done as the Center transitions from an Office to a Center and assumes grant review, funding and financial management functions. The development of a comprehensive research portfolio began with the NIH Office of Research on Minority Health and will be expanded to include the medically underserved and other health disparity groups as designated by the Agency for Health Care Research and Quality. As a part of its mandate to build capacity for minority health and health disparities research, the Center also will expand it's support of training and the development of research infrastructure at Minority Serving Institutions.

The complexity of the disparity in health status relates to convergence of multiple factors in unsuspecting ways to cause differences in disease progression and in health outcomes. If one tried to identify a priori all of the factors that could potentially impact the overall health of an individual, the results would look something like the attached schema. Accordingly, the Center will promote and increase participation in minority health and health disparities research by expanding the number of investigators involved in such research and by providing sustained funding for a wide breadth of studies—basic, clinical, and population research; studies on the influences of health processes; and research on the societal, cultural, and environmental dimensions of health—all aimed at identifying potential risk factors for disparate health outcomes.

LEVERAGING RESOURCES WITH THE NIH INSTITUTES AND CENTERS

The NCMHD will continue to provide funding support to assist the NIH Institutes and Centers (ICs) in the following ways: piloting new health disparities programs, improving recruitment and retention in clinical trials, and in providing competitive supplements to expand the focus of existing programs. The Center also will share in the support of selected targeted studies that are supported by the NIH ICs. Se-

lected examples of the ways in which the Center leverages its funds with the NIH ICs are provided below.

The Jackson Heart Study (JHS), a targeted study co-supported by the National Heart, Lung, and Blood Institute and the NCMHD, is an investigation of the causes of the high rate of cardiovascular disease in the State of Mississippi. The objectives of the JHS are to: identify risk factors for the development and progression of CVD; build research capacity in a minority serving institution; and expand minority participation in CVD epidemiology research. Initial examinations among the JHS cohort began in the fall of 2000 and will take 3 years to complete. Some of the newer areas of focus will include early indicators of disease, genetics, sociocultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity, and diabetes and their influence on CVD.

The Diabetes Genes, Treatment, and Prevention in Minorities Research program, supported by the National Institute on Diabetes, Digestive, and Kidney diseases and the NCMHD, focuses on the following groups: Hispanic diabetic adults residing in a rural Texas-Mexico border community; centrally obese African-Americans with impaired glucose tolerance; obese Hispanic high school students in Colorado; African American children, adolescents, and adults with diabetes; and Caribbean Latinos with non-insulin dependent diabetes. Its objectives include the development of treatment and prevention interventions that specifically address diabetes in a range of minority populations and elucidation of the genetic basis of diabetes in minority populations and the underlying mechanisms controlled by gene expression.

The National Institute for Nursing Research (NINR) and the NCMHD will pilot planning activities for a new partnership initiative in NINR's extramural research program. The focus will be on decreasing disparities in the burden of illness and mortality experienced by racial and ethnic populations and the medically underserved through a variety of approaches, which include basic, epidemiological, clinical and prevention, control and population research. Cultural and ethnic considerations, genetic diversity, and social and economic influences on health and health outcomes are potential areas of emphasis. The activity will include partnership research, training, and other activities between Minority Serving Institutions and research-intensive majority institutions in institutions that provide services to the rural and urban poor.

Other potential areas where the NCMHD will leverage its funds with the NIH ICs include: the intersection of non-genetic factors and genes in health disparities, infectious origins of chronic diseases and research training.

AN INDEPENDENT RESEARCH GRANT PORTFOLIO

Independent grant-making authority not only increases the Center's flexibility in leveraging its funds with the NIH ICs, but it also enables the Center to: focus on "gap areas" where such research is not conducted or supported by the NIH ICs; more effectively build research capacity in minority health and health disparities research, address barriers to the participation of minority serving institutions in the research enterprise, and to develop research capacity among community-based organizations.

With respect to research, the NCMHD recognizes several pressing priorities. Our new Division of Research will develop programs to fund interdisciplinary teams of biomedical, clinical, and social science investigators—teams that are crucial to developing strategies and tools for eliminating health disparities. Another priority of the Division of Research is to ensure that the power of bioinformatics and genomics research, including pharmacogenomics, is brought to bear on the health disparity program.

Our new Division of Community-Based Research and Outreach will identify and implement through research, effective and generalizable models of health care delivery, disease prevention and intervention, and communication that will improve community health outcomes in racial and ethnic minority and other health disparities populations. The Division will utilize available data generated by other Federal and State agencies to identify affected communities and to measure progress in outcomes associated with specific interventions. Key areas of focus will be to promote research on investigation of health behaviors, cultural health beliefs and environmental factors in community health. Validated findings will be utilized and incorporated by the Division to develop culturally sensitive and appropriate community-based prevention messages.

CENTERS OF EXCELLENCE PROGRAM

As mandated in its statutory authorities, the NCMHD also will develop and implement a Centers of Excellence Program to support minority health research and other health disparities research and research training for members of health disparity populations. The exploratory grant mechanism will be used to plan for and promote interdisciplinary biomedical and behavioral research and to plan for the establishment of stable research and training programs. Center planning strategies may focus on a specific research theme (e.g., diagnosis, therapy, epidemiology) or integrate a broad spectrum of research to include the basic, clinical, prevention, and population sciences. Partnerships between minority institutions and majority institutions will be encouraged.

RESEARCH ENDOWMENT PROGRAM

The Center also will develop and implement a Centers of Excellence Endowments Program for certain designated centers and those centers at Institutions of Emerging Excellence. Potentially a pilot initiative could begin in 2001. The purpose of the program is to provide enduring, forward-looking, sustainable support for the Center's minority health and health disparities research programs and to provide continuing research infrastructure support.

LOAN REPAYMENT PROGRAM

In fiscal year 2001, the NCMHD will develop and implement two distinct extramural loan repayment programs recently authorized by the Congress: the Clinical Research Loan Repayment Program (LRP) and the Health Disparities Loan Repayment Program (HD–LRP). The emphasis of the LRP on "clinical research" and on individuals from "disadvantaged" backgrounds is consistent with the objective of building a culturally competent cadre of clinical investigators. Such a cadre of clinical investigators not only will have the potential of having an influence on the medical processes within their communities but can also engage in and promote the development of clinical research programs that reflect an understanding of the variety of issues and problems associated with disparities in health status. The focus of the health disparities LRP is specifically on clinical research related to diseases and conditions having an increased prevalence among racial and ethnic minorities and other designated health disparity groups.

OTHER CAPACITY BUILDING PROGRAMS

To expand the number of investigators participating in minority health and health disparities research the NCMHD will promote, assist, and support research capacity building activities in the minority and medically underserved communities. These activities will focus on research infrastructure development, faculty career development, and increasing the number of under-represented minority students and students from health disparity groups with an interest in careers in biomedical and behavioral research.

HEALTH INFORMATION DISSEMINATION

Our health information dissemination activities will be multifaceted since professionals and the lay-public obtain information from very dissimilar sources. Information will be transmitted to professional medical and scientific organizations for dissemination among their membership, and also will be made available to the public through media that are most likely to reach racial and ethnic minority groups.

CONCLUSION

Recognizing that the process of medical discovery occurs in stages, the Congress has provided many new opportunities to build upon the previous efforts of the Office of Research on Minority Health. Our commitment to the research needed to ultimately eliminate health disparities will be steadfast and enduring, and we will be ever vigilant in our efforts. We are excited about these opportunities and greatly encouraged by the strong support the Center has received from the Congress, the Administration, our fellow NIH IC Directors and from groups and individuals across the Nation.

PREPARED STATEMENT OF STEPHEN E. STRAUS, M.D., DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center for Complementary and Alternative Medicine for fiscal year 2002, a sum of $100,063,000, which reflects an increase of $10,925,000 over the comparable fiscal year 2001 appropriation.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The past year, NCCAM's second, has been exciting and productive. With your generous support we continued to build a new research enterprise dedicated to defining the effectiveness and safety of diverse complementary and alternative medical (CAM) practices. Many Americans turn to these practices to relieve or prevent disease symptoms or the side effects of their treatment, despite a lack of clear and compelling data about them. We have the scientific tools, the commitment, and the resources to begin to guide their decisions regarding these practices. Consistent with our mandate, we have identified priority areas that warrant more immediate action due to pressing public health needs and either a dearth of valid scientific information or sufficient maturation of the science. Allow me to provide some examples of our approach.

MECHANISMS OF CAM INTERVENTIONS

Among NCCAM's highest priorities is the conduct of Phase III clinical trials of CAM modalities. NCCAM's Phase III clinical trials are built upon a substantial body of scientific evidence concerning a given modality. While complex enough in design and ambitious enough in scope to address critical scientific issues and patient safety concerns, these pivotal trials are also well poised to address the central question: "Does this therapy work?" In collaboration with other NIH Institutes and Centers (ICs), NCCAM supports the following multiyear, multicenter phase III clinical trials: St. John's wort for depression, with the National Institute of Mental Health (NIMH); shark cartilage for lung cancer, the National Cancer Institute (NCI); Gingko biloba for dementia, the National Institute on Aging (NIA), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Neurological Disorders and Stroke (NINDS); acupuncture for osteoarthritis pain, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); and glucosamine/chondroitin sulfate for osteoarthritis, NIAMS.

NCCAM also funds 15 specialty research centers, completing the research infrastructure platform on which to investigate the mechanisms underlying CAM treatments and their health effects. NCCAM-funded centers cover CAM approaches for many areas of major public health need, including drug addictions, aging and women's health, arthritis, craniofacial disorders, cardiovascular diseases, neurological disorders, pediatrics, and chiropractic research. These centers constitute a major investment of NCCAM's resources and serve as the focal point for initiating and maintaining state-of-the art multidisciplinary CAM research. They develop core research resources, train new CAM investigators, provide community outreach and education, and expand the research base through collaborative research and outreach to scientists and clinicians.

While CAM remedies have been employed for centuries, we still understand little about them. By studying their underlying mechanisms, we could better monitor their actions and develop biomarkers whose changes would correlate with beneficial clinical outcomes. Thus, we would be better positioned to reveal which CAM modalities work and which do not, and inform the public accordingly.

One prospect is acupuncture, which, after millennia of empiric development and widespread use in Asia, has emerged as an exciting but still poorly understood tool for pain management. The ancients imagined pain as a result of imbalances in energy flow through defined body channels, or meridians. By inserting needles at precise points, practitioners attempted to correct the pain-provoking energies. In contemporary neurobiological terms we understand chronic pain as a result of abnormal actions within key nerve-signaling pathways from the periphery to the central brain. NCCAM grantees are testing the value of acupuncture for pain relief and learning more about its mechanisms of action. Studies using remarkably sensitive imaging techniques have pinpointed pain processing centers in the brain and showed that the activity of these centers is altered when needles are inserted at the body sites defined by the ancient Chinese practitioners as affording pain control.

Acupuncture-mediated analgesia is not imagined, it is real. Our clinical trials are exploring the range of conditions for which acupuncture may provide effective pain relief. Our largest such study of acupuncture involves the pain of osteoarthritis.

In the largest and most rigorous trial of acupuncture to date, cosponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the short- and long-term safety and efficacy of acupuncture for the pain of osteoarthritis of the knee are being evaluated. In this six-week study, 570 aging Americans are being randomly assigned to: (1) true acupuncture; (2) sham acupuncture; or (3) standard education and attention. The goal is to determine whether patients receiving true acupuncture experience significantly less pain and fewer limitation than patients in the other groups. A separate follow-up of the patients in this study will evaluate the long-term outcomes and cost-effectiveness of the acupuncture intervention.

Another key area of interest is the use of CAM to treat coronary artery disease (CAD), which is the leading cause of mortality for both men and women in the U.S. Despite increasingly effective conventional treatments for CAD, many turn to alternative approaches including the use of ethylenediaminetetraacetate (EDTA) chelation therapy, a popular but controversial approach. To date, however, studies of chelation therapy for CAD have been few, very small in size, and poorly designed, affording few conclusions concerning its true safety and effectiveness. To address this important public health issue, NCCAM plans, in collaboration with the National Heart, Lung and Blood Institute (NHLBI), to fund the first major, multi-site, clinical trial to investigate the efficacy and safety of EDTA chelation therapy in individuals suffering from CAD, using rigorous trial design and validated outcomes measures: a solicitation (RFA) has been released.

CANCER

NCCAM is applying this same energy and commitment to studies of cancer. Our rapidly growing research portfolio encompasses both the study of CAM cancer interventions and palliative care. In fiscal year 2000 NCCAM funded two new Specialty Research Centers dedicated to studying the safety and effectiveness of several popular CAM cancer therapies. One center is evaluating the mechanisms of action, safety, and clinical efficacy of hyperbaric oxygen (oxygen at greater-than-atmospheric pressures) treatment for head and neck cancers. The other center conducts studies of breast cancer as well as the first randomized, placebo-controlled clinical trial of a popular mixture of eight Chinese herbs, known as PC-SPES, in men with hormone-refractory prostate cancer. This latter study will evaluate PC-SPES for disease progression, bone pain, and quality-of-life issues, such as changes in sexual function, that so often accompany prostate cancers and their treatment. (The name PC-SPES means hope for prostate cancer.)

Some menopausal and postmenopausal women find symptom relief through conventional estrogen replacement therapy (ERT). Research has also shown that ERT benefits cardiovascular, skeletal, genitourinary, and cognitive health. Despite these benefits, less than 20 percent of American women use ERT, in part because it seems to be associated with an increased risk of breast cancer. This dissuades some women from using it and excludes its use for breast cancer survivors. Many women explore alternative approaches to estrogen replacement to eliminate the risks of conventional ERT, with the hope of reaping its benefits while avoiding its potential hazards. Soybeans are rich in naturally occurring compounds with estrogen-like activity. Several preliminary studies of popular soy-derived phytoestrogens (PEs) yielded unclear and contradictory results, leaving open the question of whether soy may protect against breast cancer or, like conventional ERT, promote its emergence. NCCAM intends to conduct Phase II clinical trials to assess the impact of PE supplementation on women's health after a breast cancer diagnosis.

Cancer patients for whom a cure is not an option face not only the prospect of death, but also the diminution of quality of life and dignity, and intractable pain. Perhaps as many as 70 percent of these cancer patients seek complementary and alternative therapies to expand options for end-of-life care. NCCAM is soliciting Phase I and II clinical trials of CAM modalities for: the prevention and management of symptoms associated with the end of life, including secondary side effects of chemotherapy and radiotherapy; and the enhancement of the patient's well-being.

BOTANICALS

Botanicals, among the most popular CAM therapeutics, are relied upon for treatment and prevention of a number of conditions. In collaboration with the NIH Office of Dietary Supplements (ODS), NCCAM funds four Centers for Dietary Supplement Research with an emphasis on botanicals. The Centers identify and characterize

botanicals, assess their bioavailability and activity, explore mechanisms of action, conduct preclinical and clinical evaluations, establish training and career development, and help select the products to be tested in randomized controlled clinical trials. Our plans include studying botanical-drug interactions, the developing standardized botanical products, and examining the safety and effectiveness of cranberry products in preventing urinary tract infections.

HEALTH DISPARITIES

In conjunction with the trans-NIH effort to address U.S. health disparities, we have recruited a director for the NCCAM Office of Special Populations and charged him to expand our own research plan in this area. We plan to: identify the extent and nature of CAM use among special populations; studying the application of CAM therapies to reduce disparities; increase participation of underrepresented populations in NCCAM-supported clinical trials; and enhance the ability of minority institutions to support CAM research. This plan will serve through fiscal year 2005 as a guide for developing new initiatives to address minority health and health disparities. In the near term, NCCAM intends to determine the prevalence of CAM use by different minority and underserved populations, initiate studies on the use of magnesium sulfate in the treatment of acute asthma, and use the National Research Training Award (T32) mechanism to support pre- and post-doctoral trainees in CAM research at minority and minority-serving institutions.

INTEGRATIVE MEDICINE AND RESEARCH TRAINING

NCCAM has initiated a series of specific activities to facilitate the successful integration of safe and effective CAM modalities into mainstream medical practice. We conduct research that provides compelling evidence of efficacy and safety and publishing these findings in peer-reviewed journals, study factors that promote or impede integration, support the development of model curricula for medical and allied health schools and continuing medical education programs, and inform the public in a clear and definitive manner. In fiscal year 2001, we launched a new integration initiative to study factors that promote or impede integration, determine whether CAM research results can be translated to real-world settings, and support the evaluation of programs that integrate CAM and conventional care. Integrative medicine is also a key component of NCCAM's Intramural Research Program and a component of NCCAM's Specialized Research Centers.

NCCAM's ability to achieve its research goals depends on the availability of a critical mass of skilled investigators in both CAM and conventional communities. It is our goal to increase the knowledge, experience, and capacity of CAM practitioners to conduct or participate in rigorous research. We also intend to enhance conventional practitioners' and researchers' knowledge and experience in specific CAM areas. We actively support research training by making awards to both institutions and individuals. Likewise, NCCAM supports mentored and independent trainees, from the pre-doctoral level through mid-career and senior faculty members. The research spectrum of these trainees is broad, covering the continuum of basic through clinical studies. NCCAM supports all of the major training mechanisms offered by NIH.

CONCLUSION

As the graying of America progresses, more of our citizens are choosing CAM approaches when conventional medicine fails to provide complete satisfaction. It is, therefore, imperative that we continue to expand our research portfolio, train researchers, and fund research studies to scientifically establish critical safety and efficacy information for dissemination to healthcare providers and consumers. I am confident that the results of our rigorous research will further enhance the successful integration of safe and effective CAM modalities into mainstream medical practice.

I am now happy to take your questions about these or any other of NCCAM's activities and plans.

PREPARED STATEMENT OF ALLEN M. SPIEGEL

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for fiscal year 2002, a sum of $1,457,915,000, which reflects an increase of $154,098,000 over the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Govern-

ment Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The NIDDK supports research on a wide range of chronic, debilitating diseases including diabetes; hepatitis and other liver diseases; inflammatory bowel disease; interstitial cystitis and other bladder conditions; prostatitis and benign prostate enlargement; several anemias; and polycystic kidney disease and other causes of end-stage kidney failure. The economic burden of these diseases accounts for a major portion of U.S. health care expenditures. Advances in biomedical research are critical if we are to mitigate the human and economic burden of these diseases. With the generous support Congress has provided, NIDDK-supported scientists are well positioned to identify the causes of the diseases within our mission, to help identify people at risk for development of these diseases, and, ultimately, to provide novel approaches to prevention and treatment.

DIABETES

One of the most important health care issues facing our Nation is the increasing burden of diabetes. According to the Centers for Disease Control and Prevention (CDC), diabetes affects an estimated 16 million Americans, one-third of whom are unaware they have the disease and are therefore untreated. An estimated 30 million additional Americans have a pre-diabetic condition known as impaired glucose tolerance. Within the last year, scientists have made tremendous progress in understanding and treating both type 1 and type 2 diabetes. Type 1, or juvenile diabetes, occurs when the body's immune system destroys the insulin-producing beta cells in the islets of the pancreas. Type 2 diabetes, previously called non-insulin dependent or adult-onset diabetes, results from the body's inability to respond to insulin effectively—a condition known as insulin resistance—followed by a failure of the beta cells to produce sufficient insulin.

People with type 1 diabetes must take regular insulin injections to survive. However, insulin represents only a treatment for type 1 diabetes, not a cure. Recent advances have created new hope for a cure for type 1 diabetes through pancreatic islet transplantation. The NIDDK is supporting several clinical trials to expand upon a promising study in which islet transplantation permitted a small number of people with type 1 diabetes to remain healthy for over a year without daily insulin injections. We are also supporting research on many aspects of beta cell development and function so that we can address the problem of the inadequate supplies of donor pancreatic tissue for transplantation, possibly by developing alternative sources of islet beta cells. In addition, we are supporting research on alternatives to lifelong immunosuppressive drug treatment currently required to prevent rejection of transplanted islets. One innovative approach uses a short course of therapy to teach the immune system to accept a transplant as "self," avoiding tissue rejection without global immunosuppression. Not only do these novel approaches to educating the immune system increase the likelihood of achieving a true cure for type 1 diabetes, they also offer hope of preventing the disease in those at risk. Trials of innovative prevention measures will be performed as part of our newly-created type 1 diabetes TrialNet.

Type 2 diabetes is a "complex genetic disease" with subtle changes in the function of several genes contributing to disease susceptibility. Despite the technical difficulties in identifying such gene changes, researchers studying a population of Mexican Americans who are particularly prone to type 2 diabetes identified changes in a gene—NIDDM1—that correlate with development of the disease. The product of this gene—calpain 10—is present in pancreatic islets, muscle, and liver—all tissues that are involved in insulin and glucose processing. Scientists have identified at least three other chromosomal regions whose products may interact with NIDDM1 to increase susceptibility to type 2 diabetes. Knowledge of the genetic basis for diabetes susceptibility paves the way to improved prevention and diagnosis by identifying individuals at risk, and to improved treatment by providing new targets for therapy.

Obesity is a major risk factor for type 2 diabetes. The alarming increase in the number of people who are overweight or obese in the U.S. population has led to a coincident increase in type 2 diabetes in adults, and even in children and adolescents. Successful control of body weight could therefore profoundly diminish the incidence of type 2 diabetes. In just the past few years, there have been major advances in our understanding of how weight is regulated. Scientists have identified many of the steps in a complex pathway that controls both appetite and metabolic rate. An imbalance in this regulation can lead to the accumulation of excessive body fat.

Until recently, the precise mechanism by which excess fat led to insulin resistance and type 2 diabetes was unclear. However, several recent advances have changed the way scientists view fat, and have underscored that fat—far from being an idle repository of excess energy—is in fact a dynamic tissue that produces a number of hormones with the potential to influence appetite and metabolism.

Leptin, a protein produced by fat cells that acts on the brain to suppress appetite, was discovered just six years ago, but has already entered clinical trials in humans. More recently, by "mining" mouse and human genome sequences, scientists have identified other hormones produced by fat cells that act on muscle and liver—the primary sites in the body of glucose metabolism and insulin action. For example, NIDDK grantees identified a protein produced by fat cells they termed "resistin," because it promotes insulin resistance. Obesity causes increased levels of resistin in blood, thus providing a direct link between excess body weight and the diminished insulin sensitivity often seen in overweight individuals. Another group of NIDDK-supported investigators identified another protein produced by fat cells—called Acrp30—that acts to increase fat metabolism in muscle, thereby promoting weight loss. Together, these studies indicate that fat cells produce hormones that may either promote or inhibit insulin responsiveness. Under normal circumstances, these two opposing signals keep each other in check. However, in obese individuals, this balance may be perturbed, and drugs that block or mimic these hormones may prove useful in both prevention and treatment of obesity and type 2 diabetes.

In addition to genetic susceptibility, the environment exerts an influence on the development of obesity and type 2 diabetes. The NIDDK is therefore supporting initiatives on environmental approaches to obesity prevention, including educational efforts. We are launching a major initiative aimed at prevention and treatment of type 2 diabetes in children and adolescents. A major multi-center clinical trial, the Diabetes Prevention Program (DPP), is testing the ability of lifestyle and drug intervention strategies to prevent type 2 diabetes in individuals with impaired glucose tolerance who are at high risk for the disease. The results of this trial, slated for completion in 2002, may have major public health implications for the prevention of type 2 diabetes.

Diabetes is the leading cause of end-stage kidney failure, new cases of blindness in adults, and non-traumatic lower limb amputations. It also causes increased susceptibility to urinary tract infections and a progressive form of fatty liver disease known as non-alcoholic steatohepatitis (NASH). Heart disease is the leading cause of death in diabetics, and the NIDDK is sponsoring a clinical trial—Look AHEAD—that will determine whether sustained weight loss in obese people with type 2 diabetes can reduce the incidence of cardiovascular complications. According to the American Diabetes Association, diabetes cost the country $98 billion in 1997, and over half of this expense was related to the disability, lost productivity, and early mortality associated with the disease. We know that prevention of diabetes, and where prevention is not possible, optimal management of the disease, not only alleviates human suffering but is cost-effective. For this reason, the NIDDK is exploring many avenues of prevention and treatment for diabetes and its complications, including basic genetic and molecular studies, development of animal models to facilitate testing of new drugs, therapeutic gene transfer techniques, and drug intervention trials. We are also increasing the resources available to our Diabetes Research and Training Centers to enhance efforts in diabetes prevention and treatment, and are expanding the National Diabetes Education Program (NDEP), which supports community-based multi-cultural efforts to increase diabetes awareness, to improve care of people with diabetes.

HEPATITIS C AND OTHER CHRONIC LIVER DISEASES

The NIDDK supports research on many other serious diseases, including liver disease arising from a range of causes. In the U.S., infection with the hepatitis C virus is a leading cause of liver failure and can lead to liver cancer. The newly-initiated HALT–C trial is testing whether long-term antiviral treatment can eliminate the hepatitis C virus in patients who fail to respond to conventional treatment. We are also initiating a trial of interferon treatment for hepatitis C in African Americans, whose disease is often resistant to the standard treatment regimen.

The NIDDK is also studying NASH, a disease characterized by fat deposition in the liver that can lead to inflammation, fibrosis, and cirrhosis. NASH is most often seen in overweight individuals and is associated with diabetes and insulin resistance. NIDDK plans a clinical research network to study the natural history, complications, and possible therapies for NASH. Whatever the precipitating cause, liver failure is ultimately only treatable currently through liver transplantation. Unfortunately, the need for donor livers far outstrips the supply of available organs. The

NIDDK organized a workshop in December 2000 to assess recent advances in adult-to-adult living donor liver transplantation. An important outcome of this meeting is the development of a research initiative for a prospective database to further knowledge about the consequences of living donor liver transplantation, both for the donor and the recipient.

INFLAMMATORY BOWEL DISEASE AND OTHER DIGESTIVE DISEASES

The NIDDK sponsors studies on the inflammatory bowel diseases (IBDs), ulcerative colitis and Crohn's disease, including efforts to identify their genetic and environmental causes. A contributing factor to both conditions is believed to be an inappropriate reaction by the body's immune system to the bacterial flora normally present in the gut. Previous research on mouse models of IBD led to the discovery of a factor responsible for gut inflammation, and ultimately to development of an antibody to neutralize this factor that has been shown to be effective in treatment of Crohn's disease. In recent studies, NIDDK-supported investigators have identified a strain of mice that spontaneously develop intestinal inflammation remarkably similar to Crohn's disease. They have shown that these mice can be efficiently used to test new treatments for the disease. In the future, the NIDDK plans an IBD Genetics Consortium to facilitate identification of susceptibility genes, and a clinical network to accelerate studies of prevention and treatment of IBD.

END–STAGE RENAL DISEASE AND POLYCYSTIC KIDNEY DISEASE

According to the United States Renal Data System, individuals with diabetes account for approximately 45 percent of patients with end-stage kidney disease. Because of this, the NIDDK is concentrating its efforts on preventing diabetic kidney disease and slowing its progression. The Institute is expanding the FIND (Family Investigation of Nephropathy and Diabetes) consortium to identify genetic loci and, ultimately, the specific genes that influence susceptibility to, and severity of, diabetic nephropathy. The Institute is also investigating the causes and possible new treatments for FSGS (Focal Segmental Glomerular Sclerosis), an important cause of kidney failure in children and young adults. The Institute plans a multi-center clinical trial to study treatment approaches for FSGS.

NIDDK support is also making a difference in understanding other important causes of irreversible kidney failure such as polycystic kidney disease (PKD). NIDDK-funded researchers are studying non-invasive means of assessing PKD progression, which will facilitate a planned clinical trial of drug intervention to slow progression. A new prospective observational study is aimed at understanding the factors responsible for the high incidence of heart disease in patients with end-stage kidney disease. Because folate lowers levels of homocysteine, a known risk factor for heart disease, we are also planning a clinical trial on the use of high doses of this vitamin in the prevention of heart disease in renal transplant recipients. We are also launching a National Kidney Disease Education Program to address the rising incidence of end-stage kidney disease, particularly in various minority groups.

UROLOGIC DISEASES

The NIDDK is sponsoring initiatives to promote understanding of a range of urologic diseases, including interstitial cystitis, benign prostatic hyperplasia (BPH), and chronic prostatitis. The Institute is working to organize a compendium of "Urologic Diseases in America" that will describe the changes in the epidemiology, health economic impact, and practice patterns for each of the diseases currently included within the scope of urology. The Institute has recently organized a Progress Review Group for Bladder Research to develop a future research agenda. We are also building on our Medical Therapy of Prostatic Symptoms (MTOPS) Trial with a national registry of prostate tissue samples that will allow urology investigators to harness genomic technology to study BPH and prostate cancer.

The NIDDK continues to pursue many approaches to combat the serious diseases within its mission in order to relieve the burden they place on individuals, families, and the Nation. I appreciate the opportunity to address the Committee, and I thank you for your attention. I look forward to answering any questions you might have.

PREPARED STATEMENT OF LAWRENCE A. TABAK, DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) for fiscal year 2002, a sum of

$341,898,000, which reflects an increase of $35,687,000 over the comparable fiscal year 2001 appropriation.

The first-ever Surgeon General's report on oral health was released last year, and the good news was that Americans as a whole have benefitted greatly from advances in disease prevention and health promotion in recent decades. Improvements in oral health because of research have saved the nation an estimated $5 billion a year in dental bills-an annual savings amounting to more than the cumulative funding for NIDCR since its inception in 1948.[1] Our work is not finished, however. Millions of Americans still experience pain and suffering from complex diseases affecting the mouth and face, including oral cancer, cleft lip and palate, dental caries (tooth decay), periodontal (gum) diseases, and temporomandibular disorders. More research is needed to understand the associations between oral infections and conditions such as diabetes and low birth weight. We also need new studies to help us understand and eliminate oral health disparities in this country. By funding cutting edge biomedical and behavioral research, NIDCR strives to fulfill our mission of improving oral health for all Americans.

REDUCING ORAL HEALTH DISPARITIES TO IMPROVE QUALITY OF LIFE FOR ALL AMERICANS

Scientific advances have led to substantial gains in the nation's oral health, but not all Americans have shared equally in these gains. Disparities in oral health exist at all ages and in many different population groups within our society. For example:

—Cancers of the mouth and throat, which kill about 8,000 Americans a year, take a disproportionate toll on African Americans, particularly men. African American men are one-third more likely than whites to be diagnosed with oral cancer, and their 5-year survival rate is only 28 percent, compared to a 53 percent survival rate for white men.[2]

—Dental caries, or tooth decay, is the most common chronic disease of childhood—five times more common than asthma and seven times more common than hay fever. Children from low-income families suffer twice as much dental decay as their better-off peers, and their disease is more likely to go untreated.[3]

—African American adolescents are 10 times more likely than white teens to suffer from early-onset periodontitis, a severe and rapidly progressive form of gum disease that destroys the bone supporting the teeth.[4]

The causes of these and other oral health disparities are not fully understood, but genetic, environmental, and behavioral factors all likely play a role. This year, NIDCR will establish Centers for Research To Reduce Oral Health Disparities. The centers will conduct a broad range of interdisciplinary research aimed at reducing health disparities. Much of this work will be focused on, and conducted in, the communities where the disproportionate disease burden is evident. The centers will provide ideal environments for training new scientists, particularly those from minority groups underrepresented in the scientific workforce. Because cross cutting research is essential for reducing health disparities, we are using mechanisms designed to encourage training in multidisciplinary research. Recognizing the need to establish the effectiveness of interventions for different population groups, we are also taking steps to ensure that all population groups are appropriately represented in clinical trials. These steps include providing investigators with the tools to facilitate community-based linkages for research. One advance with potential for application in community settings is the use of saliva-based diagnostic tests. Saliva, which is easier and less invasive to collect than blood, is already being used in a number of tests, and may provide a means of detecting diseases such as oral cancer at an earlier, more curable stage.

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[1] Brown, L.J., T. Beazoglou and D. Heffley. "Estimated Savings in U.S. Dental Expenditures, 1979–1989". *Public Health Reports*, 1994, 109, 195–203.

[2] Miller, B.A. et al, editors. Racial/Ethnic Patterns of Cancer in the United States, 1988–1992. National Cancer Institute, National Institutes of Health. NIH pub. No. 96–4104. Bethesda (MD): National Institutes of Health, 1996.

[3] National Center for Health Statistics 9NCHS). Third National Health and Nutrition Examination Survey (NHANES III) reference manuals and reports. Hyattsville, MD: NCHS, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, 1996.

[4] Albandar JM, Brown LJ, Loe H. Clinical features of early-onset periodontitis. *Journal of the American Dental Association* 1997 Oct;128(10): 1303–9.

CHRONIC INFECTIOUS DISEASES: DENTAL CARIES AND PERIODONTAL DISEASES

The most common oral diseases, and among the most prevalent of all chronic infectious diseases, are dental caries (tooth decay) and periodontal (gum) diseases. These diseases affect people throughout the life span, requiring lifelong attention by both the individual and health care providers. The Health Care Financing Administration estimates that dental expenditures by 2000 approached $60 billion, most of which was spent repairing teeth and periodontal tissues.

Dental caries and periodontal diseases are infections caused by bacteria that accumulate in the form of a "biofilm" on the surfaces of teeth and soft tissues. NIH and NIDCR recently sponsored a Consensus Development Conference on the diagnosis and management of dental caries that pointed to the need for earlier detection of dental decay to allow for more conservative intervention.

Long considered localized infections, periodontal diseases are now linked to a number of systemic diseases and conditions. For example, periodontal disease in pregnant women may contribute to the risk of delivering pre-term, low birth weight babies. The destructive inflammatory processes that define periodontal disease are also intertwined with diabetes. Periodontal diseases are exacerbated in individuals with uncontrolled diabetes, and researchers are examining the effects of periodontal infections on blood sugar control. These and other interrelationships were highlighted at a recent symposium co-sponsored by the NIDCR entitled "The Periodontal-Systemic Diseases Connection."

RESEARCH CREATES NEW MATERIALS FOR REPLACING AND RESTORING DAMAGED TISSUES

As people continue to live longer, the demand increases for "new parts" to repair or replace those lost to disease, injury, and wear-and-tear. Each year, millions of Americans suffer some type of tissue loss or end-stage organ failure, at a cost of more than $400 billion annually.[5] Included in these figures are millions of dental, oral, and craniofacial procedures, ranging from tooth restorations to major reconstruction of facial tissues.

Biomimetics (literally, to mimic biology) and tissue engineering are new disciplines that have emerged to meet the challenge of rebuilding the body. In the same way that Velcro inventor George de Mestral imitated the natural adhesion of burrs, biomimetics researchers take cues from nature to design "bio-inspired" materials. For example, NIDCR-supported scientists have created a biomimetic material that promotes bonding of bone-forming cells to artificial surfaces, an achievement with tremendous potential for improving dental and orthopedic implants. Poor bonding to surrounding bone is one of the biggest reasons for dental implant failure. The researchers synthesized a material that mimics a natural binding site for bone-forming cells; when an artificial surface is coated with the material, bone-forming cells respond by building new bone around the surface, creating a strong bond.

Using the new technology of tissue engineering, NIDCR researchers are developing an artificial salivary gland that could restore salivary flow to patients whose own glands are destroyed by disease or radiation therapy for head and neck cancers. Currently no effective treatments exist for these patients, whose quality of life is severely compromised by difficulties in chewing, swallowing, and speaking and by an increased risk of rampant tooth decay and other oral infections. The NIDCR scientists are creating a small tube that could be implanted in a patient's cheek. The tube will be lined with cells engineered to secrete a saliva-like fluid. The artificial salivary gland could be ready for clinical testing within 5 to 7 years.

GENETIC RESEARCH IS KEY TO UNDERSTANDING CRANIOFACIAL DISORDERS

Genetic research by NIDCR scientists is revealing the basis for a number of craniofacial birth defects, offering hope to thousands of Americans who suffer pain, dysfunction, and emotional consequences from malformations of the mouth and face. Cleft lip, with or without cleft palate, is among the most common of human birth defects, affecting 1 in 1,000–2,500 newborns. Most cleft disorders-in which the lip or palate fail to fuse properly-occur alone, although they may also be part of birth defect syndromes that affect many organs and tissues. Many cleft disorders are caused by single gene mutations. NIDCR-supported scientists recently identified a gene called PVRL1 as the cause of one form of cleft lip/palate. The gene codes for a cell surface adhesion protein called nectin–1. In mice, this protein aids in the development of the palate, teeth, and skin—the same tissues that are malformed in humans with a mutation in PVRL1. Other NIDCR-funded researchers have found

[5] Langer, R. and Vacanti, J.P. "Tissue Engineering", Science, May 14, 1993, 260. 92.

that a mutation in a gene called PAX9 results in missing molar teeth. Their work may lead to a better understanding of congenital disorders in which teeth fail to develop. Approximately 20 percent of the population is born unable to develop a full set of permanent teeth.

INVESTIGATING THE ORAL CAVITY'S CONTRIBUTION TO DEFENDING THE BODY AGAINST HIV INFECTION

The specific factors that result in relatively high rates of HIV–1 transmission by breast milk but minimal rates of transmission by saliva are not known. Therefore, studies of oral defense systems may prove instructive for development of new preventive strategies for HIV infection. One intriguing finding is that saliva consistently exhibits anti-retroviral activity, whereas breast milk only displays this property when collected during the first three weeks after childbirth. The potentially important anti-retroviral activity appears to be lost three weeks postpartum. While many factors likely contribute to the anti-retroviral activities observed in saliva and breast milk, one factor, called secretory leukocyte protease inhibitor (SLPI), is found at high levels in saliva. While SLPI levels are high in breast milk at birth, this antimicrobial substance virtually disappears from the milk three weeks after delivery. Despite the risk of HIV–1 transmission from breast-feeding, the risk of death from malnutrition for nonbreast-fed children in many parts of the world has resulted in controversial recommendations about breast-feeding. Studies on the timing of postnatal transmission of HIV–1 and the innate protective correlates may provide a better understanding of a "safer" window of breast-feeding and the specific roles of anti-retroviral substances in natural secretions that could be exploited as future therapies.

NEW METHODS NEEDED TO TREAT CHRONIC PAIN AND TEMPOROMANDIBULAR DISORDERS

Most people have experienced some form of oral-facial pain. A variety of painful facial conditions may interfere with vital functions such as eating or speaking. NIDCR scientists are continuing to develop novel approaches to selectively block pain receptors in the body. A recent study in an animal model makes use of gene therapy to deliver a message to cells that "tricks" them into producing reduced levels of pain receptors on their surfaces. If similar techniques can be designed to work in humans, this approach may benefit chronic pain patients.

Various factors, including trauma, can give rise to pain and dysfunction in the temporomandibular joints and surrounding muscles—conditions collectively called TMD. The multiplicity of factors that may cause or contribute to TMD has unfortunately led to an even greater number of treatments that have not been validated. NIDCR is conducting clinical trials looking at the effects of conservative versus surgical interventions, with preliminary findings indicating that surgical interventions offer no increased benefits. To address the needs of patients who require joint replacement, NIDCR is conducting basic research on engineering more biocompatible implants. Given the complexity of TMD and the need to approach this condition in a multidisciplinary manner, the Institute established the TMD Interagency Working Group to facilitate progress in dealing with these disorders through cooperation, communication, and collaboration among the many Federal agencies that conduct or support TMD-related research and direct provision of health care services.

GOVERNMENT PERFORMANCE AND RESULTS ACT

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) Of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

I became Director of NIDCR eight months ago with great enthusiasm about the opportunities to make a difference in improving the nation's oral health through biomedical research. As NIDCR Director, one of my main goals is to accelerate our progress toward relieving the burden of the many chronic and costly diseases that affect the mouth and face. Having been an NIDCR grantee for many years, I knew before arriving how important the Institute is to the scientists who conduct oral, dental, and craniofacial research and to the well being of the people of this country. Seeing it work from the inside has given me a new appreciation for the organization, its talented and dedicated staff, and the role of the Institute nationally and internationally.

Thank you for the opportunity to provide you with information on NIDCR's research efforts.

PREPARED STATEMENT OF DR. JUDITH L. VAITUKAITIS, DIRECTOR, NATIONAL CENTER FOR RESEARCH RESOURCES

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the National Center for Research Resources (NCRR) for fiscal year 2002, a sum of $974,038,000, which reflects an increase of $156,785,000 over the fiscal year 2001 appropriation.

It is a pleasure once again to have the opportunity to present the accomplishments of NCRR-supported research and future directions for NCRR programs. With the human genome and several others essentially sequenced, biomedical research is entering a new age. Up until now, biomedical science has benefitted greatly from a reductionist perspective which examines single genes or their encoded macromolecules to determine the cause of disease. But today, new research technologies enable scientists to pry ever deeper into the cell to uncover the structural and functional secrets of the ribosome which serves as the cell's protein factory and also to find hundreds of disease-associated proteins. With advanced technologies investigators have discovered defective membrane potassium channels responsible for some forms of epilepsy or abnormal heart rhythms that may be fatal if the genetic abnormalities resulting in altered potassium channel function are not detected and treated.

Sophisticated biomedical research now frequently requires a multidisciplinary approach with teams that include physician-investigators, physicists, bioinformaticists, physical chemists, structural biologists, and others. The research team must not only take full advantage of existing novel research tools but must also develop novel ones to solve new complex research problems.

To facilitate this new paradigm for research, NCRR's programs need to modify or generate new, more sophisticated resources to enable research in the 21st century. NCRR provides the critical research infrastructure that enables all lines of biomedical inquiry, from the molecular level to the whole organism. Specially adapted clinical research facilities assure that the fruits of bench research reach the patient. The network of NCRR's General Clinical Research Centers (GCRCs) require sophisticated core laboratories and bioinformatics tools to facilitate research. To foster multisite research collaborations, NCRR supports development of web-based research networks for clinical trials and research on the molecular and other causes of disease.

To enhance access to costly technologies, NCRR works in partnership with other Federal agencies, such as the Department of Energy and the National Science Foundation (NSF). For decades, NCRR has funded a substantial research effort to improve x-ray crystallography techniques. NCRR has been a pivotal player in developing very high intensity x-ray sources for biological research at the national synchrotron facilities, through cooperative approaches with DOE and NSF staff. The nation's synchrotron facilities are critical for ascertaining the structures of biological molecules encoded by thousands of genes. With the incorporation of robotics, newer imaging technologies along with methods to automate data collection and processing, an appropriately equipped research resource may conduct more than one hundred thousand crystallization experiments per day! Using NCRR research resources, studies in the past required years of effort, will be accomplished in a week!

NCRR also supports programs to enhance the research capabilities of minority-serving graduate institutions through the Research Centers in Minority Institutions (RCMI) program. Separately, through the Institutional Development Award (IDeA) program, NCRR provides funding for capacity building for biomedical research in those States which have not previously participated fully in the research programs of the NIH. The current cohort of 23 IDeA-eligible States and Puerto Rico receives about five percent of NIH grant funds annually.

GENOMICS AND GENETIC MEDICINE

To determine the genetic causes of diseases, large numbers of patients must be screened for specific gene variants. NCRR proposes to support national genotyping laboratories to provide a cost-effective, high throughput approach. Genotyping attempts to find nucleotide substitutions at specific points, or loci, within a gene that may be defective and cause disease. In addition, NCRR proposes to expand the capacities of its mouse mutant regional resource centers network to accommodate a rapidly expanding pool of mouse mutants and to support a web-based catalog of their genetic variants and physical characteristics or phenotype. The mutant mouse

network's catalog will facilitate investigator access to mouse mutants needed for their research.

Scientists today urgently need improved or new technologies to study the thousands of proteins that interact with one another to make a cell function as a tightly controlled unit. This complex research requires an integrated or systems approach. In response, NCRR proposes to develop and support comprehensive Integrated Biomedical Technology Resource Centers, where multiple complementary technologies examine the inner workings of both healthy and diseased cells. Research areas that can be facilitated through integrative approaches include those for proteomics, imaging, structural biology and glycobiology.

NCRR proposes to develop the rhesus macaque as an nonhuman primate model of genetic disease in humans. In collaboration with the National Human Genome Research Institute, NCRR will provide support for the development of BAC (Bacterial Artificial Chromosome) libraries as well as for genetic and radiation hybrid maps. New technologies have made it theoretically possible to selectively modify genes of nonhuman primates to create defects that mimic human diseases, such as cystic fibrosis. Studies will also address how risk factors modulate gene function in polygenic disorders such as type 2 diabetes mellitus and hypertension.

BIOENGINEERING, BIOIMAGING, AND BIOINFORMATICS

Today's biomedical research depends on sophisticated research technologies more so than in the past. NCRR proposes to increase support for instruments in the $100,000 to $500,000 range through its Shared Instrumentation Grant (SIG) Program. The off-the-shelf instruments in greatest demand through the SIG program include confocal microscopes, NMR spectrometers, cell sorters, mass spectrometers and protein/DNA sequencers. To address the broad research community needs of the instrumentation that costs between $500,000 and several million dollars, NCRR proposes to initiate a new program to provide advanced instrumentation that includes very-high-field NMR spectrometers, synchrotron facilities, mass spectrometers, cryoelectron microscopes, and high-performance supercomputers.

To further enhance the national infrastructure for biomedical research, NCRR will establish a biomedical imaging research network (BIRN) test bed for development of hardware, software, and protocols to effectively share and mine data in a site-independent manner for both basic and clinical research. For this undertaking, NCRR has teamed up with the San Diego Supercomputer Center, one of three National Science Foundation-supported centers for advanced computational infrastructure, to provide biomedical investigators access to sophisticated modeling and computational tools. Other partners include the NSF, University of California at San Diego and several NIH Institutes along with seven institutions with NCRR-supported general clinical research centers, co-located with imaging technology centers. The BIRN will include image data with high-bandwidth requirements, as well as genomic, structural, and gene expression data. The BIRN will be designed so that it can be readily expanded to meet the evolving needs of basic and clinical investigators across a network of resource centers that provide access to specialized research facilities, repositories and regional core facilities to enable research nationwide.

NEW PREVENTIVE STRATEGIES AGAINST DISEASE

Not all research advances lie in medical genetics. Scientists have observed recently that transplantation of insulin-producing human pancreas cells, called islet cells, to patients with type I diabetes can free them from the need for insulin injections. But to get a sufficient supply of these scarce and difficult-to-isolate cells, cell-harvesting efficiency and islet cell stability need to be optimized. To pursue these very promising results, which eventually may provide a cure for type I diabetes, NCRR—together with the National Institute of Diabetes and Digestive and Kidney Diseases and the Juvenile Diabetes Research Foundation International-will establish several Islet Cell Resource Centers to optimize the isolation, purification, and function of islet cells for transplantation into patients with type I diabetes.

As clinical research becomes more complex and promising new therapies are evaluated, more attention to the safety of research subjects must be taken. The NCRR will provide support for a Research Subject Ombudsman (RSO) at each General Clinical Research Center (GCRC) and RCMI Clinical Research Center to ensure that the research subject monitoring plan at these resources is fully implemented and carried out according to the Institutional Review Board-approved protocol. The Ombudsman will also ensure that investigators report serious adverse events within a required time frame to appropriate agencies, offices or Boards. Th RSO will also keep patients and volunteers informed about the research projects and clinical trials in which they participate.

HEALTH DISPARITIES

To address the health concerns of minority populations, NCRR proposes to establish Comprehensive Centers for Health Disparities Research at minority-serving medical schools associated with the NCRR-funded Research Centers in Minorities Institutions. These Centers will further develop their medical schools' capacities to conduct basic and clinical research on type II diabetes and cardiovascular disease, which disproportionately affect minority populations. The Centers will support further development of the host institution's research infrastructure, including laboratories, faculty recruitment of established clinical investigators and development of promising junior faculty. Collaboration with nearby research-intensive universities will be strongly encouraged. To further strengthen these minority institutions, NCRR also proposes to establish a Web-based clinical trials network for minority-serving institutions. This new network will better position minority-serving medical schools to more fully participate in NIH-supported research, including multi-site clinical trials that address diseases that disproportionately affect minorities and underserved populations.

RESEARCH TRAINING AND CAREER DEVELOPMENT

Proper training in research methodology is essential for young scientists. NCRR proposes to initiate new mentored programs for medical and veterinary students to develop their research skills and pique their interests in research careers to enhance the pool of well-trained young physicians and veterinarians who will become the independent investigators for tomorrow's health-related research.

In addition to expanding support for the Mentored Patient-Oriented Research Career Development Award (K23), NCRR proposes to initiate a new career development program for physicians and dentists through a mentored institutional Clinical Research Scholars (CRS) program. That CRS pilot program will be phased in over several years at approximately ten institutions. The flexible program will provide tuition support for didactic courses, leading to an M.S., Ph.D. or M.P.H. degree. The CRS program support for candidate development of clinical and bench patient-oriented research skills in a mentored setting is central to this new program. The long term CRS program goal is to enhance the pool of high quality independent clinical investigators.

RESEARCH CAPACITY

Adequate, up-to-date facilities are indispensable for biomedical research, but according to a 1998 NSF survey, biomedical research institutions had to defer $5.6 billion for needed construction and renovation projects. The greater biocomplexity of modern research requires state-of-the-art research facilities. The NSF survey estimated that less than half of existing research facilities could conduct sophisticated biomedical research. Through the NIH Research Facilities Improvement Program, NCRR will expand its support to help address this need.

Modern research facilities are also needed to provide care and housing for chimpanzees that were originally bred for AIDS research. So far, chimpanzees have not proven to be suitable models for studies of AIDS pathogenesis, but they are essential for studies of respiratory syncytial virus, hepatitis, malaria, and possibly for AIDS vaccine and gene vector development. To consolidate the NIH-supported chimps into just two or three sites, animal housing must be constructed to provide cost-effective facilities that will assure the well-being and safety of the animals and people who work with them. Funding to construct a chimpanzee sanctuary system is also needed to accommodate chimpanzees no longer eligible or required for research.

NCRR proposes to increase the level of support for the Animal Facilities Improvement Program. About half of all NIH research grants include animal research models and institutions need to build specially adapted, modern research facilities to accommodate these genetically altered rodents. A special initiative to upgrade the research animal facilities of minority graduate and health profession schools will be continued to help those institutions meet PHS standards and receive accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (International).

Through the Biomedical Research Infrastructure Network (BRIN), the NIH's Institutional Development Award program enhances the educational infrastructure and research capacities of institutions within 23 eligible States and Puerto Rico. The BRINs provide support for laboratory renovation and scientific equipment, as well as the recruitment and support of faculty at eligible institutions. In fiscal year 2002, NCRR proposes to further develop the BRINs that were initially established in fiscal

year 2001. In addition, those States that did not receive a BRIN award in fiscal year 2001 will have a special opportunity to compete for this award in fiscal year 2002.

The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

My colleagues and I will be happy to respond to any questions you may have.

PREPARED STATEMENT OF JACK WHITESCARVER, PH.D. ACTING DIRECTOR, OFFICE OF AIDS RESEARCH

Mr. Chairman and Members of the Committee: I am pleased to present the President's budget request for the AIDS research programs of the NIH for fiscal year 2002, a sum of $2,501 million, an increase of $258 million above the comparable fiscal year 2001 appropriation. The NIH budget request includes the performance information required by the Government Performance and Results Act (GPRA) of 1993. Prominent in the performance data is NIH's second annual performance report which compares our fiscal year 2000 results to the goals in our fiscal year 2000 performance plan. As performance trends on research outcomes emerge, the GPRA data will help NIH to identify strategies and objectives to continuously improve its programs.

The National Institutes of Health (NIH) represents the largest and most significant single public investment in AIDS research in the world. It supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies to better understand the basic biology of HIV, develop effective therapies to treat it, and design interventions to prevent new infections from occurring. This research is conducted through intramural and extramural studies in the U.S. and around the world, sponsored by nearly all of the NIH Institutes and Centers. Each NIH component supports HIV/AIDS-related research activities, consistent with its individual mission. It is the role of the Office of AIDS Research (OAR) to plan and coordinate this research, setting the scientific agenda and the budget necessary for this large and diverse NIH AIDS research program.

THE EXPLODING PANDEMIC

The AIDS pandemic is the greatest international challenge of our generation. HIV has infected more than 50 million people around the world. AIDS already has killed more than 21 million people, surpassing tuberculosis and malaria as the leading infectious cause of death worldwide, according to data released by the Joint United Nations Programme on HIV/AIDS (UNAIDS) in the "AIDS Epidemic Update: December 2000" and the World Health Report 2000 of the World Health Organization (WHO). (Chart 1)

The impact of AIDS on developing nations and many former communist countries is staggering, with even greater potential disaster to come. AIDS is reversing decades of progress from important public health efforts, lowering life expectancy, and significantly affecting education, food supplies, and international businesses. Lost productivity and profitability, the cost of sickness and death benefits, and the decline in a skilled workforce in the developing world will have economic effects worldwide. AIDS is affecting the military capabilities of some countries as well as the international peacekeeping forces. In Africa, the epicenter of the pandemic, AIDS is killing ten times as many people as war, sabotaging economic development, leading to massive social breakdown, and creating a generation of orphans. (Chart 2)

If the global spread of HIV/AIDS continues unchecked, South and Southeast Asia, and perhaps China will follow the disastrous course of sub-Saharan Africa. Rapid increases also are occurring in Eastern Europe and Central Asia, and AIDS remains a serious threat in Latin America and the Caribbean. During the year 2000, more new HIV infections were registered in the Russian Federation than in all previous years of the epidemic combined.

THE EVOLVING EPIDEMIC IN THE UNITED STATES

In the United States, the HIV/AIDS epidemic continues to evolve. Although the incidence of new AIDS cases has declined, attributed largely to expanded use of new antiretroviral therapies that prevent progression of HIV infection to AIDS, the decline in death rates observed in the late 1990s has leveled off. Further, according

to the Centers for Disease Control and Prevention (CDC), the rate of new HIV infections has been constant at approximately 40,000 new cases each year since 1990, meaning that the overall epidemic is continuing to expand. In fact, HIV infection rates are continuing to climb in a number of subpopulation groups, such as women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age. The appearance of multi-drug resistant strains of HIV presents a serious public health concern. These data forebode an epidemic of even greater magnitude in the coming years, and they shape our most urgent research priorities.

COMPREHENSIVE AIDS RESEARCH PLAN AND BUDGET

The OAR develops an annual comprehensive trans-NIH AIDS research plan and budget to address these priorities, based on the most compelling scientific opportunities that will lead to better therapies and prevention for HIV infection and AIDS. The planning process is inclusive and collaborative, involving the NIH institutes as well as non-government experts from academia, foundations, and industry, with the full participation of AIDS community representatives. The plan provides objectives and strategies for the five Scientific Areas of Emphasis of AIDS research: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science; as well as for key Areas of Special Interest, which cross-cut all of the scientific areas: Racial and Ethnic Minorities; International Research Priorities; Training, Infrastructure, and Capacity Building; and Information Dissemination. This year, the OAR also led an NIH effort to develop a strategic plan for microbicide research, which will become an integral part of the overall plan. In addition, the fiscal year 2003 plan, now underway, will include a new section devoted to research priorities for AIDS in Women and Girls. The Plan serves as the framework for developing the NIH AIDS budget for each Institute and Center, for determining the use of NIH AIDS-designated dollars, and for tracking and monitoring those expenditures.

Four major themes frame the fiscal year 2002 NIH Plan for HIV-Related Research: prevention research to reduce HIV transmission here in the United States and around the world; therapeutic research to treat those who are already infected; international research priorities, particularly to address the critical needs in developing countries; and research targeting the disproportionate impact of AIDS on minority populations in the United States. All of these efforts require a strong foundation of basic science, the bedrock of our research endeavor.

PRIORITY: PREVENTION RESEARCH

The transmissible nature of HIV makes it radically different from non-transmissible diseases such as heart disease and cancer. The transmissibility of HIV—between individuals and across borders and populations—is what most defines the global pandemic and makes it imperative that the U.S. help address prevention and treatment needs worldwide. The transmissibility of the infection means that there is the potential for unlimited global spread. But it also means that, with the development of appropriate biomedical and behavioral interventions, there is the possibility for dramatic reductions in new infections—and ultimate control of the pandemic—in a way that will not be possible for noninfectious diseases.

NIH supports a comprehensive approach to HIV prevention research that includes contributions from the biomedical, behavioral, and social sciences. The OAR prevention science research agenda targets interventions to both infected and uninfected at-risk individuals to reduce HIV transmission. Our biomedical prevention research priorities include the development of topical microbicides, strategies to prevent perinatal transmission-including a better understanding of risk associated breastfeeding-and management of sexually transmitted diseases. NIH also supports behavioral research strategies, including prevention interventions related to drug and alcohol use and risky sexual behaviors. Efforts continue to identify the most appropriate intervention strategies for different populations and sub-epidemics in the U.S. and around the world.

PRIORITY: VACCINE RESEARCH

A safe and effective HIV preventive vaccine is essential for the global control of the AIDS pandemic. NIH funding for HIV vaccine research increased by more than 170 percent between fiscal year 1997 and fiscal year 2002, resulting in the award of new grants to foster innovative research on HIV vaccines, including vaccine design and development, and the invigoration and reorganization of the NIH vaccine clinical trials effort. (Chart 3) Construction of the new intramural Vaccine Research Center has been completed. In February 1999, NIH-supported investigators initiated

the first AIDS vaccine trial in Africa. The investment in this area over the past few years will have enormous significance, not only for AIDS research but for other diseases as well, as progress made in the development of an AIDS vaccine will have implications for vaccines against other life-threatening illnesses.

PRIORITY: TREATMENT RESEARCH

Today, many HIV-infected people are living with the benefits resulting from NIH-supported research in this area. The development of combination regimens including protease inhibitors has extended the length and quality of life for many HIV-infected individuals in the United States and Western Europe. Unfortunately, however, highly active antiretroviral therapy (HAART) has failed to eradicate HIV, and a growing proportion of patients receiving therapy experience treatment failure. Some patients find it difficult or impossible to comply with arduous treatment regimens, develop toxicities and side-effects, or cannot afford their high cost of approximately $15,000 per year. Others fail to obtain a satisfactory reduction in viral load even while adhering to treatment regimens. In addition, metabolic complications, including insulin resistance, and body composition changes such as deforming deposits of abdominal adipose tissue, have emerged in individuals who have been on long-term antiretroviral regimens. Finally, an increasing number of treatment failures are linked to the increasing emergence of drug-resistant HIV. Thus, the need for simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated opportunistic infections (OIs), malignancies, and other complications, continues to be a high priority. (Chart 4)

PRIORITY: INTERNATIONAL RESEARCH

To address the increasing urgency of the global AIDS pandemic, the OAR has established a new initiative and strategic plan for global research on HIV/AIDS aimed at slowing the disaster and reversing its destruction of communities, economies and nations worldwide. The Global AIDS Research Initiative and Strategic Plan reaffirms NIH's long-standing commitment to international AIDS research and will significantly increase research efforts in the coming year to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted as well as people affected by HIV/AIDS worldwide. It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To that end, NIH supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries where the research is conducted.

PRIORITY: RACIAL AND ETHNIC MINORITIES

Research to address the disproportionate impact of the HIV/AIDS epidemic on U.S. racial and ethnic minority communities (Chart 5) continues to be a high priority. We are directing increased resources toward new interventions that will have the greatest impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities, and we will continue to assure the participation of minority subjects in AIDS clinical trials as well as in natural history, epidemiologic, and prevention studies. OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research. One of these projects is a series of Training and Career Development Workshops for racial and ethnic minority investigators.

PRIORITY: BASIC SCIENCE

Of paramount importance in our fight against HIV/AIDS is maintaining a strong commitment to basic research. Tremendous progress has been made in understanding the fundamental steps in the life-cycle of HIV, the host-virus relationship and the clinical manifestations attending HIV infection and AIDS. Groundbreaking research on basic HIV biology and AIDS pathogenesis has revolutionized the design

of drugs, the methodologies for diagnosis, and the monitoring for efficacy of antiviral therapies. Thus, OAR will continue to devote a substantial portion of NIH AIDS-related research funds to fundamental biomedical, behavioral, and social science research.

SUMMARY

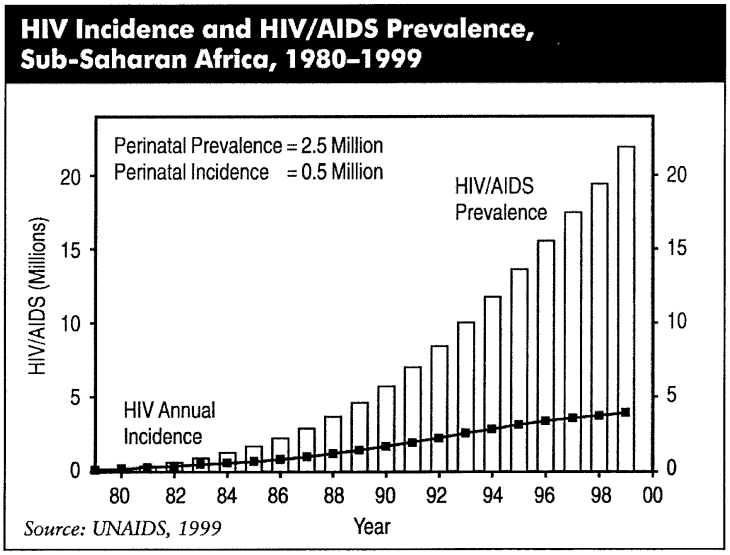
The worldwide human and economic toll of this insidious disease is profound, and we will never solve the problem of AIDS for our own citizens without controlling the epidemic in the rest of the world. The nation's investment in AIDS research is reaping even greater dividends, as AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune and metabolic diseases. We deeply appreciate the support of this Committee for our efforts.

THE EXPLODING GLOBAL HIV/AIDS PANDEMIC

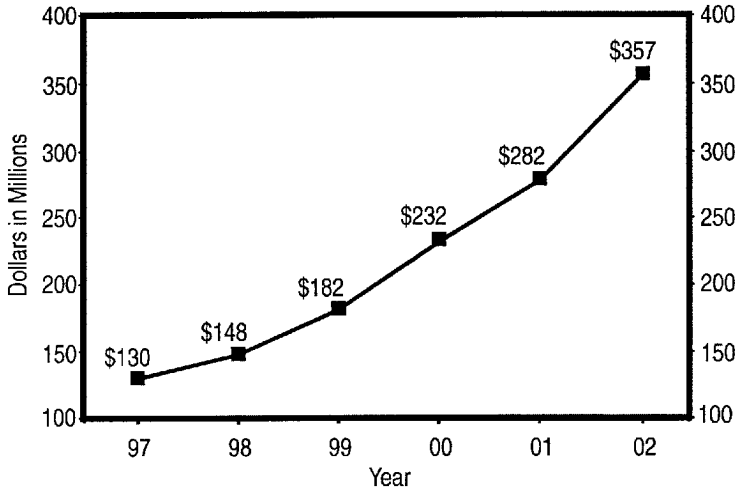
[In millions]

Group	People newly infected in 2000	People living with HIV/AIDS	AIDS deaths in 2000	Total AIDS deaths
Adults	4.7	34.7	2.5	17.5
Women	2.2	16.4	1.3	9.0
Children	.6	1.4	.5	4.3
Total	5.3	36.1	3.0	21.8

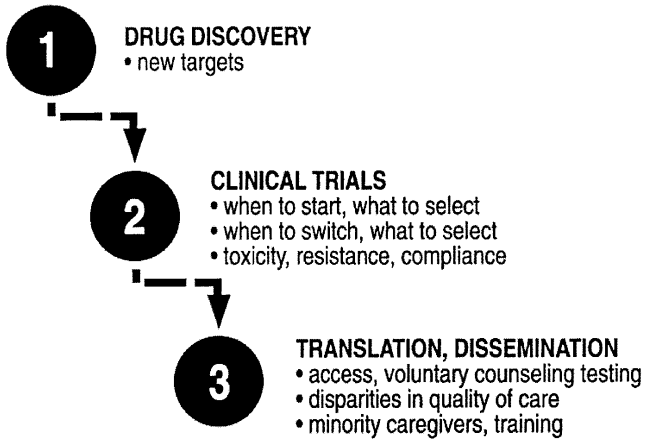
Source: UNAIDS

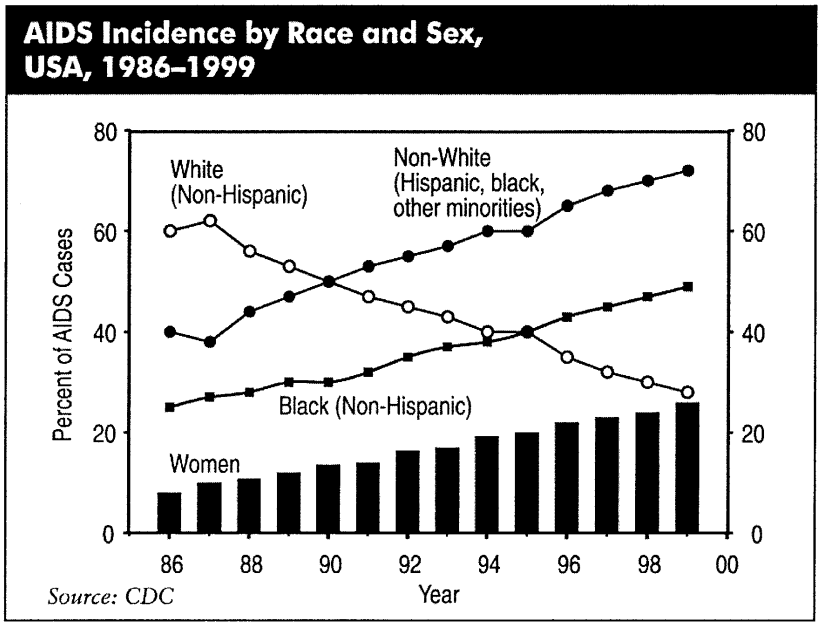


Funding for Vaccine Research



AIDS Therapy: Drug Discovery and Clinical Trials





Senator SPECTER. We have been joined by my distinguished colleague, Senator Thad Cochran.

Senator Cochran, do you care to make an opening statement?

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Well, Mr. Chairman, thank you. I join you in welcoming Dr. Kirschstein thanking her in joining us for this discussion of the budget for the fiscal year 2002 for NIH.

I think she deserves our commendation, too, for her service to the National Institutes of Health, particularly during this recent transition period, but this budget is a very important step toward our goal of doubling the NIH budget by the year 2003. It addresses very oppressing health needs in our country, and around the world, as a matter of fact.

There are two areas I hope to see the Institutes address during this year. We have to deal with the disparities in under-served areas of our country, as well as funding disparities. The IDeA program is one way of enhancing research effort in my part of the country, where NIH research has not traditionally been conducted. It is interesting to note that these are also some of the same areas with glaring health disparities. The IDeA program has the potential to improve the health of millions of needy patients in these areas.

An additional area of concern for me is bio-imaging and radiology research. The newly authorized National Institute of Bio-Imaging and Bio-Engineering will require a transfer of existing radiology and bio-engineering research to this new institute. We are looking forward to working with you and helping to provide you the benefit

of our counsel and advice. Thank you again for being here, and for your dedicated work for millions of Americans.

Thanks, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Cochran.

Dr. Kirschstein, a question which is repeatedly posed to me by my colleagues is, are we providing too much money too fast to the National Institutes of Health. What are your best assurances, as specific as you can be, that this rapid increase in your budget is being put to good use?

Dr. KIRSCHSTEIN. Mr. Chairman, the scientific opportunities are immense, and they have been for some time. The increases that the Congress has provided to the National Institutes of Health have been put to extraordinarily good use over the last several years.

Programs in clinical research that could not possibly be started before have been begun, in drug abuse, in heart disease, new testing of vaccines, new testing of therapies for HIV AIDS, new studies in cancer. Dr. Klausner can describe several new drugs that have been developed, as can all my colleagues.

The momentum is there. What is needed is to continue to make progress, because every question that is answered leads to several more questions that need to be answered, and this is a moment of enormous opportunity.

Senator SPECTER. Is $3.4 billion sufficient to utilize and follow all of the existing leads?

Dr. KIRSCHSTEIN. Mr. Chairman, I think that the increase that the administration has given us is very fine, indeed. It is 13.5 percent, $3.4 billion would be even more, clearly, but I think we could use those funds extremely well. We have investigators who are full of burgeoning ideas. We have clinical trials that we want to do.

We need to do some work in the states that Senator Cochran is talking about. Our BRIN program has been started, and the Senator knows. I came down and saw him last week, and we have all sort of wonderful opportunities. I would like to give my colleagues a chance to tell you about them, if possible.

Senator SPECTER. You pick the first colleague to give us as specific an illustration as he or she can as to what this additional funding has meant.

Dr. KIRSCHSTEIN. Dr. Klausner.

Senator SPECTER. We heard from Dr. Klausner 10 days ago, and we know his answers.

Dr. KIRSCHSTEIN. In that case, I will go to Dr. Lenfant. Either way.

Senator SPECTER. Go ahead, Dr. Klausner.

Dr. KLAUSNER. Senator, just in case you forgot, over the last couple of years, with the increase in funding, we have been able to do a variety of things, including beginning to change the entire way cancer is diagnosed, as we talked about a few weeks ago, switching from a hundred years of pathologic diagnosis alone, to the new molecular diagnosis.

We are suddenly discovering rapidly that there are new types of cancers that we only imagined exist, we now see exist. For the first time, with that, we can align therapies to the appropriate diagnosis.

Senator SPECTER. Dr. Klausner, you testified at the hearing on breast cancer about the impact of stem cells. I think it would be good for you to summarize that here this morning.

Dr. KLAUSNER. Yes. What I pointed out is that in cancer we believe that there are two types of opportunities in stem cells. Of course, in cancer research we have been using stem cells to replace organs, generally, the bone marrow, that are damaged, either because of disease, or, more commonly, therapy.

The two areas of promise with stem cell research for cancer are, one, understanding the fundamental biology which underlies cancer, and that is, how do cells make the decision to either keep proliferating, or to differentiate. That fundamental switch which underlies stem cell biology is, we believe, fundamental to understanding the switches that lead to cancer cells.

The other issue in cancer is the fact that until we have better therapies currently, cancer itself, or the therapies, are often quite destructive of tissues, or particular organs, and stem cells, as they have been used successfully in cancer therapy, hold the promise of regenerative approaches to deal with the damage due to therapy or the disease.

ADULT STEM CELL EXPERIMENT

Senator SPECTER. Dr. Lenfant, I am turning to you next. As Dr. Kirschstein suggested. Thank you for the response to my letter, in which you had pointed out that in the next 5 years it's projected that there will be an ability to engineer tissues for damage heart valves, muscles, and blood vessels, and the delivery of therapeutic genes, and in 10 years, projecting complete heart ventricles, regeneration of cardiac tissue, and organ growth in infants born with cardiovascular malformations. That is very good news, indeed. To what extent do the stem cells play a part in that?

Dr. LENFANT. Well, so far, Mr. Chairman, we have been developing a fairly significant experiment in the use of adult stem cells and the results have been extraordinarily exciting and significant, as to what you were mentioning, the recreation of tissues which have been damaged, and quite successfully in the formation of new valves, new blood vessels. And in the case of, say, heart failure, which is the ultimate complication, so to speak, of the repeated heart attack, we can now regenerate some heart cells, and restore some of the functionality of the myocardium, which has been damaged by a repeated heart attack.

Senator SPECTER. Why do you particularize adult stem cells, Dr. Lenfant?

Dr. LENFANT. Excuse me?

Senator SPECTER. Why did you specify adult stem cells?

Dr. LENFANT. Because so far that is the only experience that we have, Mr. Chairman.

Senator SPECTER. Have you not had stem cells available from embryos?

Dr. LENFANT. No. No. Not in our areas of research. They have not been used.

EMBRYONIC STEM CELL POTENTIAL

Senator SPECTER. We have had expert testimony that embryonic stem cells offer a great deal more flexibility and ability to differentiate that is much superior to adult stem cells. Would you agree with that?

Dr. LENFANT. Yes, I would agree with that. In my scientific opinion, it is something that needs to be explored, but so far it has not been done, and all the comments that I can make are on the basis of what we have learned from other stem cells.

Senator SPECTER. Well, I think it is very good news, indeed, to people who have heart disease what you have accomplished, and what you have the prospects to accomplish beyond.

My red light went on, so I will turn to my colleague, Senator Cochran.

Senator COCHRAN. Mr. Chairman, I have some specific questions about the IDEA program, and some other issues, which I am prepared to submit for the record, and let you move along. You have a lot of people here, and I have another commitment that requires me to leave now, but I appreciate your conducting the hearing, and having everyone here for the committee.

Senator SPECTER. Thank you very much for joining us, Senator Cochran. I appreciate it.

The issue of stem cells, I know, has been very much in the forefront of Parkinson's. Dr. Audrey Penn, a question that I have asked in each of our previous sessions has been "When," and we had an estimate within 5 years to conquer Parkinson's. In light of all of the money you have gotten for research, how far can you advance that completion date?

That is what you call a leading loaded question, Dr. Penn. You can handle it any way you like.

Dr. PENN. I hope we can advance it. There are two responses to your question on record. One was 5 years and one was 10 years, I will not claim either one, but we feel that we are moving very quickly on measures that will control this disease much better than we have ever done before. A cure is going to be harder, as we know, and it will take a little longer. There are several issues.

In terms of the stem cell question, we have evidence already using stem cells or precursor cells in mouse models that we can really impact the types of models of Parkinson's Disease that we already have, these are chemically induced models, but the response is tremendous.

We have not yet moved beyond that, and there may be another way. There may be a way of using the cells already resident in the brain to mobilize them. There is already evidence that that can be done. We hope that we can do this, because it solves things like gene therapy, it solves things like putting special factors in that could help those cells that are left to work. We very much think that this is a way of approaching the problems we are having in really curing this disease.

Senator SPECTER. Let me move quickly to a couple of other questions——

Dr. PENN. Yes, sir.

Senator SPECTER [continuing]. Dr. Penn. Amyotrophic lateral sclerosis, what is the progress there, and to what extent are the stem cells implicated there?

Dr. PENN. I would say, sir, that there is a group organized by private donors that are very much involved in doing just this, and they are making progress working with some of the best investigators in the country.

Senator SPECTER. On stem cells——

Dr. PENN. They are monitoring this. They are working with stem cells.

Senator SPECTER. And they are private donors?

Dr. PENN. They are private donors, and they have a very specific target, as you can well imagine.

Senator SPECTER. What are the prospects for delaying the onset of ALS?

Dr. PENN. I do not know that this approach will delay the onset, but it certainly could put back working motor neurons, so that this disease could be slowed way down. The whole group in the amyotrophic sclerosis community is very much involved in doing clinical trials.

They want to do clinical trials as soon as possible with almost anything that will work, so they are organized and mobilized. We are still trying to put pertinent factors back in the spinal cord, but there is some very interesting evidence that stem cells may work.

Senator SPECTER. And Alzheimer's comes within your branch as well.

Dr. PENN. Yes, it does. Again, Dr. Hodes and NIA is the primary institute dealing with Alzheimer's disease.

ALZHEIMER'S DISEASE RESEARCH

Senator SPECTER. Well, let me turn to him then, sort of spend around the speaking parts, and ask you, Dr. Hodes, for your evaluation as to what progress we are making on Alzheimer's, and to what extent the research is moving ahead, and if stem cells factor in there.

Dr. HODES. Thank you for the opportunity. If you will remember, we had the chance to speak with you before a hearing here not so long ago, during which there was a summary of the very dramatic progress in Alzheimer's research over the past years. The identification of genetic and molecular underpinnings of the disease has very directly been translated now into new approaches to treatment.

They include attempts to actually interfere with some of the molecules, enzymes that cause some of the toxic products in the disease. You heard in particular about an approach to immune therapy, or vaccination, against Alzheimer's peptide, that is very exciting.

In terms of the role of stem cells, there has been very exciting news over the past year indicating that in some of the areas of the brain that are affected by Alzheimer's, there is, indeed, stem cell activity, the sort Dr. Penn referred to, that is stem cell activity resident within the brain. One approach is to try to trigger differentiation of these very cells in the brains of individuals affected, and repair damage caused.

In addition, there is work that has been occurring in animal models in which cells from a variety of sources unexpectedly have been shown to have the capacity, for example, bone marrow stem cells, to differentiate into stem cells for neurons, which can, indeed, repopulate the brain. So these are some very recent and exciting findings, which suggest that stem cells from a variety of sources may be capable of differentiating into functional neurons in the brain, and provide relief, or even prevention for Alzheimer's disease.

Senator SPECTER. Let me turn now to Dr. Allen Spiegel, Diabetes Institute. The question is: I understand that the stem cells have been very instrumental in moving ahead on diabetes. Can you bring us up to date on that, please?

ISLET TRANSPLANTS IN TYPE 1 DIABETES

Dr. SPIEGEL. I would be happy to, Chairman Specter. As you know, and as we discussed with your colleague, Senator Harkin, the Edmonton trial in Canada has demonstrated that islet transplantation can be a successful potential cure for type 1 diabetes. The follow-up for this trial was updated just in April in a paper published in the journal Diabetes, which indicated that 11 of the 12 people receiving these islet transplants are still insulin independent. This is very promising.

This protocol is being replicated in NIH-supported studies around the country, and at the NIH Clinical Center there has already been experience with four such patients, again, showing some success.

INADEQUATE SUPPLY OF ISLETS

This is the good news. However, roughly 1,000 donor cadaveric pancreases, from which these islets are harvested, are insufficient to ever meet the need for the roughly million type 1 diabetics. This is why we are working intensively on many, many approaches to providing the supply of islets. Stem cell work is very important in this regard.

STEM CELL RESEARCH

I will summarize briefly some of the progress to date of which I am aware. Mouse adult stem cells, derived from the pancreatic ducts, have been used in an experimental study published in Nature Medicine to reverse type 1 diabetes in the mouse model. That has not been replicated, and there have been some concerns as to whether there are really adequate amounts of insulin produced.

In human efforts for adult stem cells coming from the pancreatic duct, investigators at the Joslin Clinic, whom we support, have isolated such adult stem cells that can turn into islets, but unfortunately, the amounts, to date, are inadequate.

Senator SPECTER. The amount of what is inadequate?

Dr. SPIEGEL. These cells are precursors in the pancreatic ducts from adult pancreases that are cadaveric pancreases, grown into islet-like clusters, and unfortunately, the amounts generated, according to the investigators in that paper, are as yet inadequate to be useful.

Senator SPECTER. The amount of adult stem cells?

Dr. SPIEGEL. That is correct, according to those investigators.

Senator SPECTER. Do you concur with Dr. Lenfant that the embryonic stem cells would be superior?

Dr. SPIEGEL. I cannot give you a simple answer to that, but I can tell you about work on mouse embryonic stem cells, which is what I was coming to.

The mouse embryonic stem cell work, which can be supported by NIH, was actually done intramurally in the National Institute of Neurological Disorders and Stroke. Researchers demonstrated in a very, very exciting fashion that they could differentiate these mouse embryonic stem cells into islet-like clusters. Unfortunately, these cells made about a fiftieth of the amount of insulin of a normal beta cell, and they were inadequate to be able to cure diabetes in a mouse model. This is work of Dr. Ron McKay and colleagues, published in Science.

As far as human embryonic stem cell work, undoubtedly it is going on in the private sector, perhaps in foreign countries, but because there are no publications that I am aware of, I cannot really comment.

Finally, I would comment on the work with bone marrow stem cells. We have heard so much about their plasticity—the fact that they can turn into so many other kinds of stem cells. However as yet, to my knowledge, there is no evidence that they turn into islet cells—liver cells, possibly, but not islets.

In summary, we just do not know at this very early stage of investigation which of the two types of cells—adult stem cells or embryonic stem cells—would be superior. I think, as a scientist, that one has to be cautious and not make pronouncements when there is no sort of adequate data yet.

Senator SPECTER. Would you like to have the availability of embryonic stem cells to at least find out?

Dr. SPIEGEL. That is something that is under review by the Administration, and I think we will have to see how that works out.

Senator SPECTER. Excuse me, but what does that have to do with my question, what the administration wants to do? I am asking you as a scientist, would you like to have embryonic stem cells available.

Dr. SPIEGEL. What I can certainly say is that a number of scientists, I think there were 80 Nobel Laureates, that I am aware of, have articulated the desire to be able to compare these. I think scientists around the country in the various centers have said exactly that. As a scientist, yes, I think we would like to be able to do this.

Senator SPECTER. That is what I was looking for, as a scientist.

Dr. SPIEGEL. Yes, absolutely, as a scientist, that is absolutely the case.

USE OF STEM CELL IN VISION RESEARCH

Senator SPECTER. Let me move quickly before yielding to Senator Harkin and get some comments from Dr. McLaughlin, of the Eye Institute, with the focus on new cornea studies showing promise with stem cells. Dr. McLaughlin, how about that?

Dr. MCLAUGHLIN. Yes, sir. That is probably, in the eye, field the most advanced situation for stem cell transplantation. In conditions such as alkaline burns, where the normal cells that would lead to the clear cover——

Senator SPECTER. Speak more directly into the microphone, please, Dr. McLaughlin.

Dr. MCLAUGHLIN. The cornea of your eye is covered by a single layer of cells, and this is very important. If those cells are unhealthy, your cornea will cloud, and you will not be able to see. In situations, for example, like an alkaline burn, the cells that normally would produce those, that single layer of cornea cells, they are destroyed.

So what investigators are doing, they are taking cells—this is from adults—that are stem cells, or precursors to those cornea cells, growing them up in culture, and then transferring them to patients who have these various corneal problems, and so far the results are very promising.

Senator SPECTER. Let me turn now to Dr. Stephen Katz, National Institute of Arthritis, Musculoskeletal and Skin Disease, with respect to the stem cell treatment on arthritis, which, as I understand it, shows promise on pre-growth of skin, what is your view of that, Dr. Katz?

Dr. KATZ. Thank you, Senator. In all of the areas of the interest of the National Institute of Arthritis and Musculoskeletal and Skin Diseases stem cells have shown promise including regenerating cartilage cells in the joint in osteoarthritis, which is the most common form of arthritis. In the area of osteogenesis imperfecta, stem cells have been shown to be effective in regenerating some of the bone-forming cells.

In the muscular dystrophies, stem cells in work that has been supported by the Neurology Institute, as well as our institute, have shown promise in what are called satellite cells, which are thought to be stem cells of muscle, to regenerate those muscle cells. We know also that in skin, stem cells are very important, as Dr. McLaughlin said, to regenerate epithelium that covers the skin.

Senator SPECTER. Let me turn now to Dr. Anthony Fauci, Allergy and Infectious Diseases, with respect to the stem cell treatment on AIDS.

Dr. FAUCI. Senator—thank you for the question.

One of the characteristics of HIV/AIDS disease is a rather dramatic and catastrophic depletion of immune system functions, specifically a very important cell of the immune system. Similar to the reconstitution of bone marrow that Dr. Klausner alluded to just a few moments ago in patients who are treated for cancer, the same would hold true with regard to the reconstitution of the human immune system by stem cells. Stem cell research is very much at the forefront of the ideas of individuals who are planning strategies. Once you get the virus under control with anti-retroviral therapy, to help the immune system, which might not be able to spontaneously regenerate itself, it may be possible to help the immune system to regenerate itself by providing it with these precursor cells.

Senator SPECTER. Dr. Kirschstein, let me come to this question about their letters and the late arrival, and then I will turn to my distinguished colleague, Senator Harkin.

We did not get the responses until yesterday afternoon at 3:45. There were 42 pages, as I understand it, instead of 70. Why such a late return?

Dr. KIRSCHSTEIN. Mr. Chairman, the Institute directors received your letter on May 4th, and they were assigned for completion to the various institutes, to be returned to the central focus, the Executive Secretariat of NIH, by May 9th. I met you at the event for the Society for Women's Health, and told you, as I had told Ms. Taylor, that I was going to send those letters for clearance, which is the policy, to the department.

Our responses, except one, which was delayed, were sent to the department for clearance on May 14th, and we did it—by the way, we always send such responses through the NIH Executive Secretariat, from our Executive Secretariat. At that point, the work was to be done, whatever, in the department for clearance.

Senator SPECTER. Well, I am told that the letters were rewritten in the department, is that true?

Dr. KIRSCHSTEIN. Yesterday, I was called, and asked whether the letters, which had been reviewed, when there was an issue as to whether letters from individual Institute directors raised issues more broadly than the mission of that institute, would the Institute directors consider narrowing their focus to their own mission, and talking strictly about the scientific aspects, which is what I think we always address.

I had a meeting with the Institute directors, and asked each of them to review what they had said, and see whether they wished to, in any way, modify the letters, based on whether they thought their letters were more broad ranging. The letters were then——

Senator SPECTER. Whether their letters were what?

Dr. KIRSCHSTEIN. More broad ranging than focusing on the particular mission of the Institute. Each of the Institute directors then reviewed their letters, and some made changes, and some did not.

Senator SPECTER. Well, this subcommittee would like to get copies of the original letters and a copy of the modifications. It has been reported to me that the instructions were given, quote, "The answers and questions based on science, and not on political speculation or personal views," closed quote. Is that accurate?

Dr. KIRSCHSTEIN. It was not on speculation, but it was on following the mission of the Institute. The term "personal views" was never told to me; it was never mentioned to me.

Senator SPECTER. Mr. Whitaker, Assistant Secretary for Legislative Affairs, I understand, is present. Would he step forward, please?

Come up front. We can make a place for you at the head table.

Mr. WHITAKER. Okay.

Senator SPECTER. Why the long delay, Mr. Whitaker?

Mr. WHITAKER. Honestly, Mr. Chairman, first of all, I want to apologize to you for the delay, but I also want to assure you that there was in no way an attempt on the Office of the Secretary's part to withhold information or control the information that was sent to you.

[CLERK'S NOTE.—Page 27–32—Mr. Whitaker's office, Assistant Secretary for Legislation, informed ASMB that the letters and an explanation concerning the distribu-

tion of the letters were sent to the Committee the end of May, we were not informed of the exact date.]

Senator SPECTER. Well, I am interested in your conclusions—

Mr. WHITAKER. It was simply——

Senator SPECTER [continuing]. But only a little. Let me find out what the facts are here. Why the delay? What happened? Were those letters submitted on May 14th, as Dr. Kirschstein testified? Why the delay?

Mr. WHITAKER. I was told by our Executive Secretariat, which is the part of the Department that controls correspondence for the entire department——

Senator SPECTER. And who is that?

Mr. WHITAKER. Anne Agnew is our executive secretary. Some of the letters were received on the 14th, but not all the letters, and that she——

Senator SPECTER. But not what?

Mr. WHITAKER. Not all of the letters were received on the 14th from the Institute directors.

Senator SPECTER. Is that true, Dr. Kirschstein?

Dr. KIRSCHSTEIN. I believe, from what I know, that all of the letters, except one, were received on the 14th. The National Cancer Institute was working on its letter, and it came in 1 day later.

Senator SPECTER. So one letter was 1 day late, is that so, Mr. Whitaker?

Mr. WHITAKER. That is not what I have been told by the Executive Secretariat. I do not control that information. The information is only passed on to me. I am told that the final letter did not come in until——

Senator SPECTER. I want you to pursue that and find out whether Dr. Kirschstein is correct or not——

Mr. WHITAKER. Yes.

Senator SPECTER [continuing]. And submit a written response within a week, please.

Mr. WHITAKER. I will do that, sir.

Senator SPECTER. So how about the letters that were submitted? Why were they not transmitted to the subcommittee?

Mr. WHITAKER. As a matter of policy, the Secretary has asked for the right to review correspondence to Congress, as well as testimony to Congress, and those letters were received in the Office of Legislation on Thursday night, and on my desk on Friday evening.

Senator SPECTER. Which Thursday and which Friday?

Mr. WHITAKER. This past Thursday. The date would have been the 17th. Then I saw the letters the following Friday evening.

Senator SPECTER. What happened to them between Monday and Friday?

Mr. WHITAKER. I do not know, sir. The letters were——

Senator SPECTER. Would you find out for me?

Mr. WHITAKER. I will find out. My assumption is that the letters were at the Executive Secretariat's office, and they were probably being compiled so that they had a complete package to forward to the Office of Legislation. That is my guess as to——

Senator SPECTER. Were there any requests made for modification by——

Mr. WHITAKER. We made no specific requests to modify any of the letters. We simply asked——

Senator SPECTER. Aside from a specific request, did you make a generalized request?

Mr. WHITAKER. We made a generalized request that we thought it would be best that the letters be focused on the science, and the science only, and that——

Senator SPECTER. Well, what were the letters focused on, that these scientists were not writing the letters based on science?

Mr. WHITAKER. I believe, and Dr. Kirschstein talked to me about this, and to our chief of staff, and Dr. Kirschstein agreed, that some of the letters may have gone beyond exactly what the mission of each institute was, and based on some non-scientific speculation, and Dr. Kirschstein——

Senator SPECTER. These letters had non-scientific speculation.

Mr. WHITAKER. That was my understanding from my conversation with Dr. Kirschstein.

Senator SPECTER. Would you make available to this subcommittee the specifics as to what you are talking about, what letters you received, and what you considered non-scientific speculation?

Mr. WHITAKER. As a general rule, sir, we receive draft letters from all agencies, from HCFA, to AOA, to NIH, to CDC, for review. These come to us in the form of draft letters for us to review, and that is general policy——

Senator SPECTER. I am not so much interested in that as I am in response to my question. Will you submit to this subcommittee the letters which you concluded were based on speculation?

Mr. WHITAKER. I will go back and look at those letters, sir, and I will get a response to you.

Senator SPECTER. Will you submit those letters to this subcommittee?

Mr. WHITAKER. I would be happy to do that, sir. I obviously would have to clear that with the Secretary.

Senator SPECTER. Well, let me be direct in my concerns here. This subcommittee is interested in what the potential for stem cells may be, and we want the scientific facts. When I get a report that the answers to my questions are based not on science, but on political speculation and personal views, closed quote, I am more than a little concerned. This would be an indication of the kind of scientists which we have here, if the responses were not based on science.

If you, top-flight men and women, do not respond to the subcommittee based on science, I have a hard time understanding why we are appropriating $24 billion for you. You are scientists, and I would expect you to submit answers based on science, and I would be shocked if you did not, because I know your caliber and your qualifications.

So I want to see what those responses are, whether they are based on science, or maybe some of you did not like the answers. Then when it goes on to say not on political speculation, well there is no place for politics in the work in your unit, and I want to know what the facts are on stem cells.

I have had a discussion with the President of the United States on this subject, and he wants to know what the facts are, too, and we want them unvarnished. I talked twice to the Secretary of Health and Human Services about this matter. I was not very happy, at mid-day, the day before this hearing, not to have those letters.

There are other things on my agenda between yesterday afternoon and this morning, like voting in the United States Senate on the tax bill. So I intend to get to the bottom as to what is going on here. Really the basic consideration is what is the potential for stem cells.

There is a political fight brewing over this matter, and it is going to be decided in the Congress and by the President. When we have these extra embryos created for in vitro fertilization, and they create more embryos than necessary. Some are going to be destroyed, and there is an argument, a theological, philosophical, political argument about whether life is in existence. If life were to be created, I would be the last one to say let us use these embryos for stem cell research, but if they are going to be destroyed, it is another matter. But that is something to be decided in the Congress and by the President in accordance with our laws.

We can pass a bill, he can sign it or veto it, and we can override the veto, if there are two-thirds necessary. That is the way these judgments are made, but from you we would expect the facts and the scientific evaluation. And from you, Mr. Whitaker, and your department, we would expect the transmission without editing and alteration, but we will get the details as to what was originally submitted, and whatever objections you had, and we will make our own evaluation of that.

Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman. I will just ask that my statement be made a part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Thank you, Mr. Chairman. You've been a great champion for medical research over the years, and I thank you for holding this hearing.

Dr. Kirschstein, it's a pleasure to welcome back you and your colleagues to testify before this subcommittee. Most people probably don't realize how important your work is to their daily lives, and how lucky they are that you do it so well. But all of us on this subcommittee are grateful for your extraordinary dedication and service.

A lot has happened since we met last spring to discuss the NIH budget for fiscal year 2001. Two months after that hearing, NIH scientists announced the completion of a draft sequence of the human genome—without a doubt, one of the most significant events of our lifetime.

And just two weeks ago, the NIH made another exciting announcement: the FDA approval of the most promising cancer drug ever developed. This drug, called Gleevec, was given to 54 patients with chronic myelogenous leukemia (CML), a disease in which too many white blood cells are made in the bone marrow. In 53 of those patients, the disease basically disappeared. A year later, 51 of those patients still had a normal blood count.

One thing that's so exciting about this drug is its potential for fighting other diseases as well. As I understand it, Gleevec turns off the same molecular targets that also cause some forms of cancer in the abdomen and brain. It's hard to believe that a single drug could work against three cancers that seem so different on the surface, but that seems to be a real possibility.

And if it's true, we might have to re-evaluate the way we think about the nature of disease itself. Instead of describing a disease by where it shows up in the body—

the liver or the brain or the lung—the key issue is really what part of the molecule is causing the problem.

This is exactly the kind of discovery that the NIH is all about. First, scientists did basic research about how molecules work; then they translated it into a direct application that could save thousands of lives.

And it's an encouraging sign to those of us on this subcommittee who have supported the NIH over the years. When I first started talking about doubling NIH's budget back in the early 1990s, most people didn't take that idea very seriously. Now, thanks to the work of Chairman Specter and many others, it's on the verge of happening. Next year, fiscal year 2002, will be Year 4 of our five-year effort to reach that goal.

The president has called for a $2.7 billion increase, but Chairman Specter and I would like to boost that figure up to $3.4 billion. Of course, our ability to do that will depend greatly on what kind of appropriations allocation we get; we certainly weren't helped by the budget resolution that Congress adopted earlier this month. But I'm hopeful we'll prevail.

And if we do, Dr. Kirschstein, I don't need to remind you that the additional money will bring added responsibilities—$3.4 billion means a lot more grants to award, a lot more clinics to staff, and a lot more employees to manage. It will take a great deal of vigilance to ensure that the money is spent wisely.

Again, Mr. Chairman, I want to thank you for holding this hearing, and I look forward to Dr. Kirschstein's testimony.

Senator HARKIN. I want to welcome Dr. Kirschstein and all of the other directors, the scientists and administrators who are here today.

First of all, let me just say for the record, Mr. Chairman, you have been one of the great leaders in the entire Congress in pushing for medical research all the time I have known you, and all these years, and I just want you to know that I appreciate that, and I thank you for that, and I thank you for holding this hearing, and for your strong support of unbiased, non-political interference in scientific pursuits, and I want to thank you for that.

I just want you to know, I have just been listening to this, and I know a little bit about this. If at any time that you would like to issue a subpoena to go back and get those, you will have my name on it.

Senator SPECTER. Thank you.

Senator HARKIN. I would be glad to support you in that, if you would like to do that, if that becomes necessary. If that becomes necessary, I will support you.

I was just thinking, again, Mr. Chairman, that years ago we had a lot of political interference in terms of the budget coming up, especially from the National Cancer Institute. This is a number of years ago, preceding me. So the Congress passed a law mandating a by-pass budget. So every year we get a by-pass budget that we get our hands on directly from the Institutes.

Well, maybe, Mr. Chairman, what we need to do is to ensure that any requests for letters from any of the heads of any of the Institutes that we request that comes to this appropriation subcommittee also has a by-pass that comes here, just like the by-pass budget.

Now, if the political people, in whatever department, and whatever administration, want to tinker with it, that is their own business, but at least we should get the unvarnished truth without going through it, so maybe we ought to think about how we—if we ask, if this committee, you as chairman, me ranking member, whatever, asks for information from an institute, that ought to be transmitted, and it should not have to go through other kinds of

departments, just like a by-pass budget, and maybe we ought to think about——

Senator SPECTER. Good point.

Senator HARKIN [continuing]. Changing the law in that regard. We have a vote on, and I am sorry, I apologize, we are going to have all these votes, and so I assume we are going to have to go, right?

I just want to thank all of you for all of the tremendous work you are doing in scientific research, the great leadership you have shown. I wish we could have more time to go into a lot of these things. I have as much support for stem cell research as my chairman does, and we are pretty much in lock step on this one.

A couple of things, and you do not even have to answer this, but I perhaps need it in writing, Dr. Kirschstein, is, we have been working hard to double the budget, we are going to get it done, it is going to happen over the next couple of years, but the President's budget, looking in the forward years, calls for a 2.2 percent increase in 2004 and a 2.2 percent increase in 2005.

Now, that has important implications, because research grants run about 4 years, and we want them to run longer than shorter periods of time, so new grants that are awarded now will require commitments through 2005. But if we come to a ledge and we drop off, what is going to happen if, in fact, there will not be any money left over for anything new?

In other words, if we use all that money for all the old grants, what happens to the new grants that we want to start funding in those out years? I am really concerned about that, and I do not—we have to go. I do not know if you can respond to that shortly, and——

Dr. KIRSCHSTEIN. I can give you a short answer, Mr. Harkin. We are concerned, also, and so we are beginning to look at this, and, indeed, I am putting together a committee of Institute directors. Dr. Lenfant will chair the committee. We will have other Institute directors. We will have Dr. Baldwin, who handles the day-to-day activities of our extramural research program, and we will be working on this steadily, and we will have some plans sometime by the summer.

Senator HARKIN. Okay. Two other quick things: The status of our labs out there and extramural research. I will not go into all of the studies and all of that data, but I am just going to say that right now it is authorized at $250 million, and given the current situation, would it make sense for the NIH to spend more than $97 million out of that $250 million that is authorized? So take a look at that, will you, for me?

Dr. KIRSCHSTEIN. We will, Senator.

Senator HARKIN. I think we need to look at that a little bit longer, closer.

The last thing is—there are a lot of things I would like to get into. Gleevec, what a great breakthrough on cancer research on this drug, it seems to me. We have talked about it before, but the question I have is: How much of NIH's research went into that, supported, NIH-supported research went into that?

Dr. KLAUSNER. The reality is, that a larger amount of the underlying research that led to understanding the drug target has been supported by NIH-funded research, starting back in about 1960.

Senator HARKIN. Now, Rick, you know what my next question is. When I talked about—I was in my home state, and we were talking about this new drug, and this new candidate, and it looks like it has maybe applications for other types of cancers, too——

Dr. KLAUSNER. It does.

Senator HARKIN [continuing]. But then the news reports carried the report that it would come in at around $2,000 or $3,000 a month, to which one person said, "That is wonderful. I cannot use it. How are you going to pay for it?"

So I am just wondering about the pricing of this, and whether or not there is some recapture, or something like that. We have to figure this one out, about what we do about the pricing, and if it is that expensive, how much comes back into NIH to help us out. I do not know, but I—that is coming down the road. If you want to respond to that, fine.

Dr. KLAUSNER. We, of course, are not involved in the pricing of a particular drug.

Senator HARKIN. I understand that. I understand that.

Dr. KLAUSNER. But we really are very concerned about making sure—that individuals, individuals that need drugs, have access to those drugs.

Senator HARKIN. Yes. Well, this is something I think we, up here, are going to have to figure out on what we want to do on that, but I just wanted to mention it. We have 4 minutes left.

Thank you, Mr. Chairman. Three minutes.

Senator SPECTER. Thank you all very much for coming. I am always reluctant to take the time of this many distinguished scientists who could be back in the laboratory moving ahead. America is very fortunate to have such an extraordinary organization like the National Institutes of Health.

You have heard me say on many, many occasions that you are the crown jewel of the Federal Government. I stopped saying you are the only jewel of the Federal Government—I have had too many complaints about that—but we thank you for what you are doing.

Senator Harkin and I will continue to fight hard to bring you more resources, and I think you will have the backing of the Congress and the President.

Thank you.

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

NDRI EXPANSION

Question. What have you done to expand NIH support for NDRI?

Answer. Approximately two-thirds of the National Disease Research Interchange (NDRI) enterprise activity is supported by private foundations and fees charged to for-profit corporations. The remaining one-third of the activity is supported by an NCRR/NIH cooperative agreement, now in its tenth year. The National Center for Research Resources (NCRR) provided sole support during the first eight years of the grant. Currently, four additional NIH components (the National Eye Institute (NEI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Office of Rare Diseases (ORD), also provide co-funding for the grant.

Question. More specifically, have you met with each Institute Director and encouraged them to work with NDRI to access its human tissue resources to meet the special needs and initiatives of each Institute?

Answer. A memorandum was sent to the directors of the various Institutes in July of 1999, inviting them to participate with NCRR in support of this endeavor. The scope of the NDRI service to the biomedical research community has been reviewed by a committee of experts and NCRR's National Advisory Council. The level of support provided for NDRI reflects the recommendations of the peer review process. The total level of NDRI funding would be the same whether NCRR alone or NCRR along with several other NIH components supported the NDRI award.

Question. If not, why not?

Answer. The NDRI user (investigator) list and the NIH institutes or Centers relevant to the research areas were systematically reviewed. As a result of that analysis, four additional NIH components were invited to cofund the NDRI application and all four agreed to participate. The other NIH components supported only a very small percent of the user activity.

Question. If so, please report what next steps have been taken by each Institute Director.

Answer. As noted above, the NEI, the NIAID, the NIDDK, and the ORD have joined NCRR in cofunding the cooperative agreement entitled "Human Tissue and Organ Research Resource (HTOR)."

Question. When will you begin providing NDRI with supplementary funding through the Multi-Institute Initiative?

Answer. Cofunding by the above-mentioned Institutes and Centers is currently in place. As noted above, the total level of funding for the NDRI application is independent of the number of NIH components which cofund the application. The peer review process provides recommendations to NIH staff as to the scientifically and technically meritorious aspects of the NDRI application and the applicant provides estimated costs for those costs. These same principles hold for the peer review and subsequent funding of other meritorious research or resource grant applications. Question. How much direct supplementary funding will NIH provide NDRI through the Multi-Institute Initiative beginning July 1, 2001?

Answer. The Notice of Grant Award will be augmented by $300,000 from NIAID in support of the second year of the demonstration pilot project to obtain HIV positive tissues. The increased level of support reflects additional NDRI activity related solely to NIAID.

Question. What is your plan to secure supplementary Multi-Institute Initiative funding for NDRI beyond June 30, 2003?

Answer. A memorandum will be sent again to the Institute Directors inviting them to support the Human Tissue and Organ Research Resource (HTOR) cooperative agreement.

NINDS STROKE STRATEGIC PLAN

Question. Dr. Penn, I am concerned that stroke remains a leading cause of permanent disability and the third largest killer of men and women in the United States. Last year this Committee encouraged the National Institute of Neurological Disorders and Stroke, as part of your strategic planning, to work with the research community, clinicians, voluntary health organizations, and patient advocacy groups to discuss new avenues of basic and clinical stroke research opportunities. Please provide us with an update on this activity.

Answer. Stroke research is a high priority of NINDS because this neurological disorder is the most common cause of disability, and the opportunities for progress in both prevention and treatment of stroke are very great. The Institute's overall strategic plan, Neuroscience at the New Millennium, addresses research questions of

importance to stroke in its discussion of neural environment, experimental therapeutics, funding of research in this area and clinical trials. Evidence of the importance of stroke to our Institute's efforts, funding of research in this area is supported in both "Clinical Trials" and "Neural Environment" extramural program groups.

TRANS-AGENCY CONFERENCE ON HEART DISEASE AND STROKE

Question. Dr. Lenfant, several years ago this Subcommittee encouraged the National Heart, Lung, and Blood Institute to hold a trans-agency conference on heart disease and stroke to obtain an assessment of progress and opportunities and develop a comprehensive research and prevention agenda on heart disease and stroke for the 21st Century. I have heard that the report on this conference was released in December of 2000. What was the conclusion in the report and how do you plan to implement the findings?

Answer. The report of this conference was published in the December 19/26, 2000 issue of the journal Circulation. Among the conclusions were that, for the United States as a whole, the coronary heart disease (CHD) death rate is still declining, but more slowly than it did between 1970 and 1990; stroke mortality rates have declined little since 1990; striking differences exist in levels and trends of cardiovascular disease (CVD) by race/ethnicity, socioeconomic status, and geography (for example, rates of CHD death have declined more slowly among black men than among white men); and trends in levels of risk factors are consistent with the slowing in the decline in the death rate (little change since 1990 in smoking prevalence, physical inactivity, and hypertension control and striking increases in prevalence of obesity and type 2 diabetes). The conference also concluded that although there is considerable activity in prevention and treatment of CVD, much more needs to be done with respect to assessing risk factors and applying proven approaches to treat them. A number of recommendations were made with respect to application of current knowledge and further research.

Concerned about data presented at the conference that some Americans are not enjoying the improvements in health that can be realized by applying existing clinical guidelines and other medical information, the NHLBI recently developed and implemented several new programs. One, an education initiative, entails Enhanced Dissemination and Utilization Centers (EDUCs) in communities with heart disease and stroke death rates that far exceed the national average. These centers will become the foundation of a network of Healthy People 2010 performance partners committed to eliminating of racial/ethnic and geographic health disparities in underserved high-risk populations. Funded centers are using information generated by the national education programs of the NHLBI to inform their communities of the public heath burden of CVD and are developing, implementing, and evaluating educational strategies to reduce the burden through changes in behavior of health care providers, patients, and the general public related to the prevention and control of CVD. The six current centers are located in Arkansas, North Carolina, Virginia, West Virginia (two), and Texas. One of the EDUCs, West Virginia Health Right, Inc., in Charleston, is a free primary care clinic that serves the uninsured and under-insured poor. At the North Carolina EDUC, Wake Forest University School of Medicine will collaborate with the Robeson County Partnership for Community Health, Columbus County Hospital, and Columbus County Healthy Carolinians to reach low-income blacks and Native Americans with CVD screening and cardiovascular health education activities. The University of North Texas Salud para su Corazón Outreach Initiative EDUC is a collaboration among the University, the Dallas Concilio, Northside Clinic, Hispanic Health Coalition of Fort Worth, and Harris Methodist Hospital to use lay health educators to reach Hispanics with cardiovascular health promotion and disease prevention activities.

EDUCs are one element of a larger heart-health agenda that the NHLBI launched as part of its efforts to meet the cardiovascular health goals and objectives in the federal government's Healthy People 2010 Report. On February 1, the NHLBI, several other federal health agencies, and the American Heart Association (AHA) signed a Memorandum of Understanding (MOU) to speed progress toward heart disease and stroke goals set forth in Healthy People 2010. This historic MOU has created a working partnership that promises to improve greatly the nation's cardiovascular health by the year 2010. The federal agencies and the AHA will work to accomplish four cooperative knowledge application goals for heart disease and stroke: prevent the development of risk factors; detect and treat risk factors; achieve early identification and treatment, especially in the acute phases of disease; and prevent recurrence and complications. The NHLBI also sponsored a workshop in March as the first step in developing an ambitious agenda for a new women's heart

health education effort. It brought together a group of about 60 key researchers, public health leaders, women's and minority health advocates, health communicators, health care delivery experts, patients, and others who have a stake in improving women's cardiovascular health to develop a science-based blueprint for a comprehensive health education effort for patients, health professionals, and the public. Late this summer an award will be made for program support to launch the nationwide education effort. In addition, the NHLBI is continuing to collaborate with the National Recreation and Park Association to develop and implement a nationwide, community-based program to reduce the growing trend of obesity and the risk of CHD in the U.S. by encouraging Americans of all ages to aim for a healthy weight, follow a heart-healthy eating plan, and engage in regular physical activity. The program targets high-risk and underserved neighborhoods through community park and recreation programs.

The NHLBI will continue its ongoing projects in African American and Latino communities and is now taking steps to implement strategies to improve the health behavior of several underserved Asian American/Pacific Islander (AAPI) groups, including those of Philippine, Vietnamese, Native Hawaiian, Samoan, Cambodian, Hmong, and Laotian heritage. To begin formulating culturally and linguistically sensitive heart health education materials for these AAPI ethnic groups, consumer interviews and discussions with community leaders are being conducted and efforts to build community-based networks in these underserved AAPI communities have begun. So far, 15 community-based network partners across the country have been enlisted to assist in the implementation of outreach activities in underserved AAPI communities. The NHLBI is also beginning the second phase of its three CVD projects in American Indian and Alaska Native (AI/AN) communities to develop and implement community-based interventions to increase awareness and to expand adoption of heart-healthy behaviors and thereby reduce health disparities. The three communities are the (1) Ponca Tribe of Oklahoma with about 2,500 members, (2) Bristol Bay Area Corporation with 32 villages in Southwestern Alaska, and (3) Laguna Pueblo in New Mexico with about 4,000 members. The NHLBI has joined forces with the Indian Health Service to use the tools and materials developed during the first phase of the project to implement community-based outreach and education activities in the three communities over the next 3 years.

To continue the dialogue regarding the issues and recommendations put forth at the CVD Trends Conference, the NHLBI is sponsoring a National Cardiovascular Health Conference, "Cardiovascular Health for All-Meeting the Challenge of Healthy People 2010," to be held in April, 2002 in Washington, D.C. We expect an onsite attendance of 2,000 health professionals committed to eliminating the racial/ethnic, gender, and geographic disparities reported at the CVD Trends Conference. Conference cosponsors include the AHA, the CDC, HCFA, and HRSA. The Institute has also developed an innovative NHLBI Healthy People 2010 Gateway Web site and integrated Health Information Network (HIN) at http://hin.nhlbi.nih.gov. Visitors to the Gateway are offered quick access to a wide range of resources that can be used for planning and implementing community-based Healthy People (HP) 2010 activities. The current NHLBI HP 2010 performance projects are defined, and ongoing activities and progress of performance teams are reported through a variety of means including Webcasts of major meetings, electronic communication memos, and special Web pages that provide details about performance partners, major project events, pilot project results, and access to the latest NHLBI-developed resources. Visitors are encouraged to complete an electronic application to become a HIN partner. Partners receive electronic notifications of new NHLBI educational products and services, late-breaking news of NHLBI-funded research findings, notification of NHLBI conference Webcasts, distance learning opportunities, and special Web-based applications such as interactive disease mortality maps to assess the magnitude of the public health burden of disease by state and Health Service Area. Network membership has been increasing on a daily basis-it currently numbers over 11,000 health care providers, public health practitioners, patients, and other interested consumers nationwide as well as a growing international representation.

The Institute is also funding a program of grants to evaluate interventions in clinical care settings that are designed to improve adherence to medically prescribed lifestyle changes used to treat heart disease. This program targets racial and ethnic minorities and/or persons living in poverty. In addition, the NHLBI is initiating an evaluation of innovative strategies that can be used in clinical practice to improve implementation of evidence-based guidelines for treatment of heart disease.

NEW CHOLESTEROL GUIDELINES

Question. Dr. Lenfant, I am a staunch proponent of prevention. Cholesterol is a major risk factor for heart disease, the leading cause of death of Americans, and for stroke, the No. 3 killer in the United States. The National Heart, Lung, and Blood Institute's new cholesterol guidelines have received a lot of attention. These guidelines are the first major revision in about 10 years. Please explain to this Committee how these guidelines have changed from the ones published nearly a decade ago and how well can you insure that these new cholesterol guidelines are implemented.

Answer. The new cholesterol guidelines developed by the Institute's National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) are evidence-based. The ATP III report states explicitly the nature and strength of the evidence, derived from a rigorous and systematic review, that forms the basis for its conclusions and recommendations. Compared with the previous guidelines, which were released in 1993, the ATP III guidelines have several new features. First, they call for more aggressive lowering of LDL (bad) cholesterol, the primary target of therapy, in individuals at high risk for a heart attack or death from coronary heart disease (CHD). This high-risk group includes those who have CHD itself, diabetes, or multiple (2 or more) CHD risk factors and a 10-year risk for CHD greater than 20 percent. These high-risk people have the most stringent LDL goal: <100 mg/dL. Individuals with multiple risk factors and a 10-year CHD risk of 10–20 percent are also at substantially elevated risk and often require aggressive therapy, but their LDL goal is somewhat less stringent: <130 mg/dL. The ATP III report provides a risk assessment tool to identify individuals who require intensive cholesterol-lowering treatment; based on data from the NHLBI Framingham Heart Study, it enables calculation of 10-year CHD risk. A second new feature is a more intensive set of Therapeutic Lifestyle Changes (TLC) that constitute the mainstay of cholesterol-lowering therapy and offer greater potential to lower LDL than the previous guidelines. Third, the new guidelines define and recommend treatment for a cluster of CHD risk factors known as "the metabolic syndrome," which is related to the increasing prevalence of obesity and overweight in the United States. Fourth, the ATP III report urges greater clinical attention to high triglycerides and low HDL (good) cholesterol, both of which are linked to increased risk for CHD. Fifth, the guidelines recommend a complete lipoprotein profile (total, LDL, and HDL cholesterol and triglycerides) as the preferred initial test for detecting cholesterol problems. Sixth, ATP III sets a new level at which low HDL becomes a major CHD risk factor (<40 mg/dL, as compared with <35 mg/dL in ATP II). Seventh, ATP III recommends ways of improving professional and patient adherence to the guidelines and to appropriate therapy.

The new guidelines identify many people who are at higher risk for CHD than had previously been recognized and, thus, their application will increase the number of people who need cholesterol-lowering lifestyle therapy from about 52 million to about 65 million. Of these, about 36 million will need to combine drug treatment with lifestyle changes to achieve an adequate reduction in CHD risk; the vast majority (80 percent) of them are in the two highest categories of CHD risk.

The results of cholesterol-lowering clinical trials suggest that full implementation of ATP III guidelines could produce approximately a 30 percent reduction in the rate of CHD, which continues to be the leading cause of death of women and men in this country and currently accounts for almost 500,000 deaths annually. To help ensure implementation of the ATP III guidelines, the NCEP has developed an array of new products and tools. For professionals, the aids include an Executive Summary of the evidence and recommendations that was published in the Journal of the American Medical Association (JAMA) together with a patient page on cholesterol and an editorial from the JAMA editors urging physicians to implement the guidelines. Other tools include a PowerPoint slide show for teaching the guidelines to professional audiences; an ATP III At-A-Glance Desk Reference that outlines the basic action steps in management of LDL, HDL, and triglycerides; a Palm OS interactive tool that puts the guidelines at the fingertips of physicians for use at the point of care; and a 10-year CHD risk calculator in online and downloadable (Excel spreadsheet) versions. To empower patients to be active partners in their care, the NCEP has developed a new patient brochure entitled "High Blood Cholesterol—What You Need to Know," a 10-year CHD risk calculator for lay audiences, and an updated Web site ("Live Healthier, Live Longer") that reflects the new information in the ATP III report. All of these tools are available on the ATP III Web page, which can be accessed by going to the NHLBI Web site (www.nhlbi.nih.gov). In addition to developing and distributing these new products the NHLBI, through the NCEP, has established a strategic partnership with the National Committee for Quality Assurance (NCQA)

to promote adoption of the new guidelines. The NCQA and the NHLBI cosponsored a national conference for professionals on ATP III implementation June 3–5, 2001. The HEDIS (Health-plan Employer Data and Information Set) performance measures of the NCQA can help ensure implementation of ATP III, and NCQA involvement will extend the reach of the new recommendations into managed care. By these various means, the NHLBI and the NCEP are seeking to speed adoption of the ATP III guidelines.

RETURN ON INVESTMENTS

Question. As you know I believe that NIH is the crown jewel of the federal government and an institution that deserves our highest priority. I am always concerned, however, about the returns we see from our investment.

I realize that establishing deadlines in science such as predicting when a certain disease will have a cure is difficult to do, however, how do you propose that we measure the return we are getting from our investment in NIH?

Answer. As required by the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001, the NIH will be addressing the issue of return on NIH investments by submitting a report by July 2001 that includes a listing of therapeutic drugs which are FDA approved, have reached $500 million per year in U.S. sales, and have received NIH funding.

POPULATION MORBIDITY AND MORTALITY RATES

Question. Do we see an improvement in morbidity and mortality rates as a result of government funded research?

Answer. It is difficult to attribute the exact share of improvements in population morbidity and mortality rates that is due to government funded research. Historically, we know that health and longevity are influenced by increases in income, education, public sanitation and access to care. Of course NIH does not control access to care or participate directly in the delivery to care. However, there is much evidence from clinical trials that new research-based technologies can reduce mortality and morbidity rates when applied appropriately. And recent declines in population morbidity and mortality rates for specific conditions and disorders can be attributed, at least partially, to research-based diagnostic screens, vaccines and other preventives and therapies.

The age-adjusted death rate for all causes fell from 577.0 per 100,000 in 1979 to 471.7 in 1998 (Use of the age-adjusted rate adjusts for increases in deaths due to growth and aging of the population).[1] The corresponding rate for Diseases of the Heart, the leading cause of death, fell from 199.5, to 126.6. over the same period. The recent data on age-adjusted decline in heart attacks and deaths due to heart disease is based on years of research to identify and refine our ability to control risk factors for heart disease such as hypertension and high blood cholesterol levels. Research confirmed the effectiveness of diet and exercise in controlling risk factors and conditions such as high cholesterol levels, hypertension, obesity and diabetes. Preliminary, unpublished analysis suggests that the majority of the reduction in the Cardiovascular Disease mortality rate from 1950 to 1990 may be attributable to providing this information to the public. Information about risk of hypertension, smoking, and high cholesterol levels was made available and diffused widely to individuals and to physicians throughout the country. In response, people modified their diets and exercise patterns, and physicians changed their testing protocols and medical advice, according to a Harvard University study.

The use of the common aspirin, to reduce the risk of heart attack and as part of the immediate post heart-attack treatment, is another example of an application of research which, at small expense, reduces health care costs.

Another example comes from research on the prevention of stroke patients who suffer from atrial fibrillation. The two million Americans who have atrial fibrillation are six times more likely to have a stroke than people who do not, and this accounts for as many as 80,000 strokes a year. A decade long study, by NINDS, carefully examined the best strategy for balancing prevention of strokes versus the risk of adverse side effects among such individuals. Aspirin was recommended for patients with atrial fibrillation in the low risk category and warfarin for those with more risk factors for a stroke. This is another significant example of careful research to provide a tailored, low-tech strategy to prevent a high cost disease.

Another example of a low-tech alternative therapy was provided when research, supported by NIDDK, confirmed the efficacy of a new therapy for peptic ulcers using already available pharmaceuticals. Treatment of the cause of these ulcers, a bac-

[1] National Vital Statistics Reports, Vol. 48, No. 11, July 24, 2000. Table 7.

terium (Helicobacter Pylori), using a "triple therapy" of available drugs—tetracycline, metronidazole, and bismuth subsalicylate (Pepto-Bismol)—speeds the cure and cuts the recurrence rate of ulcers. Research found the recurrence rate for peptic ulcer fell to the 12 percent to 13 percent range, compared to the 74 percent to 95 percent recurrence rate with the previous conventional treatment using antacid preparations and surgery. The resulting annual savings in treatment costs are estimated in the hundreds of millions of dollars. Cataract surgery is another example of an intervention which extends working life and enhances functioning and independence of the retired. Intervention to restore sight is essential for human well-being. What once required a long hospital stay including days in intensive care, is now performed on an outpatient basis. Meanwhile, the National Eye Institute continues to support research aimed at understanding and preventing cataracts, as well as other vision disorders.

Another evidence of advance is the reduction in infant deaths from all causes from just less than 5 per 100 live births in 1940 to less than one per 100 today. The causes are multiple, but many are research based. Infant mortality rates from congenital cardiovascular malformations, for example, have declined as a result of rapid advances in the field of infant heart surgery. Several research projects have contributed to improved evaluation and treatment guidelines, the development of 3-D imaging techniques, echocardiography, and deep hyperthermia surgical technique.

HIV/AIDS remains a national and international epidemic, but there has been research based progress in this area as well. In the U.S. the incidence rate of new cases dropped for the first time in 1993 and deaths among people with AIDS declined for the first time in 1996, dropping 25 percent.[2] As a result of new, more effective combination therapies, people are living longer with HIV and development of opportunistic infections are being delayed.

These are but a few examples of where medical research has improved health and reduced morbidity and mortality.

NEW TECHNOLOGIES IN NIBIB

Question. I note that you are requesting $40.2 million for a new National Institute of Biomedical Imaging and Bioengineering for creating new technologies. Is there any thought given by yourself or your staff about the cost-effectiveness of these new technologies?

Answer. We are excited about the new opportunities that the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) will create for support of fundamental research that applies principles of engineering, mathematics, computer science and the physical sciences to biological processes, disorders and diseases. NIBIB has great potential to promote innovation and discovery that could have a significant impact on virtually every area of medical science. We have just begun to constitute our research portfolio and identify programmatic gaps and prioritize the many scientific opportunities before us. As the application of these scientific disciplines to medicine is still relatively new, it would be premature to make ironclad promises as to their cost-effectiveness. However, we plan to conduct technology assessment and outcome studies as authorized by legislation. As the science and the NIBIB research portfolio mature, we will plan to conduct such evaluations to answer the question you propose.

Question. Are we at risk of developing technology that is unaffordable to many people as we are seeing with some of the AIDS antiviral drugs?

Answer. NIBIB will support fundamental research that applies principles of engineering, mathematics, computer science and the physical sciences to biological processes, disorders and diseases. In some respects, such an approach to human health is still relatively new. We will support studies that examine incremental changes from technologies as they are applied today, as well as new and innovative approaches that reject current technologies in favor of completely new paradigms. The studies that NIBIB will support will add to biomedicine's knowledge base. At this juncture, there is no way to tell which as yet undeveloped technologies may make the largest impact on health and what the cost of these technologies would be. NIBIB's is authorized to conduct technology assessments and outcome studies, and such evaluations will address these key issues.

RESEARCH PROJECT GRANTS

Question. I also note that the funding rate for grant applications has remained at around 1 in 3. Are the remaining two-thirds of significant less quality?

[2] MMWR. "HIV and AIDS in the United States" June 1, 2001/Vol. 50/No. 21. Figure 1, page 432.

Answer. Success rates for Research Project Grants (RPGs) represent a complex set of factors. They represent the ratio of RPG awards to the total RPG applications received for that fiscal year. Success rates vary among Institutes, among RPG activities such as single-investigator initiated traditional (R01s) grants and multiple investigator program projects (P01). Success rates and submission of applications also vary among types of grants, such as new grants, first time awardees, and competing renewals which depend on the cycling of grants from noncompeting to competing status. Furthermore, there is not a linear relationship between budget level, number of applications, and number of awards. That is, an increase of twice the current budget levels will not result in an increase in twice the number of applications or twice the number of grants awarded. This is because institute portfolios are based on a number of interrelated mechanisms and factors, including the balance between intramural and extramural research, investigator initiated projects, contracts, centers, as well as the number of grant applications, the size of grants, the length of project periods.

With the recent increases in the NIH budget, we have funded research project grants that typically have larger budgets, such as clinical trials, epidemiologic studies and various genomic projects. We have also witnessed an increase in the number of applications, but not to the extent that has significantly affected our success. There are always some projects that would ordinarily remain unfunded, but which have some particular value and for which we might make a modest award. However, our experience is that those applications that are in the lower half of all applications received are generally in need of significant revision before we would consider funding.

MERITORIOUS RESEARCH

Question. Are we shutting out the majority of meritorious research with our current budget?

Answer. No, we are not shutting out the majority of meritorious research with the current NIH budget. While peer review remains a highly competitive process, the NIH is firmly committed to funding meritorious research. The Institutes and Centers (ICs) have developed various strategies to fund applications that are of particular significance or importance to public health, e.g., through selective pay or bridge grants. In some cases it may be desirable to fund a portion of an application or provide seed money to help an applicant develop a fuller research plan for resubmission and review at a later date.

CLINICAL RESEARCH CAREER DEVELOPMENT PROGRAMS

Question. Are the programs in place at the NIH to attract clinical researchers sufficient?

Answer. The NIH launched three new clinical research career development programs in fiscal year 1999—Clinical Research Curriculum Award (K30), Mentored Patient-Oriented Career Development Award (K23) and Mid-Career Investigator in Patient-Oriented Research Award (K24). These programs have been successful and continue to attract enthusiastic response from the community. Since their inception, NIH has funded 278 K23, 158 K24, and 55 K30 awards.

In addition to these programs, the NIH is currently developing a program announcement to provide support to institutions to develop degree-granting programs in clinical research. It is anticipated that the National Center for Research Resources will take the lead in this initiative and launch it in fiscal year 2002. We believe that these new programs, along with the other existing clinical career development awards, e.g., K08, K12, etc, have gone a long way in addressing the need for training more qualified physician scientists.

Question. Are you seeing an adequate number of clinical research grant applications in comparison to basic science?

Answer. In fiscal year 2000, the NIH funded over 11, 000 clinical research awards out of a total of 44,363 awards (26 percent), both new and continuing projects. This number of awards includes all types of NIH-supported extramural awards, including training grants, fellowship awards, construction grants, NLM resource awards, and research and development contracts. The percentage of clinical research awards has remained relatively stable for the last five years.

STEM CELL

Question. I asked for detailed responses from each of your institute directors on the role of stem cells in the mission of their respective institute. Most of these reports give overwhelming support to the potential of stem cells in their field. I also

understand that you have only received 3 applications for stem cell grants this year. Is this surprising to you?

Answer. Still in review. Will provide an answer upon completion.

CANAVAN'S RESEARCH

Question. Please explain to the Committee what research is currently being conducted at the NIH on Canavan's Disease.

Answer. Canavan's disease is one of a very large number of childhood brain diseases, each caused by inherited defects in a different enzyme. In this case, the enzyme affected is called aspartoacylase and the disease is very severe. About a decade ago, scientists identified the enzyme that was at fault. About five or six years ago, the gene causing the defect was identified. Just last year, an NIH-funded scientist succeeded in creating a genetically engineered mouse model of Canavan's disease. The mouse model of the disease will enable researchers to study precisely how the gene defect harm the brain and to develop and test possible therapies. More generally, NIH supports considerable efforts to develop therapeutic interventions for the many inherited enzyme disorders, such as Canavan's, for which the gene is now known, but no therapy is available. These potential interventions include conventional drugs, gene therapy, use of stem cells, and enzyme replacement. NIH is encouraging more research concerning these diseases through workshops, solicitations and other efforts.

A recent report indicated that an application that was pending before the NINDS was not funded because of the lack of a control group.

Question. Please provide a detailed description of the problems involved in funding a safety trial for persons with Canavan's Disease.

Answer. As you have noted, an application to study the transfer of the aspartoacylase gene to children with Canavan's disease is pending. As you can well imagine, the issues and considerations involved in the design of a clinical trial to establish the safety of a gene-based intervention for children with Canavan's disease are extensive. Such a study involves not only gene transfer, but gene transfer to the brain by neurosurgical procedures in children. First, the grant application must ensure that the preclinical and preliminary clinical data are of sufficient strength to support proposing such a trial in children. Then, the study design presented must thoroughly address numerous safety and ethical issues including concerns about the establishment of outcome measures; the use of anesthesia during diagnostic MRIs and surgery; safety controls in production of the vector, that is, the agent being used to transfer the genetic material; potential immune responses to the vector; safety of administration of the vector including the number and location of injection sites in the brain and the rate of administration; the risks of the neurosurgery itself; the plans for post-operative care; the adequacy of the informed consent process; the procedures established for the monitoring and reporting of adverse events; and the overall plan for data and safety monitoring. In addition, the NINDS must ensure that all required reviews and approvals for a trial of this nature have been received. These would include not only approval of the investigational new drug (IND) application by the Food and Drug Administration, but protocol submission to the NIH Recombinant DNA Advisory Committee (RAC), and approvals of the research protocol, including the informed consent and safety monitoring processes, by the local institutional review boards (IRBs).

I can assure you that members of the NINDS staff have been working closely and intensely with the principal investigator of the proposed study to which you refer, so that the pending application can be given every consideration in accordance with applicable policies and procedures. The Institute is committed to advancing research on Canavan's disease as well as the other childhood brain diseases caused by enzyme deficiencies that result from inherited genetic defects.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

VARIANT vCJD THREAT

Question. As you may be aware, Senate Subcommittee on Consumer Affairs, Foreign Commerce and Tourism held a hearing on April 4 of this year on transmissible spongiform encephalopathies, also known as TSEs. One type of this TSE called variant Creutzfeldt-Jakob Disease (vCJD), has been a particular problem for our friends in Britain where 97 people have died from vCJD, presumably from the consumption of prion infected beef. In your opinion is vCJD a threat to the United States?

Answer. We should keep proper perspective since there has not been a case of the human disease, vCJD, in the United States, but we must remain vigilant to ensure

that we take the proper steps to make sure that vCJD does not affect people in this country. There is strong evidence that the distinctive biological and molecular features of the infectious agent isolated from cattle infected with BSE, or mad cow disease, are identical to that in the human cases of vCJD, so that prevention of the animal disease, BSE, is important for prevention of the human disease, vCJD. BSE has not been detected in the U.S., but it would be unwise to assume that it can't happen here. We still don't know for sure how BSE first arose in Britain-it might have been from "rendered" cattle feed containing remnants from sheep with the related disease scrapie, or perhaps BSE arose spontaneously as the form of CJD in humans can do. We do have sheep with scrapie in this country, as well as other animals such as deer with a closely related disorder, chronic wasting disease (CWD). Furthermore, most cattle are slaughtered at an age too young to show obvious symptoms of BSE or to be detected as infected on currently available tests, so a spontaneous case capable of harboring and transmitting the disease could go undetected. So, the important thing is that we must make sure that we have procedures in place to prevent an isolated case of BSE from spreading if it does occur.

As discussed at the hearing you noted, the U.S. Department of Agriculture, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention CDC) have imposed a series of safeguards to protect human and animal health. In Britain, it was later learned that the spread of BSE was greatly increased because carcasses of BSE-infected cattle were used to make animal feed (meat and bone meal), resulting in contaminated product that was fed to other cattle. The FDA in 1997 published a regulation to prevent this type of spread of BSE, should BSE occur in this country. The FDA regulation prohibits the use of most mammalian protein to make feed for cattle or other ruminant animals. We should also keep brains and spinal cords, which are most likely to carry the disease, out of the human food chain.

We must continue to examine whether our practices are adequate and update these measures as new evidence or better scientific understanding dictates. Congress has charged the General Accounting Office to do just that, and we have briefed the GAO on TSE science and research. NIH has played an important role since the 1950's in laying the scientific foundation for confronting the public health and economic threats from the group of diseases that includes CJD and BSE. In the past year, we have increased our efforts, especially those towards developing practical tests for early detection that are badly needed. We will continue to work with other agencies to make sure vCJD does not become a problem in the United States.

vCJD ON THE RISE?

Question. Have we seen the worst of this disease yet?

Answer. The unsettling truth is that we just don't know. The British are monitoring the incidence of vCJD closely. This class of diseases has an incubation time that can be as long as decades, so it is too early to tell. The numbers of vCJD cases in Britain each year from 1995 through 2000 have been 3, 10, 10, 18, 15, and 27. Three additional cases have occurred in France and one in Ireland. Great Britain, France, and Ireland all have BSE among cattle, unlike the United States. The small numbers don't allow any reliable prediction of a trend, so we don't know whether 2001 will show the incidence is still on the rise, leveling off, or starting to decline. In this country, the CDC monitors cases of classical CJD and conducts disease surveillance to detect the possible ocurrence of vCJD. So far, no cases of vCJD have been detected in this country.

ROLE OF NIH IN vCJD RESEARCH

Question. What do you perceive the role of the NIH to be in researching and finding a cure for a disease such as vCJD that has yet to infect a single American?

Answer. Although variant of Creutzfeldt-Jacob disease (vCJD) has not affected a single American, the conventional form of CJD kills about 250 to 300 Americans each year. We should not forget that if BSE were to occur in the United States, it could potentially devastate the cattle industry as it did in Britain. This would have major economic consequences. We are also quite concerned about the prevalence of related diseases such as the spontaneously occurring chronic wasting disease (CWD) in deer and elk in the United States.

NIH has supported pioneering research on CJD and other TSEs since the 1950's. This research that has been recognized by the award, to U.S. scientists, of two Nobel prizes because of its significance to science and medicine. The scientific foundation of the work supported by NINDS has been essential for confronting the public health threat of vCJD with appropriate safeguards and without panic.

These are unusual diseases. We would not have been able to detect the disease, how it is transmitted, where to focus our future work, and what precautions to take, without those years of scientific investigation supported by NINDS before BSE and vCJD appeared. We are actively engaged in strengthening our broad program of investigation into these disorders, including work towards developing diagnostic tests and treatments. Last year, we awarded major contracts focused on developing tests capable of detecting early stages of the disease, tests that at this point, are critical to confront the public health and economic threats.

Finally, rare diseases often show us the way toward understanding common diseases, and there are some intriguing suggestions this may be so in this case, too. Many scientists, including the Nobel winners I noted, believe that the study of CJD may offer clues to more common neurodegenerative disorders such as Alzheimer's and Parkinson's.

VIRAL SIMILARITIES

Question. Do you see any similarities between vCJD and the West Nile Virus or the AIDS virus?

Answer. The most significant feature shared by all three of these viruses is that they all originated as an infection of a non-human species and humans were, or still are, the "accidental" hosts. Infections such as these are known as "zoonosis." The origin of variant Creutzfeld Jacob Disease (vCJD) is thought to be bovine spongiform encephalopathy (BSE) or mad cow disease. The mechanism of transmission to man is still not understood. Ironically, cows may also be an "accidental" host probably acquiring the infection from sheep infected with scrapie, another related disease.

West Nile Virus (WNV) is only spread to humans by the bite of a female mosquito, usually Culex pipiens. Humans are considered to be "accidental hosts" in a cycle of transmission of WNV, that is normally from mosquito to bird and then back to mosquito, when it feeds on infected birds. Unfortunately, infected mosquitoes can also spread disease to man, horses, cats and dogs.

Although HIV is now most commonly spread by sexual transmission or contact with blood from another infected human, the origin of HIV was likely the accidental transmission to humans of a related non-human primate virus.

While the HIV virus, vCJD, and WNV also share certain biological properties such as the ability to affect the brain, they are caused by different agents, take different paths to infect man, produce different symptoms, and differ in other important ways. The agent that causes vCJD is believed to be a "prion", agent containing protein only and without a genome. Its pathology results from a chain reaction when the prion initiates a series of repetitive improper folding of a normal brain protein. Classic CJD is a "slow" disease that may take many years between exposure and disease and the course of the disease itself is slow, in the range of four to five years. One of the frightening features of the new variant vCJD is that the course of disease is more rapid, and patients progress from first symptoms to death in about a year.

The West Nile virus is a flavivirus. This is a family of viruses whose genome is single-stranded RNA. Unlike vCJD, WNV causes an acute infection in that both the incubation period and the time of symptomatic infection are short. Most infections are mild but the severe form of the infection, encephalitis, may occur if the virus is able to migrate from the blood to the brain.

The genome of HIV is also RNA, but during replication it is transformed to a double-stranded DNA copy which integrates into host cellular DNA. HIV, like vCJD, causes a chronic infection with disease developing long after initial exposure, although some individuals may have mild flu-like symptoms within a few weeks of infection.

These three diseases taken together serve as reminder that we must take a global perspective on research and public health. Each of these diseases has its origin outside of the United States. Vector-borne diseases, such as West Nile Virus infection, which have a complex life cycle in nature that involves an animal host that amplifies the infection and the mosquitoes that transmit virus, have never respected borders, and the reality of commerce and air travel today accelerates the spread of such diseases. With modern transportation, a person or other carrier with an infectious disease can travel to the United States from any part of the world, often during the incubation period of a disease—that is after infection begins but before any symptoms are apparent. In the future, we will certainly confront other new or "emergent" diseases, like AIDS HIV infection or vCJD, diseases previously unseen or rare in the United States, like West Nile or Hantavirus, and drug resistant forms of old diseases, like tuberculosis and malaria. Thus, we must maintain a broad research

base and a responsive public health infrastructure so we can deal with the unexpected. NIAID has a long-standing commitment to research directed toward understanding, identifying, preventing and controlling emerging and re-emerging infections (for more information see the website, www.niaid.nih.gov/dmid/eid).

VCJD AND PRION INFECTED BEEF

Question. To your knowledge, is the consumption of prion infected beef the only way for humans to contact vCJD?

Answer. The evidence is quite compelling that vCJD is linked to BSE, or "mad cow disease," but we are not certain exactly how people acquired the disorder from cows. Consumption of beef, especially beef products that contain spinal cord and brain tissue, is the most likely route. However, the FDA has also been considering potential risks posed by the use of drugs, dietary supplements, cosmetics, and processed foods derived from cattle. The agent of CJD cannot be destroyed by sterilization. Thus, while CJD cannot be transmitted from human to human by casual contact, it can be transmitted by brain material on contaminated surgical instruments, or by drugs derived from certain tissues, so this presents another range of possibilities, though probably quite limited if the number of vCJD cases remains low. There is a theoretical possibility that CJD might be transmissible by blood products, but there is no evidence that this has ever occurred, despite several ongoing investigations of blood donors, and specifically, of people who received blood or blood products from donors later diagnosed with CJD, and hemophiliacs, who are exposed to products derived from pooled blood from large numbers of donors. So, in short, there are other possibilities through which vCJD might be transmitted, but consumption of products from cattle infected with BSE seems the most likely.

PRION RESEARCH

Question. Are you aware of any other diseases that may be better understood as a result of research in prion diseases like vCJD?

Answer. Rare disorders often provide clues to more common diseases, and scientists have certainly argued that this is the case for prion diseases. In particular, prion diseases seem to involve the formation of abnormal aggregates of proteins in the brain. Abnormal clumps of proteins are also strongly associated with several more common neurodegenerative diseases, including Alzheimer's, Parkinson's, Huntington's, and the spinocerebellar ataxias. For all of these diseases, scientists are actively studying just how the abnormal processing of proteins leads to aggregates and how that relates to the progression of the disease. All human brains have a normal prion protein but we do not know what its function is nor how it becomes abnormal and possibly can cause disease. We are beginning to learn that, when the normal prion protein and closely related proteins are not present, brain dysfunction occurs, and this might be an important clue. At this point, it is too soon to speculate as to where such research will lead.

NIH SUPPORT OF PRION RESEARCH

Question. If so, does increasing our NIH investment in prion disease make sense to you?

Answer. We are increasing our investment in this area, especially in critical areas like the development of diagnostic tests. The Department has been coordinating the NIH efforts with those in the FDA and CDC. The issues of BSE in cattle and prevention of an vCSD infections in the U.S. are of public health significance and the need for a useful, reproducible diagnostic test is essential. However, scientists with specialized training in prion diseases are needed to do productive work in this area. Much of this research requires very expensive, high level safety containment facilities, and we are working on enhancing that aspect as well. We must also maintain close communication with the considerable efforts underway in Europe, so we learn from their experience and work together toward the same ends.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

PANCREATIC CANCER

Question. Pancreatic cancer is the fourth leading cause of death from cancer for men and women, but the amount of research funding per mortality that's devoted to it is among the lowest of all cancers. What's more, the NCI's Progress Review Group on Pancreatic Cancer found that there are only about 9 principal investigators in the United States who are focused on this terrible disease. What can be done

to increase funding for research in pancreatic cancer and to get more scientists involved?

Answer. The NCI is committed to increased resources for pancreatic cancer research. The aim of this increase is to catalyze implementation of the research priorities recommended in the Pancreatic Cancer Progress Review Group (PRG) report.

The NCI has always funded outstanding research, including research focused on pancreatic cancer. The low level of NCI funding for pancreatic cancer research, and the limited number of researchers focused on this disease, largely reflects the difficulty in studying it. For example, pancreatic cancer exhibits a diversity of biological properties, and patients exhibit a variety of nonspecific symptoms. In addition, as noted in the PRG Report, pancreatic cancer care is complicated, and outcomes are nearly always disappointing. Nevertheless, the NCI is committed to a leadership role in surmounting these difficulties.

In response to the PRG Report, the NCI is undertaking a comprehensive review of its initiatives, activities, and funded projects, as they relate to the PRG's recommendations. In July, the NCI Director and other NCI staff will meet with the PRG members to identify gaps in the NCI research portfolio and discuss strategies for filling them. After the conclusion of this meeting, the NCI will prepare a plan for implementing the PRG's recommendations. This plan will include strategies for addressing recommendations that haven't been addressed adequately. It also will include information about ongoing NCI activities that address the PRG's other recommendations. The NCI will reconvene a meeting of some or all of the members of the PRG in 2–3 years to discuss and assess progress in advancing scientific knowledge and implementing the PRG's recommendations.

In summary, the NCI will aggressively increase resources for pancreatic cancer research, and it will address and implement the PRG's recommendations thoroughly and comprehensively. Through these efforts, the Institute hopes to increase the number of researchers focused on pancreatic cancer, and more importantly, to alleviate the burden of pancreatic cancer on U.S. citizens.

Last August, the general counsel for the Department of Health and Human Services said federal funding could be used for research on embryonic stem cells as long as the cells met certain NIH guidelines. But it's unclear whether any such cells exist. The only group that is known to be distributing stem cells in the United States is WiCell, and their cells do not meet NIH guidelines. There's an Australian researcher who says his cells do meet the guidelines, but this claim has not been verified.

STEM CELL FUNDING

Question. Do you know whether there are any stem cells today that are eligible for federal funding?

Answer. Still in review. Will provide an answer upon completion.

BIOMEDICAL RESEARCH INFRASTRUCTURE

Question. The president has requested a nearly 30 percent increase in funding for construction of extramural NIH research facilities, for a total of $97 million. Even that increase, however, is significantly below what's needed to address the current backlog, let alone provide adequate lab space for the influx of new research. A 1998 National Science Foundation study on the status of scientific research facilities at U.S. college and universities identified an estimated $11.4 billion in deferred construction and renovation projects, as well as a decrease in new construction of health research facilities across an array of institutions. Has the NIH collected any data on the extent of this problem?

Answer. In general, the Nation's research infrastructure has served the biomedical community well to date, allowing the United States to remain a world leader in biomedical science. There is some data that suggests that the Nation's biomedical research infrastructure is fast becoming outdated or insufficient, for example the NSF report. NIH has not collected any data itself on the extent of the problem.

The need for modern research facilities will become increasingly urgent in the coming years. As research becomes more complex, which in turn, requires a multidisciplinary research team with complementary scientific expertise there are even greater demands on the nation's already overburdened research facilities. In addition, entirely new types of research facilities are needed to keep pace with today's rapid rate of change in the biomedical sciences and the need to accommodate high through-put technologies. Many emerging disciplines and technologies require new types of specialized facilities, such as biocontainment laboratories for handling infectious agents or clean rooms for producing clinical-grade gene vectors. As a result,

facilities once expected to last for two or three decades can become technologically obsolete in less than half that time.

The Acting Director of NIH, Dr. Ruth Kirschstein, appointed a Working Group of the Advisory Committee to the Director, NIH, to identify some of the factors that limit the construction and renovation of biomedical research facilities. The Working Group's primary charge was two-fold: (1) To examine the adequacy of current funding mechanisms for enhancing the infrastructure of research facilities in the biomedical sciences, and (2) To propose Federal actions that might bolster needed construction and renovation of such facilities at a variety of institutions. The Report of the Working Group was presented at the meeting of the Advisory Committee to the Director at the meeting this June. Dr. Kirschstein requested that the members of the ACD further discuss the recommendations in the Report with colleagues at their institutions; the report may be modified as a result of that process before the ACD accepts the Report. Question. Extramural NIH construction is authorized at $250 million. Given the current situation, would it make sense for the NIH to spend more than $97 million?

Answer. The fiscal year 2002 Budget provides $100 million for extramural construction, a $22 million increase (+28 percent) over fiscal year 2001. This funding level will enable the NIH to continue to support infrastructure upgrades at biomedical research facilities through the Research Facilities Construction grant program.

NCCAM SUCCESS RATE

Question. The success rate for research project grants in the National Center for Complementary and Alternative Medicine is projected to be just 16 percent in fiscal year 2002, compared with an NIH average of 30 percent. Why is it so low? What can we do to bring that number up?

Answer. Success rates for Research Project Grants (RPGs), the ratio of RPG awards to the total number of RPG applications received for a given fiscal year, represent a complex set of factors. Success rates typically vary among Institutes and Centers, among RPG activities, such as single-investigator initiated traditional grants (R01s) and multiple-investigator program projects (P01s), and among types of grants, such as new grants, first time awardees, and competing renewals which depend on the cycling of grants from noncompeting to competing status.

Furthermore, there is not a linear relationship between budget level, number of applications, and number of awards. That is, an increase of twice the current budget levels will not result in an increase in twice the number of applications or twice the number of grants awarded. This is because the NCCAM portfolio is based on a number of interrelated mechanisms and factors, including the balance between intramural and extramural research, investigator initiated projects, contracts, and centers, as well as the number of grant applications, the size of grants, and the length of project periods.

For the fiscal year 2002 President's Budget submission prepared in early April, NCCAM estimated it would receive 220 applications in fiscal year 2001, and 245 applications in fiscal year 2002, for an estimated success rate of 17 percent and 16 percent respectively.

It is difficult, however, for NCCAM to predict with certainty the number of applications it will receive. Investigator-initiated applications reflect the state of a particular arena of science, public health need, the maturity of a scientific field, and even the morale of the scientific community. While the detailed outcomes of scientific discovery cannot be predicted, the current level of enthusiasm demonstrated by the research community is expected to continue, and the potential of current scientific opportunities and the successes of the past lead us to predict that NCCAM's continuing investment in all mechanisms of research support will be easily repaid in discoveries that will benefit the U.S. public.

Question. The President's proposed NIH budget for fiscal year 2002 calls for an increase of $2.74 billion, for a total of $23 billion. But he also wants to double the fee for evaluation activities from 1 percent to 2 percent. Wouldn't that change effectively reduce the NIH increase by $230 million?

Answer. As with most of the Department's other public health agencies, NIH contributes its fair share of funds to the Public Health Service Evaluation Fund, as authorized under Section 241 of the PHS Act. NIH traditionally, provides about 70–75 percent of these funds, reflecting the relative size of the NIH budget. These funds have always been used to support health statistics surveys by CDC/NCHS, health care services and health care quality research by AHRQ, and, as proposed for fiscal year 2002, national data collection surveys by SAMHSA and policy research by ASPE. NIH receives significant benefits from the projects supported through theses

funds. By financing them through the PHS Evaluation Fund, the President's Budget proposes to more fully reflect the cross-cutting value of these health surveys and health care research activities of NCHS, AHRQ, SAMHSA, and ASPE. Under the fiscal year 2002 request, NIH's evaluation fund share would increase by $189 million over its fiscal year 2001 contribution. Excluding the evaluation fund assessments in the base, as well as in the request, NIH's proposed budget would still increase by nearly $2.6 billion, or +12.7 percent in fiscal year 2002.

QUESTIONS SUBMITTED BY SENATOR ERNEST F. HOLLINGS

RETINAL DEGENERATIVE DISEASES

Question. Macular degeneration is a major and growing public health problem. Macular degeneration, Retinitis Pigmentosa and other retinal degenerative diseases can lead to blindness. How is the National Eye Institute responding to this challenge?

Answer. Macular degeneration belongs to a group of retinal degenerative diseases that includes retinitis pigmentosa (RP), Usher syndrome, Leber Congenital Amaurosis, and allied diseases. As a group, these diseases are a major cause of blindness and therefore a priority area of research focus for the intramural and extramural programs of the National Eye Institute (NEI). Macular degeneration affects the part of the retina responsible for sharp central vision. One form of the disease, age-related macular degeneration (AMD), is the leading cause of irreversible vision loss in the United States among persons over 65 years of age, the fastest growing segment of the US population. In spite of the public health significance of AMD, there is no proven treatment for most affected persons and information about its clinical course and the factors that predispose to it is limited. NEI-supported research on the identification of risk factors for AMD can help provide clues about the etiology of the condition and help to develop possible strategies for intervention. Two potentially modifiable risk factors, smoking and hypertension, have already been associated with the most severe form of AMD. The Age-Related Eye Disease Study (AREDS) is an ongoing multi-center study of the clinical course of AMD to identify additional risk factors for the development of high risk characteristics associated with severe vision loss. Another part of this study is investigating the effect of antioxidants and zinc on the progression of AMD. A major clinical trial is also underway to determine whether low intensity laser treatment can prevent the development of advanced complications of AMD.

NEI-sponsored scientists recently reported the results of a gene transfer study that restored sight in an animal model of the inherited retinal degeneration—Leber Congenital Amaurosis. Continuation and expansion of this line of research offers hope for children who are afflicted with this blinding condition and may lead to development of gene transfer therapy applications for other inherited retinal degenerations. Other scientists are actively pursuing laboratory and clinical studies on the rescue and regeneration of deteriorating neurons; the identification of genes and neurodegenerative mechanisms for macular degeneration, RP, and related disorders; and the use of growth factors and transplantation, as well as gene therapy, as potential therapeutic measures. The goals of these studies are to increase understanding of the causes and mechanisms of cell death in retinal degenerative diseases, and to accelerate the development of innovative strategies to prevent, treat, and cure these diseases.

LOW VISION

Question. Also, many eye diseases leave people with severely impaired vision. Is the NEI doing anything to help them cope with their impairment and to improve these individuals' quality of life?

Answer. To address the special needs of those with uncorrectable visual impairment or low vision, the NEI supports a program of research on visual impairment and its rehabilitation. Some individuals require simple optical or mechanical aids to perform daily functions adequately, while others may need more specialized devices or environmental modifications. The NEI supports research to understand the origins of visual impairment and assist in the rehabilitation of those who have such disabilities. The NEI supports projects aimed at improving the methods of specifying, measuring, and categorizing loss of visual function; devising strategies to help visually impaired people maximize the use of their residual vision; systematically evaluating new and existing visual aids; developing an adequate epidemiological base to understand the causes of blindness, partial loss of sight, and visual anoma-

lies; and studying the optical, electronic, and other rehabilitative needs of people with visual impairments.

Additionally, the NEI established a Low Vision Education Program as a part of its National Eye Health Education Program to increase awareness of low vision and its impact on quality of life. This program is directed toward people with low vision, their families and friends, and the health care and service professionals who care for them. It takes particular note of the growing population of people over age 65 and other high risk populations, including Hispanics and African Americans who are likely to develop low vision at an earlier age. As part of this education effort, the NEI has developed a public service campaign and a mobile exhibit on low vision that is currently traveling to shopping malls and centers throughout the United States. It contains an interactive multimedia touch screen program; provides information on low vision services and resources; and displays aids and devices that help people with low vision, all available in Spanish as well as English. The exhibit and touch screen program explain the causes of low vision; offer personal accounts of people living with low vision; and provide a self-assessment to help people determine if they or someone they know may have low vision.

QUESTIONS SUBMITTED BY SENATOR KAY BAILEY HUTCHISON

FUNDING COLLABORATION

Question. U.S./Israel Cancer Collaboration. I understand that the National Cancer Institute recently funded a workshop to explore the feasibility of a U.S.-Israel collaboration on research projects related to cancer genetics. Please describe the intention of the NIH/NCI with respect to pursuing and funding this collaboration.

Answer. NCI staff participated in the workshop and related meetings in Houston last fall to discuss this topic. The NCI was impressed with the list of areas of mutual interest for potential collaborations.

Since that meeting, the joint group has identified priorities for such collaborations. The goal is to facilitate collaborations that result in competitive research proposals that succeed in peer review.

Building toward this goal, NCI is working on two possible collaborations, both of which are very preliminary at this time:

—*Ovarian cancer screening study.*—Researchers from the Hadassah Medical Organization in Jerusalem have expressed interest in collaborating in a trial of a new screening strategy for women at high risk for ovarian cancer based in the NCI's Cancer Genetics Network (CGN). Israeli collaborators could contribute to this trial through partnership with M.D. Anderson Cancer Center. A pilot study to evaluate the feasibility of this trial is underway.

—*Behavioral research.*—Initial discussions between NCI staff and representatives of Hadassah Medical Organization have identified areas of mutual interest in research on the implications of testing individuals and families for genetic risk factors. NCI is inviting Israeli investigators to participate in the CGN Behavioral Research Working Group to develop competitive grant applications for submission in the near future.

NCI has a strong, continuing interest in facilitating international research collaborations to meet research objectives that would be otherwise difficult to address using only domestic resources. One high priority area is research on the implications for the prevention and treatment of cancer posed by interactions between genes and environmental exposures. The scarcity of appropriate high-risk individuals and families who have a genetic susceptibility and the costs associated with the necessary studies has made it clear that national and international collaborations will be crucial to the success of our research enterprise.

Existing studies at the Weizmann Institute of Science, Rehovot, are aimed at understanding the mechanism of action of the p53 tumor-suppressor gene in its normal (wild type) and mutated forms. Inactivation of the endogenous wild-type p53 gene is associated with more than one-half of all cases of human cancer. Studies are focusing on the identification and characterization of genes involved in p53 regulation. Other NCI-supported projects at the Weizmann Institute address (a) use of magnetic resonance imaging and spectroscopy as noninvasive procedures for early evaluation of breast cancer response to hormonal therapy and (b) investigation of molecular mechanisms through which the ErbB–2/HER2 oncoprotein contributes to tumorigenesis in various adenocarcinomas.

At Tel Aviv University, NCI currently supports research on the neuroendocrine and immunologic mechanisms underlying the modulatory effects of the estrous

cycle, gonadal hormones, and gender on immune competence and tumor development.

NCI is also supporting an epidemiologic study of ovarian cancer at the Chaim Sheba Medical Center, Tel Hashomer, to evaluate a broad range of potential risk factors (e.g., reproductive, hormonal, nutritional, genetic, and occupational factors). Genetic analysis is also being added to the study. Scientists are pursuing the possibility of performing a study to assess the role of the BRCA1 and BRCA2 genes in prostate cancer risk, and a study of BRCA1 and BRCA2 gene mutations in male breast cancer is also under way. In addition, a feasibility project is being conducted to ascertain whether ataxia-telangiectasia is hereditary in approximately 24 candidate families and to determine procedures for a population-based study of cancer risk in these families.

Mutations in the BRCA1 or BRCA2 gene are thought to account for about 90 percent of familial forms of breast cancer and ovarian cancer. In a study involving more than 5,000 Ashkenazi Jewish volunteers from the Washington, DC area, mutations in either BRCA1 or BRCA2 occurred in nearly 1 in 40. Collaborators on this project included scientists from the Chaim Sheba Medical Center in Israel.

INTERNATIONAL COLLABORATIONS BY INSTITUTES

Question. Considering the success of international cooperation on the Human Genome Project, do you see advantages to similar collaboration with other nations, like Israel, in other research areas, like cancer?

Answer. The NIH participates in a broad range of international collaborations with many of the Institutes striving to develop and maintain a strong and diverse selection of international collaborations and initiatives. For example:

National Cancer Institute (NCI)

NCI, in cooperation with extramural institutions and the Fogarty International Center of the NIH, supports international health research through bilateral agreements, grants, and contracts. NCI supports some 1,000 Visiting Scientists and Exchange Scientists. The work of outstanding scientists throughout the world is supported through fellowships, cooperative projects, exchanges of personnel and materials, workshops and international dissemination of cancer information.

NCI's international effort, coordinated by the Office of International Affairs (OIA) within the Office of the NCI Director, works in conjunction with programs within NCI's divisions, at other NIH Institutes and the Fogarty International Center. Advances in cancer research result from NCI support and from support by other U.S. and foreign government agencies, industries, private nonprofit institutes, and individual philanthropists.

One way in which NCI fosters joint research between U.S. and foreign scientists is by cosponsoring international workshops. The NCI workshops program brings together small groups of U.S. and foreign scientists who are at the forefront of their fields of research, to discuss their newest research that has not yet been published.

NCI is supporting several projects that are collaborative efforts with other countries:

—NCI supports the work of investigators at Tata Memorial Hospital, Bombay, India, in a community-based randomized-control evaluation of low-cost methods for early detection of common cancers in women. Breast and cervical cancers account for about 50 percent of cancer deaths in women in India. Among the diagnostic methods being evaluated are clinical breast examination without mammography, self-examination, and visual inspection of the cervix by trained female health workers. The goal is to reduce mortality by detection and diagnosis of breast and cervical cancer at an early stage. This trial is one of the first of its kind to be conducted in a developing country, and findings may be relevant to other countries and populations with limited resources (e.g., underserved populations in developed countries).

National Institute of Allergy and Infectious Diseases (NIAID)

NIAID supports a broad research portfolio that encompasses multiple infectious diseases including malaria, tuberculosis and HIV/AIDS. Because so many of these diseases occur primarily or solely outside the United States but have the capacity to emerge as public health threats in the U.S., NIH and NIAID have long recognized that programs promoting international research efforts and other disease control measures in the developing world can help to protect the health of Americans as well as the health of people living in countries where these diseases have long been endemic. Therefore, strengthening the research capability of scientists in their own countries is an important focus of NIAID efforts. One of the cores of our international programs is the rich network of partnerships—a set of alliances for con-

ducting cutting-edge research, fostering good will, and transferring technical knowledge and know-how to research institutes and hospitals in regions of the world where tropical diseases are endemic. The alliances encourage U.S. scientists to work in and obtain expertise on disease issues in those regions. They also enable investigators from those areas to collaborate on research projects on site and to visit U.S. laboratories and attend scientific conferences and workshops to discuss with global experts the challenges of studying and combating these diseases.

International Centers of Excellence:

An important component of the NIAID Strategic Plan is a focus on addressing global health disparities. In order to address the disproportionate burden of infectious diseases on third world countries, NIAID is in the process of setting up International Centers of Excellence (ICERs). These research centers will be joint ventures between NIAID's intramural and extramural divisions and host nations. Extensive infrastructure improvements, equipment procurement and personnel and financial resources will be crucial to the success of these endeavors. Three sites have been identified by the NIAID:

—The Tuberculosis Research Center (TRC) in Chennai, India will be the base for an ICER to expand research on tuberculosis, lymphatic filariasis and HIV. Research will initially focus on the interaction between pre-existing helminth infection and mycobacterial infection, studies of chemotherapy of TB in HIV infected patients and the influence of non-HIV infections on HIV expression. Longer term goals include understanding the interaction between allergic disease and helminth infection, the genetics of asthma in a tropical setting, drug resistance in both helminth infection and TB, and possible assessments of vaccines for *Plasmodium vivax*, TB, HIV or group A streptococcus.

—The Rakai District in southwestern Uganda will be a base for an ICER to focus on HIV and STDs, including the effects on pregnancy, fertility, infant survival, placental pathology and mother-to-child HIV transmission.

—The Papua New Guinea Institute of Medical Research will be the site of an ICER to conduct malaria vaccine studies. The development and testing of asexual blood stage malaria vaccines will be the primary focus.

HIV Networks:

MAID supports two global research networks, the HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN). The HVTN is a network of clinical sites in the United States and abroad that is dedicated to the development of an HIV vaccine through testing and evaluating candidate vaccines in clinical trials. The network includes 11 sites in the United States and eight sites overseas, including sites in Africa, Asia, South America, and the Caribbean. The HVTN's global capacity will allow for rapid expansion as more vaccine candidates enter the pipeline for testing and development, and for carrying out larger scale studies of suitable vaccines.

—The HPTN evaluates the safety and efficacy of non-vaccine prevention interventions, alone or in combination, using HIV incidence as the primary endpoint. Because HIV is transmitted via different routes in different populations, developing a variety of HIV prevention strategies will have a significant impact on reducing transmission rates and slowing the spread of HIV worldwide. Research through the HPTN is carried out through HIV Prevention Trials Units (HPTUs) located at nine sites in the United States and 16 sites overseas in Africa, Asia, Europe and South America.

—More recently, NIAID released a new grant program called the Comprehensive International Program of Research on AIDS (CIPRA). The goals of CIPRA are to provide long-term support to researchers and institutes in developing countries to (1) plan and implement a comprehensive HIV/AIDS prevention and treatment research agenda relevant to their populations; and (2) enhance the infrastructure necessary to conduct such research.

International Histocompatibility Working Group (IHWG):

NIAID is the primary sponsor of IHWG, a multi-national collaboration of more than 400 laboratories in 79 countries. The collective goal of this large group is to study the tremendous diversity of the human leukocyte antigen (HLA) gene complex, the most variable region of the human genome, and how this diversity affects human health. Genes of the HLA complex control immune responses and therefore determine an individual's resistance or susceptibility to autoimmune and infectious diseases. The HLA gene complex contains over 220 identified genes. Each gene may be present in several different forms (alleles), and there are over 1,000 different alleles of HLA genes. This degree of sequence variability makes the HLA complex a uniquely valuable tool in analyzing human diversity and measuring the related-

ness of distinct geographic, ethnic, and racial populations. Another feature of the IHWG that will facilitate its efforts is access to large cohorts of diverse ethnic and geographic origins. This provides tremendous statistical power for the population-based studies of HLA genetics in human diversity, transplantation, autoimmune diseases, and immune responses to infectious agents.

National Institute on Deafness and Other Communication Disorders (NIDCD)

NIDCD continues to support an international consortium with the purpose of expediting the discovery of genes responsible for hereditary hearing impairment. The consortium encompasses research on nonsyndromic and syndromic forms of hereditary hearing loss, such as Waardenburg syndrome and Usher syndrome. Scientists from countries including Belgium, Colombia, Finland, France, Germany, Israel, Japan, Norway, South Africa, and the United Kingdom, as well as scientists throughout the United States, continue their efforts to map the genes responsible for syndromic and nonsyndromic hereditary hearing impairment. Almost 60 genes have been identified for recessive and dominant nonsyndromic hereditary hearing impairment in families from Colombia, India, Indonesia, Israel, Lebanon, Newfoundland, Pakistan, Tunisia, and the United States, including Puerto Rico. The collaborative efforts fostered by the consortium have been instrumental in identifying a large number of the genes responsible for hereditary hearing impairment and in advancing the understanding of these disorders.

The Laboratory of Molecular Genetics established a collaboration with the University of Toronto on a study of hereditary deafness in Ashkenazi Jews and is actively working on the genetic mapping and identification of a novel deafness gene in a large Ashkenazi Jewish family. This has already resulted in one publication about the hearing status associated with a particular allele (variant) of a known deafness gene called connexin 26 (GJB2).

NIDCD is also collaborating with the Instituto di Genetica Molecolare of the Consiglio Nazional delle Recerche (Institute of Molecular Genetics, National Research Council), Alghero, Sardinia, Italy in a study of inherited deficits in the sense of bitter taste. This laboratory has developed a unique study population in the Ogliastra region of Sardinia, consisting of a number of genetically isolated villages. Such populations provide important experimental advantages of the study of common recessive genes, such as those that cause deficits in the sense of bitter taste in individuals of European origin. The goal of this research is to identify the genes which cause this deficit to better understand the molecular mechanisms involved in the sense of bitter taste in humans.

In another collaboration between NIDCD's Laboratory of Cellular Biology and the faculty at the Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel an attempt is underway to determine the pattern of expression and biological effects of Myosin VI during development of the auditory system. Myosin VI has been shown to be required for development of hair cells and for hearing, however the specific effects of this protein have not been determined.

National Center for Complementary and Alternative Medicine (NCCAM)

The National Center for Complementary and Alternative Medicine, in collaboration with Johns Hopkins University, Johns Hopkins Singapore and the National University of Singapore, is co-sponsoring a research symposium on traditional Chinese medicine and a workshop on clinical methodology and grantsmanship in November 2001. The symposium will present state of the art research in traditional Chinese medicine from investigators in the region. The goal of the workshop is to train potential scientific collaborators in the necessary skills to successfully compete for National Institutes of Health grants. Scientific data and conclusions from grantees in Southeast Asia, where traditional medicine is widely practiced and accepted, will broaden the knowledge base of complementary and alternative medicine interventions while providing important information on chronic diseases such as cancer and cardiovascular disease that can be targeted to reduce health disparities in Asian populations in the U.S.

Fogarty International Center (FIC)

The Fogarty International Center (FIC), the international arm of the NIH, promotes and supports international collaborations to advance medical research in virtually every area of science on behalf of the NIH. In addition, FIC focuses attention on the scientific opportunities and needs of low- and middle-income countries and works to reduce disparities in global health. Working through over 20 programs and in partnership with other NIH components, U.S. agencies and foreign counterparts, the FIC tackles global health challenges such as AIDS, mental illness, tuberculosis and maternal and children's health. FIC works through bilateral and multilateral arrangements, at times involving formal intergovernmental discussions and agree-

ments, and more frequently through scientist-to-scientist exchanges. Illustrative examples of FIC-led programs include:

Multilateral Initiative on Malaria (MIM):

Launched in 1997, the MIM brings together countries from around the world in an effort to speed discoveries in malaria research while at the same time building capacity in countries most affected to employ state-of-the-art prevention and control technologies. Among its partners are public and private science funding agencies in Great Britain, France, Japan and Norway, as well as the World Health Organization and the World Bank. Since 1999, FIC has served as the MIM Secretariat, and has advanced the MIM agenda in partnership with other NIH ICs including NIAID and NLM by: increasing malaria research funding, increasing internet access for malaria researchers, expanding the numbers of MIM sponsors, improving the sharing of research resources for malaria, and establishing new opportunities for the training of African scientists in this critical field. In addition, MIM has just recently initiated and supported the development of new estimates of malaria mortality, now known to be close to 3 million deaths per year, primarily in sub-Saharan Africa and in children under the age of five, in addition to significant disability and morbidity in Africa, Latin America and Asia.

AIDS International Training and Research Program:

Working primarily through U.S. universities, FIC supports training of scientists and health professionals from the developing world as part of international collaborative research programs. This training includes Ph.D. or Master's level degrees and is the largest program contributing to capacity to confront the AIDS epidemic in countries hardest hit. Graduates of this training are now the leaders in their country, reaching senior level positions in Ministries of Health, including the Minister of Health position. They will be essential to the design and conduct of clinical trials to test new AIDS prevention, vaccines, and treatment technologies and to ensure that such trials are conducted with scientific rigor as well as in accordance with international and local ethical norms. FIC's program, which works closely with all relevant NIH components, has led to the development of scientific infrastructure in countries such as Uganda and Senegal where HIV infection rates have been reduced dramatically or held at a low level, respectively.

Pan American Fellowship Program:

Begun with NIH counterparts in Mexico in 1995, the Pan American Fellowship Program brings post-doctoral scientists to the NIH laboratories in Bethesda for advanced training in a range of scientific areas. Building on mutual strengths and interests, fellows receive training under the mentorship of chief NIH scientists in areas such as neurobiology, infectious disease, genetics and maternal and children's health. Every year, fifteen to twenty trainees participate in this program, which is sponsored on a cost-shared basis by both countries. Based on the success of the effort with Mexico, FIC expanded the program recently to include other Latin American countries such as Argentina, Colombia, Chile, Costa Rica, and Uruguay, with additional support from the Pan American Health Organization to co-sponsor from other countries in the Latin American and Caribbean region.

National Institute of Neurological Disorders and Stroke (NINDS)

In November 2000, NINDS, on behalf of the United States, signed a Memorandum of Understanding (MOU) with the National Institute for Physiological Sciences at Okazaki, representing Japan. The purposes of this cooperative program are to stimulate studies of the molecular, cellular, and integrative mechanisms of mammalian—including human—brain function. The MOU will establish a cooperative program that will be open to all neuroscientists in both countries. Associated activities may include collaborative research projects, information sharing through workshops and seminars, short-term exchanges of scientists and other relevant activities. We believe that new knowledge about the brain and the nervous system gained through this agreement will favorably impact the health of all populations.

National Institute of Dental and Craniofacial Research (NIDCR)

Genetics of Cleft Lip and Palate:

NIDCR supports a project with the World Health Organization to serve as the umbrella organization for the development and maintenance of a global research network in the area of craniofacial anomalies (CFA). Such a network links U.S. and NIH-funded researchers with other researchers, and provides access to populations in other parts of the world for studies regarding the genetic and environmental causes of CFA, the health care systems and treatment methodologies which lead to

the best outcomes for those children born with CFA, and ways to reduce the incidence or prevent these birth defects.

As a result of this collaboration, significant progress has recently been achieved in understanding the genetics of cleft lip and palate. An NIDCR-supported research team reported the discovery of the gene responsible for cleft lip and palate when it occurs as part of a syndrome that also includes defects in the skin, teeth, and hands. The gene, called PVRL1, codes for a molecule that is important for cell adhesion. Mutations in the PVRL1 gene are responsible for a recessive cleft lip and palate syndrome, called CLPED1, which occurs with a high frequency among the population of Margarita Island. More recently, this research team has found preliminary evidence that individuals carrying one copy of the mutated gene have an increased risk for cleft lip and palate that is not associated with the other defects of the syndrome. These results may lead to the development of early diagnostic tools and prevention strategies for cleft lip and palate.

National Institute Drug Abuse (NIDA)

Pandemics such as drug abuse and HIV/AIDS require that we bring the full power of science to bear on these complex public health problems. Toward this end, NIDA has several collaborative efforts underway with the nations of Thailand and South Africa that will likely have advantages to enhance both the U.S. and the participating country's research agenda.

For example, given the extremely high rates of methamphetamine abuse in Thailand, and as a follow-up to the Pacific Regional Research Conference on Methamphetamine and Amphetamine-Type Stimulants, held in November 2000 in Bangkok, Thailand, NIDA has been working with the Thai government to determine ways to best prevent and treat addiction to this powerful stimulant. Thailand presents some unique opportunities for collaborative efforts. For one, the government in Thailand is very enthusiastic and committed to focusing on its methamphetamine problem. The population of methamphetamine abusers is also unique because of the age and symptoms of those who are abusing. Use begins at a very early age in Thailand, typically before the teen years. By the age of 12, some of these children are being diagnosed with long-term psychosis. There is much we can learn by studying this population, especially as the drug continues to spread in our own country. Also given that there are currently no medications available in the U.S. or elsewhere to combat this addiction, there is a behavioral treatment model (MATRIX) that has proven successful in the United States. This model is now being used in Thailand to help deal with their methamphetamine epidemic.

A second example of a collaborative research effort that will likely directly benefit the citizens of both nations is the efforts that NIDA has underway with South Africa. NIDA has been working with South Africa on an informal basis for over a year, but is interested in stimulating more formalized bi-national collaborative drug abuse research between the United States and South Africa. South Africa has one of the fastest growing rates of the HIV infections in the world. Although we have learned much about preventing and treating HIV/AIDS in the United States, very little is known about the potential for replicating science-based prevention and treatment approaches in settings outside of the U.S. Given the many similarities between the two countries transmission patterns and the cultural diverse populations of its citizenship, there is much the U.S. can learn from South Africa as it attempts to prevent HIV/AIDS with lessons learned from the U.S.

Finally, NIDA has also begun a collaborative research initiative with the Dutch government that includes efforts to explore areas of mutual interest. One important area is the growing use of MDMA, or ecstasy, and its short and long term effects on the brain. NIDA is hosting a workshop this fall with U.S. and Dutch researchers to review the current science and to plan for future collaborative research projects.

National Institute of Mental Health (NIMH)

As the world leader in research on effective behavioral strategies to decrease and prevent the spread of AIDS, the National Institute of Mental Health is involved in a number of international collaborative efforts that provide the opportunity to disseminate and build upon the knowledge gained, ease the burden of disease and prevent the international spread of a devastating disease. NIMH is supporting the first international trial of a U.S. tested model of community-level HIV/STD behavioral prevention program. The NIMH Collaborative HIV/STD Prevention Trial is a two-arm randomized, community-level trial being conducted in six countries—China, India, Peru, Russia, Uganda, and Zimbabwe. In addition, research collaborative agreements with the research ministries of the governments of India and South Africa have resulted in increasing the quality of the HIV behavioral prevention studies and helping to develop the research capacity of these countries.

With mental illnesses occupying such a prominent place in the global burden produced by disease, the NIMH also supports mental health research in over three dozen foreign countries.

National Institute of Child Health and Human Development (NICHD)

NICHD, in partnership with both other NIH Institutes and the Gates Foundation, has developed and implemented a Global Network for Women's and Children's Health Research. This large, international collaborative effort is essential to addressing the leading causes of morbidity and mortality in children and women of child-bearing age in resource-poor settings. Through partnerships between leading U.S. researchers and senior foreign investigators, interventions to reduce maternal and child morbidity and mortality will be tested for efficacy with advance planning that will permit the rapid and sustainable implementation of interventions judged by rigorous research to be successful.

The NICHD-sponsored study, The Hyperglycemia and Adverse Pregnancy Outcome Study is an epidemiologic investigation to clarify the association of various levels of glucose intolerance during the third trimester of pregnancy and the risk of adverse outcomes. This international collaborative study will enroll 25,000 women in the U.S., Australia, Canada, China, Israel, the Netherlands, the Republic of Singapore, Thailand, the United Kingdom and the West Indies. The study is examining glucose intolerance in a large heterogeneous, multinational ethnically diverse cohort of women in the third trimester of gestation. This international collaboration has been carefully planned and will generate robust data on the global incidence of gestational diabetes that will provide definitive international reference standards. This cooperative study makes use of state-of-the-art laboratory and measurement techniques and, via frequent steering committee meetings, facilitates the sharing of creative and innovative scientific thinking from around the globe. NICHD and NIDDK are acting jointly to support this important investigation.

The Trial to Reduce the Incidence of Type I Diabetes Mellitus in the Genetically at Risk will test the hypothesis that a nutritional intervention during infancy will reduce the incidence of type I diabetes in genetically susceptible infants. This randomized, prospective controlled clinical trial will enroll a total of 2,370 infants in the United States, Australia, Canada, Estonia, Finland, France, Germany, Hungary, Italy, Netherlands, Poland, Russia, Spain, Sweden, and Switzerland. The public health implications of this nutritional intervention will be enormous if proven successful. This study represents a collaborative international effort involving funds from the NICHD, other NIH Institutes, the Juvenile Diabetes Research Foundation, the Canadian Institutes of Health Research, and the European Foundation for the Study of Diabetes. Thus, financial contributions from both the U.S. and abroad, innovative collaborative scientific thought from an international group of diabetologists and pediatricians from the nations noted above, and enrollment of a large and diverse population will synergistically act to answer a critical public health question.

The NICHD is developing a potentially very promising research initiative with India. This initiative will foster joint research on the leading causes of morbidity and mortality among women of child bearing age and children. It also will support joint HIV/AIDS research, particularly on the prevention of HIV transmission from mothers to their children, and research on reproductive health and sexual behavior. Pursuing these lines of research in India offers great opportunities to U.S. scientists because Indian biomedical and behavioral scientists are well trained and supported by relatively strong scientific institutions. Also, because of the growing AIDS epidemic in India and the prevalence of many diseases and conditions in Indian populations of women and children, India offers unique opportunities to study new ways to improve health in large populations. Furthermore, the Government of India is committed to research co-funding so U.S. Government funding can be multiplied.

NICHD also sees important opportunities for research collaboration in Africa, which has the greatest burden of maternal and child morbidity and mortality. Research on HIV/AIDS, infectious diseases including sepsis, upper-respiratory diseases and nutrition-related disorders are a few examples of areas where research in Africa holds great potential for new discoveries. In Africa it also is most cost-effective to mount programs on a regional basis to maximize the use of trained investigators and to assure lessons learned are applied to the greatest benefit. Through the Global Network for Women's and Children's Health Research, which is co-funded by the Gates Foundation, NICHD plans to expand joint research in Africa on critical maternal and child health interventions specifically developed for developing countries. This promising program is a model for public-private partnership as well as international research collaboration.

National Institute of Environmental Health Sciences (NIEHS)

Among the many reasons for pursuing international collaborations are that some phenomena—both tools and conditions—exist in other countries that do not exist in the U.S. One is the availability of information. NIEHS is initiating a collaborative cohort study with scientists and health officials in Norway to study pregnant women and their children; this study takes advantage of that country's system of socialized medicine both to enroll the women (a very high percentage of women obtain early prenatal care) and to follow them and their children. Other studies, particularly in the field of environmental health, cast a global net to find populations and regions with higher exposure levels to pollutants of interest, in which the divisions between exposed and unexposed populations are more clearly delineated and epidemiological studies are more likely to provide clear information of either an association or a lack of an association with disease. For instance, most of the information we have used in the U.S. to assess risks from mercury exposure have come from studies in the Faroe Islands in the North Atlantic and from the Seychelles Islands off the coast of Africa, where the people eat a great deal of fish and their mercury exposure comes through that route.

SUCCESS RATE FOR GRANT SUBMISSIONS

Question. Mental Health/National Institute of Mental Health. Where does the National Institute of Mental Health (NIMH) stand relative to other NIH institutes on the rate of grants submitted and funded?

Answer. In fiscal year 2000 the average success rate (awarded grants as a percentage of total grant applications) for research project grants was 32 percent NIH-wide. Success rates across the 21 NIH Institutes and Centers ranged from a high of 43 percent to a low of 18 percent. The NIMH ranked 13th from the highest with a success rate of 29 percent.

QUALITY OF SCIENCE IN GRANT SUBMISSIONS

Question. Is the relative quality of science in the grant submissions and proposals received by NIMH rising or declining?

Answer. The striking growth and scientific development of the field of neuroscience over the last decade has served to drive a rapid, sustained expansion of the number of very high quality research programs in the areas of basic and clinical neuroscience. This expansion of excellent research programs has meant that the pool of outstanding NIH grant applications has grown at a corresponding rate. NIMH has "turned the corner" in substantially upgrading its research portfolio and retargeting research opportunities. This has resulted in a much larger pool for these areas of outstanding applications that are truly significant for NIMH's mission. Similar NIMH efforts in the areas of services and intervention research have been successful in producing and expanding a high-quality pool of better-targeted applications.

BUDGETARY INCREASES

Question. Can NIMH efficiently spend the increases enacted by Congress in fiscal year 2000 and fiscal year 2001 again in fiscal year 2002, i.e. will good science continue to keep pace with budgetary increases?

Answer. Yes. The science related to the brain and to behavior is at the frontier that now attracts the most talented investigators in the country. With the recent budget increases, NIMH has undertaken new initiatives in several scientific areas—basic and clinical neuroscience, and behavioral science—that are poised for rapid development because of technological innovation and dramatic growth in our understanding of brain function. In addition, NIMH has targeted a significant portion of its funding to initiatives deemed by the public and Congress to be health emergencies including research on the use of psychotropic medications in children, youth violence in our schools and communities, and suicide prevention. Also of note, NIMH recently launched several large clinical treatment trials to determine the most effective treatments for people with some of the most disabling mental illnesses (schizophrenia, bipolar disorder and depression). These are areas in which unprecedented advances in our understanding have emerged coincident with critical public health needs.

Judging from peer review ratings and programmatic relevance, the quality of the grant applications received in response to the majority of these initiatives has been outstanding. The fiscal year 2002 Budget level would allow additional initiatives, determined by a selective NIMH planning process, to come on-line expeditiously. Initiatives recently implemented, and those planned for fiscal year 2002, are focused

on topics such as development of therapeutics, training investigators for clinical research, and genetic/molecular neuroanatomy of the brain. Special emphasis is being placed on severe mental disorders, including, for example, a major new centers program for autism research.

INFORMATION DISSEMINATION

Question. In the last decade, many new treatments and services have been developed and proven for severe mental illnesses such as schizophrenia. Yet most individuals with these illnesses receive less than optimal care. What steps can the NIH/NIMH take to ensure that improvements in treatments and therapies can be effectively disseminated to providers and patients?

Answer. NIMH focuses on research that helps to reduce the burden of mental disorders for the American public. The Institute's research program aims to translate the understanding of basic biological and genetic processes, including knowledge of mechanisms underlying thought, emotion, and behavior, into effective treatments that reach patients with mental illness. NIMH's new generation of "real-world" treatment effectiveness studies will raise the standard of care for several major mental disorders, including schizophrenia and bipolar disorder (manic-depressive illness), by determining the best existing treatments in thousands of patients across the U.S. The National Advisory Mental Health Council (NAMHC) did a study of the effects of parity for mental health benefits which helps policymakers and the public to have the appropriate information about the costs of providing mental health insurance coverage.

Through its Office of Communications and Public Liaison (OCPL), NIMH publishes and disseminates research-based information on mental disorders and their treatment for diverse audiences including the general public, people with mental disorders and their families, health care providers, mental health professionals, scientists, advocates, and the media. Materials that cover the wide range of disorders and research areas funded by the Institute are available both in print and on the Web. At this time, the NIMH Web site (http://www.nimh.nih.gov) is receiving approximately 7 million hits each month; and recently it received commendation for the quality of its information, especially on depression.

NIMH also supports a continuing Dissemination Research Program dedicated to improving communication of research evidence to providers, patients, and other stakeholders. A program highlight in the latest funding cycle is a new study evaluating a web-based information system for families and patients dealing with schizophrenia. Furthermore, through the Small Business Innovation Research contract program, NIMH is reviewing proposals to develop dissemination tools for schools and other community settings. The Institute is collaborating with the National Association of State Mental Health Program Directors to organize workshops in the coming months to raise the profile of dissemination and evidence based treatment for mental health in children. NIMH/NIH is also partnering with other HHS agencies (ASPE, AHRQ, CDC, HRSA) in an initiative to examine dissemination and diffusion of research findings and to focus on dissemination efforts. In April 2001 NIMH sponsored a workshop on Implementing Evidence-Based Practice in the Public Mental Health Sector.

CONCLUSION OF HEARINGS

Senator SPECTER. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 9:55 a.m., Wednesday, May 23, the hearings was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2002

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

NONDEPARTMENTAL WITNESSES

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

DEPARTMENT OF EDUCATION

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

Mr. Chairman and Members of the Subcommittee, on behalf of this nation's 32 Tribal Colleges and Universities, which comprise the American Indian Higher Education Consortium (AIHEC), we thank you for the opportunity to share our fiscal year 2002 funding requests for programs within the Department of Education.

This statement will cover two areas (a) background on the tribal colleges, and (b) justifications for our funding requests.

BACKGROUND ON TRIBAL COLLEGES

The Tribal College Movement was launched in 1968 with the establishment of Navajo Community College, now Diné College, in Tsaile, Arizona. A succession of tribal colleges soon followed, primarily in the Northern Plains region. In 1972, the first six tribally controlled colleges established AIHEC to provide a support network for member institutions. Today, AIHEC represents 32 Tribal Colleges and Universities in 12 states and one in Canada, created specifically to serve the higher education needs of American Indian students. Collectively, they serve 25,000 students from over 250 federally recognized tribes.

Tribal colleges offer primarily 2-year degrees, although in recent years some institutions have begun to offer baccalaureate and graduate-level degrees. The vast majority of the tribal colleges are fully accredited by independent, regional accreditation agencies.[1] In addition to college level programming, tribal colleges provide much needed high school completion (GED), basic remediation, job training, college preparatory courses, and adult education. Tribal colleges fulfill additional roles within their respective communities functioning as community centers, libraries, tribal archives, career and business centers, economic development centers, public-meeting places, and child care centers. An underlying goal of tribal colleges is to improve the lives of students through higher education and to move American Indians toward self-sufficiency.

[1] The Tribal Colleges and Universities are accredited by regional accreditation agencies and must undergo stringent performance review on a periodic basis. The higher education division of the respective regional accreditation agency accredits twenty-seven of the TCUs. Two new TCUs are at the Pre-candidate stage as they complete work to attain Candidate status; one TCU is at Candidate status. Two TCUs are accredited as "Vocational/Adult Schools by the "schools" division of the respective regional accreditation agency.

Tribal colleges provide needed access to higher education for American Indians and others living in mostly remote, economically depressed areas of the country. These institutions are chartered by their respective tribal governments and were established in response to the recognition by tribal leaders that local, culturally-based education institutions are best suited to help American Indians succeed in higher education. Tribal colleges combine traditional teachings with conventional postsecondary courses and curricula. They have devised innovative means to address the needs of tribal populations in economically depressed regions and are successful in overcoming long-standing barriers to Indian higher education. Since the first tribal college was established on the Navajo reservation, these vital institutions have come to represent the most significant development in the history of American Indian higher education, providing access to under-represented students and promoting achievement among students who may otherwise never have known post-secondary education success.

Funding of tribal colleges is grossly inadequate. While these institutions have successfully negotiated many challenges in the history of the Tribal College Movement, adequate funding remains the most significant barrier to their ongoing success. Core operational funding for 25 tribal colleges is provided through the Tribally-Controlled College or University Assistance Act (TCCUAA), Public Law 95–471. Funding was first appropriated through the Act in 1981, and is still less than two-thirds of its Congressionally authorized level of $6,000 per full-time Indian student. In fiscal year 2001, the Colleges received $3,849 per full-time Indian student. Moreover, this amount is less than two-thirds of the estimated $6,089 per full-time student received by mainstream community colleges. While mainstream institutions have a foundation of stable state support, tribal colleges must rely on the Federal government for operational funding. Because tribal colleges are located on federal trust territories, states have no obligation to fund them. In fact, most states do not even fund our colleges for the non-Indian state-resident students who account for approximately 20 percent of our enrollments.

Since their inception, tribal colleges have achieved exceptional growth and success, yet they are the most poorly funded higher education institutions in America. Although conditions at some have improved substantially, many colleges still operate in trailers; cast-off buildings; and facilities with crumbling foundations, faulty wiring, and leaking roofs. Sustaining quality academic programs is a challenge without a reliable source of facilities maintenance and construction funds.

Today, one in five American Indians live on reservations. As a result of 200 years of Federal Indian policy—including policies of termination, assimilation and relocation—many reservation residents live in abject poverty comparable to poverty found in Third World nations. Through the efforts of tribal colleges, American Indian communities receive services they need to reestablish themselves as responsible, productive, and self-reliant citizens.

JUSTIFICATIONS

Higher Education Act requests.—The Higher Education Act Amendments of 1998 created a separate section within Title III, Part A, specifically for the nation's tribal colleges (Section 316). The Aid for Institutional Development programs, commonly known as the Title III programs, support minority institutions and other institutions that enroll large proportions of financially disadvantaged students and have low per-student expenditures. Tribal colleges clearly fit this definition. Tribal colleges are among the most poorly funded institutions in America, yet they serve some of the most impoverished areas of the country. They fulfill a vital role of providing access to quality higher education programs, which are specifically designed to focus on the critical, unmet needs of their American Indian students and communities. This funding will help the tribal colleges effectively prepare their students for the workforce of the 21st Century in a safe environment. The President's budget recommendation included increases for the Historically Black Colleges and Universities programs, and the Hispanic Serving Institutions line item under this program, while the tribal colleges' account was level funded. We strongly urge the Subcommittee to correct this oversight and fund this section—which is critical to the tribal colleges—at $25 million. We ask that $10 million of these funds be specifically designated for the competitive facilities and infrastructure improvement program created in fiscal year 2001, also administered under this section.

The importance of Pell grants to our students cannot be overstated. Department of Education figures show that at least half of all Tribal College students receive Pell grants, primarily because student income levels are so low and our students have less access to other sources of aid than students at mainstream institutions. Within the Tribal College system, Pell grants are doing exactly what they were in-

tended to do—they are serving the needs of the lowest income students by helping people gain access to higher education and become active, productive members of the workforce. We urge you to build upon increase recommended in the President's fiscal year 2002 budget.

Perkins Vocational Education Act.—Section 117 (addressing Tribally-Controlled Postsecondary Vocational Institutions) of the Carl D. Perkins Vocational and Applied Technology Education Act provides core funding for two of our member institutions: United Tribes Technical College in Bismarck, North Dakota, and Crownpoint Institute of Technology in Crownpoint, New Mexico. We support the $5.6 million included in the President's budget request for the Tribally-Controlled Postsecondary Vocational Institutions under Section 117. We request report language reaffirming that this funding remain specific to these two Tribally Controlled Postsecondary Vocational Institutions.

Greater Support of Indian Education Programs Under ESEA

American Indian Adult and Basic Education.—This section supports adult education programs for American Indians that are offered by tribal colleges, state and local education agencies, Indian tribes, institutions, and agencies. Unfortunately, the section has not been funded since fiscal year 1995. The Tribal College Act does not include funding for remediation and adult basic education, as it only supports those students enrolled in postsecondary programs. Yet, the tribal colleges must continue to provide basic adult education classes for their communities. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a GED or, in some cases, learn to read. According to a 1995 survey conducted by the Carnegie Foundation for the Advancement of Teaching, 20 percent of the participating students had completed a tribal college GED program before beginning formal classes at the tribal college. At some schools, the percentage is even higher. Lac Courte Oreilles Ojibwa Community College in Hayward, Wisconsin, for example, reports that nearly one-third of its students had earned a GED through its tutoring and testing center. Clearly, the need for basic educational programs is tremendous, and tribal colleges need funding to support these crucial activities. Tribal colleges need a minimum of $5 million to meet the ever-increasing demand for basic adult education services. Without this minimum commitment, vitally needed services for our adult student population cannot be sustained, much less increased to address the full need. It is our hope that Congress will rectify this serious oversight in fiscal year 2002.

American Indian Teacher Corps.—American Indians are severely under-represented in the teaching ranks nationally. This program, aimed at producing 1,000 new teachers for schools serving American Indian students, would provide for fellowships to college students majoring in education programs and for professional development programs in Indian Country to support current teachers. We believe that the tribal colleges are the ideal catalysts for this initiative because of our current work in this area and the existing articulation agreements tribal colleges hold with 4-year higher education institutions. We request Congress continue to support this $10 million program, included in the President's fiscal year 2002 budget request, to increase the number of qualified American Indian teachers in Indian Country.

American Indian Administrator Corps.—In fiscal year 2001, a new program was funded to establish the American Indian Administrator Corps. Like teachers, American Indian school administrators are severely under-represented in the profession nationally. This program will support the recruitment, training, and in-service professional development of 500 American Indians and Alaska Natives to become effective school administrators in schools with large Native American populations. We request Congress continue to support this $5 million program, included in the President's fiscal year 2002 budget request, to increase the number of American Indian school Administrators in Indian Country.

CONCLUSION

Fulfillment of AIHEC's fiscal year 2002 request will strengthen the mission of the Tribal Colleges and Universities, and contribute to the enormous, positive impact they have on their respective communities. Moreover, it will help ensure that American Indians will be properly educated and prepared for the workforce of the 21st Century. As the 1997 Carnegie Report on tribal colleges stated:

"Now, as strongly as ever, we repeat our conviction that tribal colleges deserve continued support. Their value has been proven, but their vision is not yet fulfilled."[2]

Tribal colleges have been extremely responsible with the Federal support they have received over the last 20 years, and have proven themselves to be a sound federal investment.

Thank you again for this opportunity to present our funding requests before this Subcommittee. We respectfully ask the Members of this Subcommittee for their continued support and full consideration of our fiscal year 2002 appropriations request.

PREPARED STATEMENT OF THE AMERICAN MUSEUM OF NATURAL HISTORY

ABOUT THE AMERICAN MUSEUM OF NATURAL HISTORY

The American Museum of Natural History [AMNH] is one of the nation's preeminent institutions for scientific research and public education. Since its founding in 1869, the Museum has pursued its mission to "discover, interpret, and disseminate—through scientific research and education—knowledge about human cultures, the natural world, and the universe." It is renowned for its exhibitions and collections of more than 32 million specimens and cultural artifacts. With nearly five million annual visitors—approximately half of them children—its audience is one of the largest, fastest growing, and most diverse of any museum in the country. Museum scientists conduct groundbreaking research in fields ranging from all branches of zoology, comparative genomics, and paleontology to earth, space, and environmental sciences and biodiversity conservation. Their work forms the basis for all the Museum's activities that seek to explain complex issues and help people to understand the events and processes that created and continue to shape the Earth, life and civilization on this planet, and the universe beyond.

Today more than 200 Museum scientists with internationally recognized expertise, led by 47 curators, conduct laboratory and collections—based research programs as well as fieldwork and training. Scientists in five divisions (Anthropology; Earth, Planetary, and Space Sciences; Invertebrate Zoology; Paleontology; and Vertebrate Zoology) are sequencing DNA and creating new computational tools to retrace the evolutionary tree, documenting changes in the environment, making new discoveries in the fossil record, and describing human culture in all its variety. The Museum also conducts graduate training programs in conjunction with a host of distinguished universities, supports doctoral and postdoctoral scientists with highly competitive research fellowships, and offers talented undergraduates an opportunity to work with Museum scientists.

The AMNH collections of some 32 million natural specimens and cultural artifacts are a major scientific resource, providing the foundation for the Museum's interrelated research, education, and exhibition missions. They often include endangered and extinct species as well as many of the only known "type specimens," or examples of species by which all other finds are compared. Within the collections are many spectacular individual collections, including the world's most comprehensive collections of dinosaurs; fossil mammals, Northwest Coast and Siberian cultural artifacts, North American butterflies, spiders, Australian and Chinese amphibians, reptiles, fishes outside of their home countries, and one of the most important bird collections. Collections such as these are historical libraries of expertly identified and documented examples of species and artifacts, providing an irreplaceable record of life on earth. They provide vital data for Museum scientists as well as more than 250 national and international visiting scientists each year.

In the exhibition halls AMNH scientific knowledge and discovery are translated into three dimensions. One of the most exciting chapters in the Museum's history culminated just over 1 year ago with the opening of the Rose Center for Earth and Space in February 2000. Greeted with critical and popular acclaim and record-setting attendance surpassing all projections, the Rose Center includes a rebuilt Hayden Planetarium, Hall of the Universe, and Hall of Planet Earth. It leads to the Hall of Biodiversity, which reveals the variety of Earth's living things and expands the Museum's efforts to alert the public to the critical role biodiversity plays in sustaining life as we know it. Together, the new planetarium and halls provide visitors with a seamless educational journey from the universe's beginnings to the formation and processes of Earth to the extraordinary diversity of life on our planet.

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[2] Paul Boyer, *Native American Colleges: Progress and Prospects.* Princeton, NJ: Carnegie Foundation for the Advancement of Teaching, 1997.

The Education Department builds on the Museum's unique research, collections, and exhibition resources to offer rich programming dedicated to increasing scientific literacy, to encouraging students to pursue science and museum careers, and to providing a forum for exploring the world's cultures. Each year hundreds of thousands of students, teachers, and schools participate in workshops, courses for college credit, and Museum visits; more than 500,000 students and teachers come on school visits, prepared and supported by curriculum resources and workshops. The Museum is also reaching beyond its walls: through its National Center for Science Literacy, Education, and Technology, launched in 1997 in partnership with NASA, it is exploiting new technologies to bring learning and discovery, materials, and programs into homes, schools, museums, and community organizations around the nation.

SUPPORT FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES MISSION AND GOALS

The American Museum shares with DHHS and HRSA a fundamental commitment to improving the nation's health and advancing the research, training, and facilities that support it. The Museum seeks a partnership with the agency to leverage our complementary resources and mutually strengthen our abilities to advance shared goals.

Genomic Science

DHHS is a leader in health-related research and genome science, advanced sequencing technologies, instrumentation, and facilities. The American Museum, in turn, is home to a preeminent molecular research effort. Indeed, natural history and genomic science are intricately related. The AMNH molecular systematics program is at the forefront of comparative genomics and the analysis of DNA sequences for evolutionary research. In its molecular laboratories, in operation now for 10 years, more than 40 researchers in molecular systematics, conservation genetics, and developmental biology conduct genetic research on a variety of study organisms.

The Museum is also expanding its collection techniques to include the preservation of biological tissues and molecular libraries in a super-cold storage facility for current and future genetic study. This collection is an invaluable resource for worldwide research in fields including genetics, comparative genomics, and medicine. Such a tissue collection will preserve genetic material and gene products from rare and endangered organisms that may become extinct before science fully exploits their potential. With nearly 40,000 samples already collected, it will be the largest super-cold tissue collection in the world and will increase the possibilities for DNA research exponentially.

Parallel Cluster Computing

Parallel computing is an essential enabling technology for phylogenetic (evolutionary) analysis and intensive, efficient sampling of a wide array of study organisms. A 256-processor cluster recently constructed in-house by Museum scientists is the fastest parallel computing cluster in an evolutionary biology laboratory and one of the fastest installed in a non-defense environment. It allows Museum scientists to examine the effectiveness and computational behavior for large real-world data sets, and will be central to all Museum projects in evolutionary and genomics research.

INSTITUTE OF COMPARATIVE GENOMICS

The Museum proposes to establish, in partnership with DHHS, an Institute of Comparative Genomics so as to contribute its unique resources and expertise to the nation's genomic research enterprise. A full understanding of the impact of the knowledge we have gained from genomics and molecular biology can come from placing genomic data in a natural history perspective; comparative work in genomics will enrich our knowledge not only of biodiversity, but also of humans, medicine, and life itself. The Museum intends to establish the Institute with funds from federal as well as nonfederal sources.

With the advent of DNA sequencing, museum collections have become critical baseline resources for the assessment of the genetic diversity of natural populations. Genomes, especially those of the simplest organisms, provide a window into the fundamental mechanics of life. One of the goals of the nation's genomic science research programs is to learn about the relevance to humans of nonhuman organisms' DNA sequences. This research can yield information that can be applied in solving critical challenges in health care. The AMNH comparative genomics program could provide vital tools in these endeavors.

The Museum has already established its parallel computing facility, enhanced the molecular labs with state-of-the-art DNA sequencers, and built the super cold storage facility. Thus initially equipped, the Institute will be one of the world's premier

research facilities for mapping the genome across a comprehensive spectrum of life forms, drawing on comparative methods and biological collections.

Working cooperatively with New York's outstanding biomedical research and educational institutions, the Institute will focus on molecular and microbial systematics, expanding our understanding of the evolution of life on earth through analysis of the genomes of selected microbes and other non-human organisms, and constructing large genomic databases for conservation biology applications. Research programs may include the study of the utility of genomic information on organismal form and function, microbial systematics, the construction of large genomic databases for conservation biology applications, and the use of broad scale comparative genomic studies to understand the function of important biomolecules.

The Institute's scope of activities will include: an expansion of the molecular laboratory program that now trains dozens of graduate students every year; the utilization of the latest sequencing technologies; employment of parallel computing applications that allow scientists to examine the effectiveness and computational behavior of large real world datasets; and operation of the frozen tissue collection as a worldwide scientific resource, with at least 500,000 samples accessioned in the first phase alone, an active loan program, and ready public on-line access.

In addition to research, the Museum has already launched an ambitious agenda of genomics-related exhibition, conference, and public education programming, including the landmark exhibition, "The Genomic Revolution," which opens in May 2001. The exhibition, the most comprehensive ever presented on genomics, will examine the revolution taking place in molecular biology and its impact on modern science and technology, natural history, biodiversity, and our everyday lives. In conjunction with the exhibition, the Museum may also display a video bulletin on genomics in the Hall of Human Biology. The bulletin would be modeled after the popular Earth, Bio, and AstroBulletins in the newest exhibit halls that display changing science news and link to computer kiosks and websites.

In fall 2000 the Museum hosted "Sequencing the Human Genome: New Frontiers in Science and Technology," an international conference featuring leading scientists and policymakers. Spring conferences will include: "Conservation Genetics in the Age of Genomics," co-sponsored by AMNH's Center for Biodiversity and Conservation and the Wildlife Conservation Society; and "New Directions in Supercomputing," which will explore how parallel computing can make sense of the huge complex data sets that genomic science and other fields generate. In September, the Museum will convene "Assembling the Tree of Life: Science, Relevance, and Challenges."

In establishing the Institute, the Museum plans to expand its curatorial range in microbial work; grow the super-cold tissue collection; and draw on our exhibition and educational expertise to offer enhanced public education and outreach. Plans entail expanding and renovating lab space and facilities to accommodate additional curators and students. By renovating an area adjacent to one of the existing molecular labs and possibly building new space, the Museum will add lab and associated office and maintenance space to accommodate the new Institute's needs.

We seek $5 million in fiscal year 2002 to partner with DHHS/HRSA in establishing the Institute for Comparative Genomics at the Museum. In partnership, the two organizations will be positioned to leverage their unparalleled resources to advance shared goals for improving the nation's health through research and facilities, education and training.

PREPARED STATEMENT OF THE BUSHNELL CENTER FOR THE PERFORMING ARTS

Mr. Chairman of Members of the Subcommittee, my name is Ronna Reynolds, and I am the Interim Executive Director of The Bushnell Center for the Performing Arts, located in Hartford, Connecticut. I am pleased to have this opportunity to share with you the exciting and successful arts-in-education programs being conducted at The Bushnell and to urge your support for funding for additional educational programs in fiscal year 2002.

The Horace Bushnell Memorial Hall is an historic and nationally recognized performing arts center. After a $34 million renovation and expansion project, the 71-year-old Hall has been renamed "The Bushnell Center for the Performing Arts." We believe it's an appropriate name to describe a center for the arts, a center for the community, and a center for education that will all come together—and bring people together—at The Bushnell.

The new Bushnell is more than just a building. It is a facility that will enhance Hartford's position as a premier performing arts destination. The 90,000 square-foot facility being built adjacent to the current Mortensen Hall will include the Belding

Theater, a Great Hall for receptions and smaller performances, and such amenities as a café, gift shop, classroom space and more rest rooms and elevators. With the current Hall booked to capacity, the expansion will enable The Bushnell to present new arts and entertainment options and better accommodate local arts organizations in multiple performance spaces. It will also give an economic boost by bringing more people to downtown Hartford.

The new Bushnell facility presents the opportunity to link the Hall's artistic programming to education and learning. For most of the 20th Century, education and serving the community has been the central focus for The Bushnell as it has dedicated considerable resources and leadership to create powerful tools for learning and building community. Our educational programs serve as the stable and sustainable base from which The Bushnell can continue to expand and deepen its education, community service and programming. The result is a performing arts center which serves as a classroom without walls; a stage "in and of" the community.

The strongest and most visible manifestation of this commitment can be found in the The Bushnell's arts education programs. The Bushnell Center for Learning is the organization-wide structure through which The Bushnell will promote and cause the arts to advance education in communities and schools through direct services, training, advocacy, and convening. This new Center represents a coalescing of all educational activities of The Bushnell under one umbrella. With a focus on direct services through classroom programs, teacher and artist training, public policy and advocacy and community and educational convener, The Bushnell Center for Learning places educational programming as central to the organization's day-to-day activities.

Several programs comprise The Bushnell Center for Learning, including direct services and programs for grade school and high school students, as well as training programs and teaching seminars. The Bushnell has over ten years of experience operating arts-in-education programs that use the arts to improve literacy and to increase the understanding of diverse cultures for over 6,000 public school students in four school districts in Connecticut.

THE PARTNERS PROGRAM

PARTNERS (Partners in Arts and Education Revitalizing Schools) is a nationally recognized arts-in-education program that strengthens language arts skills and fosters multi-cultural competence in the Hartford area schools. Implemented in 1993 in eight schools in Hartford, West Hartford and Bloomfield, PARTNERS uses the visual and performing arts to spark learning and generate excitement in the classroom. Participating in the program provides not only a foundation for artistic literacy, but more importantly, it strengthens the core educational curriculum while bringing together a great diversity of students in a unique educational experience. Since 1996, PARTNERS has been active in the Plainville Community Schools in partnership with GE Fund of Fairfield and GE Industrial Systems of Plainville.

The PARTNERS program is made up of five interlocking components: curriculum and assessment, artistic resources, staff development, The Bushnell Children's Theatre and family events. Curriculum and assessment are at the core of all PARTNERS program components. Curriculum resources ensure that cross-cultural, hands-on arts experiences are integrated into a child's classroom experience through multi-cultural children's literature, book-based activity guides, and other pertinent materials. Program assessment has been carried out each year in an attempt to review and test program components and the goals set forth in the initial program design.

In the PARTNERS program, professional artists take on the role of teaching artists who develop and lead classroom-based arts activities. Presenting artists who conduct grade level assembly presentation further students' understanding of these areas through performances delivered at the school site. Classroom and performance experiences are also enriched by museum, theatre, and science center field trips throughout the year. Through the professional development component, PARTNERS provides participating classroom, art and music teachers with exposure and hands-on access to the arts-integrated units of study. These sessions, held at The Bushnell, offer educators the opportunity to use the arts as tools to enhance the learning process for their students.

OTHER EDUCATIONAL PROGRAMS

In addition to the PARTNERS program, The Bushnell offers other educational programs and services, including:

—Professional development and support services to educators, artists, contributors, and organizations;

—Replication and dissemination of the PARTNERS technique and curriculum through building the capacities of institutions, communities and schools; and
—Integration of programming and education through a collaborative planning process and marketing strategy to be known as "Great Works".

These combined activities enrich the lives of students who are involved in the many different Bushnell educational programs, including:

—Living Laboratories in Schools
—Parent Enpowerment through Early Literacy and Read Aloud
—The Bushnell Children's Theatre
—Pre and post performance lectures
—Arts camps
—High School lecture series
—Teachers institutes and seminars and other professional development programs
—Artist training

Mr. Chairman, in order to support the expansion of arts-in-education programs at The Bushnell Center for Learning, we respectfully request $1 million through the Department of Education's Fund for the Improvement of Education (FIE) account in the Fiscal 2002 Labor/HHS/Education Appropriations bill. Thank you for your attention to this request, and for your support of programs which benefit the children of Connecticut and children across the nation.

PREPARED STATEMENT OF THE AMERICAN COUNCIL ON EDUCATION COALITION FOR INTERNATIONAL EDUCATION

Mr. Chairman and Members of the Subcommittee: We are pleased to have the opportunity to present the views of the Coalition for International Education on the fiscal year 2002 appropriations for the Higher Education Act, Title VI and the Mutual Educational and Cultural Exchange Act, Section 102(b)(6), commonly known as Fulbright-Hays. The Coalition for International Education is an ad hoc group of 28 national higher education organizations with principal focus on the aforementioned international education, foreign language and exchange programs. Together they represent the nation's 3,300 colleges and universities, and numerous disciplinary, international exchange groups and other international education organizations.

Over the history of Title VI and Fulbright-Hays, many different groups have come to the Federal Government to make their case for these programs. This usually has taken the form of small coalitions or separate voices arguing for their particular interests. However, the sense of urgency about the United States' declining international competence against a backdrop of enormous international challenges is so strong within the higher education community, that it has drawn our different perspectives into a single consensus position.

We express our appreciation for the Subcommittee's support for these programs. Title VI has grown over the last decade, and Fulbright-Hays in the last year.

To address new and expanding challenges to the nation's leadership capabilities in foreign policy, national security, economic competitiveness, and solving global problems, the Coalition recommends a 3-year strategic plan for Title VI and Fulbright-Hays. The plan proposes increasing the number of experts with in-depth international knowledge and highly proficient foreign language skills, as well as the number of U.S. citizens with global competence. Our proposed funding levels for fiscal year 2002, more fully described below, would be the first installment of this plan.

PROGRAM OVERVIEW

At the height of the Cold War, Congress created Title VI in the National Defense Education Act of 1958, and Section 102 (b)(6) of the Mutual Educational and Cultural Exchange Act of 1961 out of a sense of crisis about U.S. ignorance of other countries and cultures. Spanning more than four decades, these programs still remain the Federal Government's most comprehensive mechanisms for supporting the development and maintenance of a higher education infrastructure that produces the nation's expertise in foreign languages, and area and other international studies, including international business. The programs have grown and evolved over this time in response to the changing global environment. The fourteen funded Title VI and Fulbright-Hays programs support activities to improve our educational capabilities, from K–12 through the graduate levels and advanced research, with emphasis on the less commonly-taught languages and areas of the world. Title VI largely supports the domestic side of training and research, while Fulbright-Hays supports an essential overseas component.

FEDERAL ROLE

The Federal Government plays a critical role in international and foreign language education because of the clear relevance of international competence to the conduct of U.S. foreign policy, to the national security of the U.S., and to the health and vitality of the U.S. economy in a global marketplace. Informed decisions in these areas by public and private sectors depend on citizens who have the skills and understanding of other nations' languages, cultures and systems to function effectively within them. U.S. global leadership depends on persons who know how the people of other cultures think and work and who can competently assess the political, economic, or social implications of decisions and actions. In short, it is a critical federal role to ensure the nation is successfully prepared to respond to the challenges presented by its relationships with other nations.

Through Title VI and Fulbright-Hays programs, the Federal Government shares this responsibility with institutions of higher education, in partnership with the corporate and state/local government sectors. State and local governments and the private sector, including foundations, will not by themselves focus on long-term national needs for international expertise. While these sectors support short-term projects from time to time, they do not provide the long-term, sustained support for the 10–12 years of study and research needed to produce an expert on the Middle East fluent in Arabic, for example. Moreover, universities could not bear this responsibility alone. Outside resources are essential incentives for developing and sustaining interdisciplinary programs, underwriting high cost programs in the less common-taught languages and areas, and providing extensive outreach and collaboration among education institutions, government agencies, and corporations.

EXPANDING NATIONAL NEEDS

There is fresh evidence that the nation's needs for international competence continue to expand in the global era, and that the government, corporate and education sectors face a dangerously short supply of qualified personnel.

Responding to new demands to protect national security in a broad range of arenas throughout the U.S. and the world, virtually every federal agency now is engaged globally. One estimate is that over 80 federal agencies and offices rely on human resources with foreign language proficiency and international knowledge and experience. Hearings last fall of the Senate Subcommittee on International Security, Proliferation, and Federal Services revealed the shortage of personnel with the foreign language and area skills required to meet national security needs across the defense, intelligence, and foreign policy agencies. These agencies report shortfalls in hiring, deficits in readiness, and adverse impacts on operations. One federal agency estimated its total needs to be 30,000 employees dealing with over 80 languages, while another identified key shortfalls in Central Eurasian, East Asian, and Middle Eastern languages.

Title VI and Fulbright-Hays are among the few programs the Federal Government supports that provide the necessary long-term investment in building the language and foreign area capacity that responds to national strategic requirements. Regional expertise and language ability related to less commonly-taught areas are offered primarily through higher education institutions receiving Title VI funding. In fact, a recent study funded by the U.S. Department of Education revealed that 81 percent of the graduate language enrollments in the least commonly taught languages are located at Title VI-funded institutions. Because of the high cost per student, these programs would not exist without Title VI support.

National security is increasingly linked to commerce, and U.S. business is widely engaged around the world with joint ventures, partnerships, and economic linkages that require its employees to have international expertise both at home and abroad. A recent study on the internationalization of American business education found that knowledge of other cultures, cross-cultural communications skills, experience in international business, and fluency in a foreign language ranked among the top skills sought by corporations involved in international business. Despite new efforts to internationalize business education in the last decade, U.S. business schools continue to fall short of fulfilling the need of businesses for personnel who can think and act in a global context.

Title VI supports important programs that internationalize business education and help small and medium-sized U.S. businesses access emerging markets, a boost toward reducing the trade deficit and creating U.S. jobs. The U.S. Department of Commerce reports that 97 percent of all U.S. export growth in the 1990s was contributed by small and medium-sized companies, and yet only 10 percent of these companies are exporting. The most common reason cited by U.S. businesses for not

pursuing export opportunities is a lack of knowledge and understanding of how to function in the global business environment.

In addition to business, the ubiquitous nature of globalization also is driving new demands for globally competent citizens and international knowledge in almost all fields of endeavor, such as health, the environment, and law. Whether it be in the culturally diverse U.S. workplace or on assignment abroad, employers increasingly look for candidates who have cross-cultural skills, foreign language proficiency, and the ability to meet the international challenges of their field. Increasing the pool of underrepresented minorities who pursue international careers is a critical dimension as well.

Title VI and Fulbright-Hays programs support projects to infuse foreign language, area and other international studies into the curriculum and across disciplines, from K–12 through professional education. They support increasing the capacity of predominantly minority-serving institutions to produce globally competent graduates who enter the international service. Extensive outreach programs serve government, education and corporate needs for international knowledge.

Finally, it does not appear that our education system is positioned to produce the increasing numbers of international experts needed, or even ordinary citizens who are globally competent. Recent studies and surveys suggest that overall our education institutions are falling behind in international education:

—The vast majority of students is being provided with only rudimentary levels of international skills and competencies;

—Foreign language enrollments in United States higher education fell from 16 percent in 1960 to just 8 percent today and the number of 4-year colleges with foreign language entrance and graduation requirements also declined. On the positive side, foreign language enrollments in community colleges and at the K–12 levels are increasing;

—There is a shortage of trained teachers and faculty in foreign languages, especially the less commonly-taught languages, and in area and international studies; and

—Only about 3 percent of United States students enrolled in United States colleges and universities study abroad.

Title VI and Fulbright-Hays programs support the training of teachers and faculty in foreign languages and international education. They support overseas research, the development of study abroad programs in underrepresented areas, research in the teaching and learning of foreign languages, and the application of new technologies to all of these efforts.

FISCAL YEAR 2002 FUNDING PROPOSAL

Funding for this account during President Clinton's Administration did not keep up with increased national needs for global competence or with increases in overall federal education funding. When adjusted for inflation, the Department of Education's budget for discretionary programs grew by about 50 percent since fiscal year 1994, while these programs combined increased by only 14 percent. Despite the increase, Title VI and Fulbright-Hays continue to be funded below their constant dollar level of the late 1960s. (For example, only half as many Foreign Language and Area Studies fellowships are being awarded today, compared with fiscal year 1967.) Moreover, funding for the Institute for International Public Policy has not been increased since its inception in fiscal year 1994.

Our 3-year strategic plan proposes three policy goals to meet the growing national needs described above:

—Increase the production of the nation's international expertise and knowledge to meet national strategic needs;

—Enhance the knowledge and skills of our citizens for a global workplace; and

—Expand education, government and private sector access to international expertise and knowledge (outreach and dissemination)

To address these goals, we recommend as a first year installment, a total of $96.32 million for the International Education and Foreign Languages Studies account. This represents an $18.3 million increase over fiscal year 2001.

We recommend our proposed increase be allocated as follows:

—A $13.5 million increase in Title VI–A & B domestic programs ($80.5 million in total). Title VI–A & B programs ensure a national capacity of expertise and knowledge in foreign languages, area and other international studies, including international business education. The proposed increase would strengthen activities addressing national strategic needs and shortfalls in capacity: (1) training the next generation of experts and producing research on the foreign languages, world areas and global/regional issues of emerging economic and secu-

rity importance; (2) infusing foreign languages and area studies into the professional disciplines; (3) increasing outreach and linkage activities to government agencies, business, the media, and education institutions; (4) accessing and making widely available expensive foreign information resources using innovative applications of technology; and (5) enhancing the knowledge, understanding and skills of our citizens for a global workplace.

—A $3.3 million increase in Fulbright-Hays ($13.3 million in total). Fulbright-Hays complements Title VI programs by providing U.S. students, faculty and teachers a vital overseas research and training dimension in foreign languages and area studies. For example, in a recent survey of former doctoral dissertation research abroad grantees, nearly all indicated they could not have achieved their level of expertise without this support, and that they utilized the skills gained abroad in teaching and research. Yet under this program in fiscal year 2000, only 88 fellowships could be awarded out of an applicant pool of 417. In recent years the average number of fundable applications for all four Fulbright programs has been roughly double the number actually awarded with available funds. An additional $3.3 million would enable about 75 more awards for doctoral dissertation, faculty research, group projects and seminars abroad.

—A $1.5 million increase for the Title VI–C Institute for International Public Policy ($2.52 million in total). The IIPP responds to the national need for a diverse pool of well-trained, language-proficient professionals to enter the foreign service and related careers. Students completing this program have earned the distinction of passing the foreign service oral exam on the first attempt. Level funding for the IIPP since fiscal year 1994 has caused a scaling back of several program components. An additional $1.5 million will enable full funding of the graduate fellowships and reinstatement of the institutional capacity—building grants to HBCUs, HSIs, and other minority institutions, in keeping with the program's statutory mandate.

We consider our request to be a modest one for programs vital to our nation's long-term security and economic well being. Thank you for your consideration and for the opportunity to express our views.

PREPARED STATEMENT OF THE COLONIAL WILLIAMSBURG FOUNDATION

Dear Mr. Chairman: Colonial Williamsburg Foundation hereby submits for the record, testimony regarding an electronic field trip project called the "Outreach Education Initiative."

SUMMARY

Colonial Williamsburg, the nation's oldest and largest living history museum, continues to inspire Americans. Our national history is a dramatic story that continues to influence the present. The story of America's colonial history and the coming of the American Revolution are the heritage of every American. Colonial Williamsburg explores the history behind the critical issues that still challenge American society—how diverse people, holding different and sometimes conflicting personal ambitions, evolved into a union that valued both liberty and equality.

This history that defines us as a nation should be understood by all school children. Technology is the means by which this message can be clearly delivered to schools across America.

Each year, one million adults and children from all fifty states and several foreign countries, visit Colonial Williamsburg's Historic Area in person, including over 160,000 students on school study trips.

For most students, however, a personal visit to the Historic Area is not a realistic option.

To reach students and teachers throughout the country, Colonial Williamsburg launched its Educational Outreach Initiative with the electronic field trip project in the fall of 1996. This initiative takes the museum's dynamic methods of history education beyond the streets and buildings of Williamsburg and transports them directly into the nation's classrooms. Electronic field trips replicate, to the greatest extent possible, an actual visit to Colonial Williamsburg and create a palpable excitement for learning.

With the best technological communication resources at our command, Colonial Williamsburg reaches millions of students and teachers throughout the country. Through electronic field trips, this experience is taken directly to the nation's classrooms. These programs currently reach an estimated one million registered students in forty-six States with a total viewing audience of more than five million unregistered students and home viewers.

Colonial Williamsburg's Electronic Field Trips—"lightspeed learning" experiences—are live, interactive television programs, linked to comprehensive teacher's guides, and Internet activities and discussion groups. Several weeks before each program airs, registered schools receive a teacher's packet, which includes an instructional videotape and short introduction to Colonial Williamsburg, a comprehensive teacher's guide, full-color classroom poster, and links to national standards of learning. The teacher's guide includes historical background materials, facsimiles of historical documents and prints, photographs of Colonial Williamsburg and its costumed interpreters, glossaries, timelines, and several suggested lesson plans written by classroom teachers.

Electronic field trips are eight live broadcast events each school year. Each field trip consists of two or three historical dramas depicting aspects of eighteenth-century life, ranging from a young recruit's view of military preparations for the Revolution to a free black man's efforts to buy his wife's and children's freedom from their owner.

After each dramatic vignette, students from registered schools can speak directly to the historical interpreters on live television, asking questions and expressing opinions about the issues presented in the programs. Those students that do not make it on air can speak via the telephone and the Internet to more than thirty interpreters and historians behind the scenes. During an electronic field trip, Colonial Williamsburg staff will respond to over 1,300 phone calls in four hours and reply to as many as 1,000 email and Internet bulletin board inquiries. Students can also vote on issues raised during the program to see how their votes compare with others across the country.

The field trips are also much more than history lessons. History is just a starting point for high-tech interdisciplinary learning in civics, mathematics, science, art, and government, and an excellent venue for honing critical thinking skills—so necessary for creating a job-ready work force.

Through the electronic field trips Colonial Williamsburg is able to teach our country's history and encourage the use of technology in the classroom for a wider audience. Here's what one California teacher had to say about the impact of an electronic field trip on her classroom and on one "at-risk" student in particular:

"One of my boys, who is an at-risk student and who has had lots of problems, was able to get on the air with his question and was so excited! He was the fifth grade star because the other fifth grade classes were also watching the program to hear his question. . . . The kids are now primed for our study of the American Revolution."——Sally White, Teacher, George White Elementary School, Laguna Niguel, California

AUDIENCE SERVED

The target audience for Colonial Williamsburg's electronic field trips includes the nation's entire student population, generally students from fourth through twelfth grade.

Extrapolating information from registered schools and the number of students asking questions and voting via telephone and the Internet, Colonial Williamsburg estimates that at least 500,000 registered students actively participated in the 1996–1997 electronic field trips. Current estimates predict that approximately 1 million registered students will have participated in the 1999–2000 electronic field trips, with a total viewing audience of more than 5 million.

Communities across the country are concerned about studies showing the erosion of young people's American history knowledge and the need for teacher and student training in the use of educational technology. Last year Congress made additional funds available for history education programs. Colonial Williamsburg's electronic field trips are an important contribution to improving history education and helping students become more knowledgeable and excited about the past while relating it to their current environment.

Electronic field trips help students discover positive role models from history to which all young people, from gifted to at-risk students, can relate. They increase teacher familiarity with technology and their understanding of appropriate methods for utilizing it. These programs are standards—based in multiple disciplines, providing opportunities to engage students in cross-discipline learning. They are very low cost and accessible through almost any level of technology available to the classrooms. In addition, Colonial Williamsburg staff members work with teachers independently to help them get the most out of the programs.

Colonial Williamsburg's electronic field trips provide opportunities to integrate technology in the classroom and enhance technical skills. Teachers and students in

less-advantaged communities might have access to communication hardware but don't have the training to use those technology resources. Because information tools and familiarity in using them are increasingly important to individual success, it is essential to correct this imbalance. Technical competence is integral to the success of today's students and tomorrow's adults and, without such competence, a large portion of the nation's citizens will be left behind, unable to compete, and increasingly distanced from the means by which many people are receiving information, producing work, and participating in their communities.

METHODS

Begun in the fall of 1996, Colonial Williamsburg's Electronic Field Trips craft comprehensive teacher materials, live interactive broadcasts, and Internet activities into an interactive learning experience for students. Each field trip follows a similar format combining production, educational material, and new media components.

Production

The main component of each field trip is a live, one-hour, interactive broadcast, offered twice on the broadcast day so that students in all United States time zones can participate. Each program is of broadcast quality and is sent via satellite, as well as via public and educational broadcasters, to schools across the United States.

Colonial Williamsburg historical interpreters host each program, introduce students to life in colonial America, and are available for questions from registered viewers.

Interaction—the exchange of ideas and opinions—is the heart of a Colonial Williamsburg electronic field trip. The intent is to make students feel as if they have traveled back to the eighteenth century and are active participants in the process of history. Based on the responses from teachers and students, this format works extraordinarily well.

Traditional Educational Material

The teacher's guide includes historical background materials, facsimiles of historical documents and prints, photographs of Colonial Williamsburg and its costumed interpreters, and several suggested lesson plans. Colonial Williamsburg's teacher advisors develop these teacher guides and lesson plans. Because classroom teachers create them, they are practical and useful. Feedback from educators indicates that the teacher's guides are excellent resources, particularly the primary source documents, which are often difficult for educators to find.

Media Components

The Internet component of the field trips provides another venue for the students to engage in interactive, distance learning. Each field trip provides a forum that allows students to discuss issues and ask questions of each other and of Colonial Williamsburg's historians. The forum remains available throughout the school year so those educators who wish to revisit the material later in the school year can still interact with Colonial Williamsburg. Also, the teacher's guide is available on-line along with several participatory student activities. Student on-line activities provide an opportunity to explore topics in-depth, and to extend and amplify the classroom and broadcast lessons.

PROJECT NEED

Colonial Williamsburg believes that Thomas Jefferson was correct: an educated populace is essential for the maintenance of a free democracy. The fundamental premise of our government is that political power derives from the informed consent of the people, which, we believe, can come only from knowledge and understanding of the people and events that shaped American society. Through historical knowledge, Americans come to appreciate their pluralistic society and see other racial, ethnic, and religious groups as part of the nation's genius and strength. An understanding of the principles on which this country was founded is indispensable in the development of an informed citizenry. Furthermore, the study of history promotes the critical thinking skills that are so necessary for a job-ready work force.

An increasingly disturbing portrait of American education is emerging from research on schools; parents and educators alike are concerned about students' lack of knowledge and preparation. Often, in the efforts to address deficiencies in language arts and math skills, history is virtually left out of the curriculum. Many elementary school teachers do not receive enough exposure to the subject during their classroom training. Students who can keep pace with state-of-the-art computer technology may find little to capture their imagination in events that took place decades

or centuries ago. As a result, youngsters simply do not form a basic understanding of American history and, therefore, are not interested in the subject.

Schools nationwide are finding that resolving the crisis in education calls for a new pedagogy. Many schools, particularly those that and present the classic profile of a student population at risk, are struggling to make instruction both meaningful and effective and fun.

The confluence of several successful Colonial Williamsburg programs and the needs of the schools suggests that now is the time to create a comprehensive program targeting both teachers and students in our nation's school system and promote a renewal of history education.

REQUEST

While Colonial Williamsburg currently reaches over one million registered students with innovative, state-of-the-art programs, we feel we have an obligation to help more schools and students better understand the history of our nation. Recently, Colonial Williamsburg received a private donation of $5 million to endow the Electronic Field Trip programming.

As stewards of an important segment of our American heritage, we are asking for a one-time appropriation of $5 million to leverage with the $5 million private endowment. Federal money would allow Colonial Williamsburg to do the following:

—Support distribution of the video program across the country.
—Support the further development of web casting.
—Support coordination with the various state standards of learning.
—Support disadvantaged schools to integrate technology and education in their schools.

The Colonial Williamsburg Foundation wishes to express its deep appreciation to this Committee for permitting us to submit this presentation on the "Outreach Education Initiative." Your positive response for Colonial Williamsburg's request for support will have a positive impact on our nation's education crisis by teaching history to our children.

PREPARED STATEMENT OF FLORIDA STATE UNIVERSITY

Mr. Chairman, I would like to thank you and the Members of the Subcommittee for this opportunity to present testimony before this Committee. I would like to take a moment to briefly acquaint you with Florida State University.

Located in Tallahassee, the capitol of Florida, FSU is a comprehensive Research I university with a rapidly growing research base. The University serves as a center for advanced graduate and professional studies, exemplary research and top quality undergraduate programs. Faculty members at FSU maintain a strong commitment to quality in teaching, to performance of research and creative activities and have a strong commitment to public service. Among the faculty are numerous recipients of national and international honors, including Nobel laureates, Pulitzer Prize winners as well as several members of the National Academy of Sciences. Our scientists and engineers do excellent research, have strong interdisciplinary interests, and often work closely with industrial partners in the commercialization of the results of their research. Having been designated as a Carnegie Research I University several years ago, Florida State University currently is approaching $125 million per year in research awards.

Florida State attracts students from every county in Florida, every state in the nation, and more than 100 foreign countries. The University is committed to high admission standards that ensure quality in its student body, which currently includes some 192 National Merit and National Achievement scholars, as well as students with superior creative talent. We consistently rank in the top 25 among U.S. colleges and universities in attracting National Merit Scholars to our campus.

At Florida State University, we are very proud of our successes as well as our emerging reputation as one of the nation's top public universities.

Mr. Chairman, let me tell you about a project we are pursuing this year involving the U.S. Department of Education and distance learning. Florida State University is pioneering the use of distance education to provide access to baccalaureate degrees for students with Associate of Arts degrees who, due to family or work situations, may not be able to relocate to a college or university to complete their degree work. FSU is currently offering upper-division programs entirely online for students to receive their baccalaureate degree in Computer Science, Information Studies, and Software Engineering—all areas central to our economy. An essential part of this program is the use of mentors, who take a proactive stance toward the students, contacting them on a regular basis to provide assistance, and are available electroni-

cally to students as needed. Student mentoring is key to insuring successful outcomes in distance courses.

This program is a model of effective distance learning that can be used anywhere at the undergraduate level. Our focus has been on Florida, though we have a small number of out-of-state students in our distance degree programs. With additional support, additional majors can be added and the program can be expanded to serve a wider range of students geographically. Front-end development activities are essential for quality courses and require significant expenditures to add majors, train mentors and offer degree programs on a larger scale.

Additionally this year, we plan to address the issue of preparing students to become K–12 teachers. Governor Bush has stated that he would like to see teachers trained both by traditional and alternative means and wants skills of current teachers to include the use of technology. We will utilize the same articulation we have between the AA and the bachelor's degree in Florida to offer first the general teacher certification courses online, then begin placing specific areas of certification online. In addition, we plan to build on our "Troop-to-Teachers" project and have a robust alternative certification program available online. Many qualified people in mid-life or retires who may want to become teachers are discouraged by the typical format for teacher certification which requires then to return to a campus to take undergraduate courses. The state of Florida is pioneering with an alternative certification program that allows the local school board to certify teacher if they go through a process while employed at the school. Florida State has take the first steps in developing an online curriculum for alternative certification that could be used by any of Florida's 67 school districts, and for that matter anywhere else in the country where the alternative certification model is employed. It is being piloted in two school districts this year. We will service students in Florida and will expand to draw students from other states that plan to relocate to Florida. Further, this can serve as a demonstration project which if successful could be adopted across the nation to help alleviate our teacher shortage. We will do this with the guidance of the recent reports—the first, Investing in Teaching, which was prepared by a consortium composed of The Business Roundtable, the National Alliance of Business, the National Association of Manufactures, and the US Chamber of Commerce. The other report, Professional Standards for the Accreditation of Schools, Colleges and Departments of Education, has been published by the National Council for Accreditation of Teacher Education (NCATE).

Florida State University is heavily invested in new technologies and learning and is ideally positioned to provide further leadership in student supported high quality distance learning. Last year, FSU received $170,000 in fiscal year 2001 to begin its efforts. We are seeking an appropriation of $3 million within the Department of Education's Fund for the Improvement of Post-Secondary Education account to continue and expand this activity in fiscal year 2002.

Finally Mr. Chairman, I would like to discuss construction needs of the FSU College of Medicine. Last year, the State of Florida approved the establishment a Medical School at Florida State University. The FSU College of Medicine is the first medical school to be established in the United States in a quarter of a century. This initiative is a major opportunity for FSU and will be a tremendous asset to the State of Florida. By establishing this medical education program in a unique fashion, which is our plan, we are convinced that its creation can have a national impact on medical education. The University is seeking to implement this new approach to medical education in extremely innovative and nontraditional ways, and we will be doing so in an efficient fashion that will meet today's and tomorrow's challenges to the practice of primary care matched with Florida's unique demographics. The College's focus will not be on centralized campus clinical care facilities. We intend to maximize the University's statewide visibility to create networks of collaborative relationships with public health clinics, hospitals, and other primary health care delivery systems throughout the State. We will employ approaches that include unique and extensive distance learning technologies, telecommunications and telemedicine capabilities; we will focus on public, community, and rural health; we will develop expertise and interest in health policy issues, health statistics, and demographic research; we will focus on an aging population; and we will emphasize health professions development. The University will build upon existing strengths in many of these areas to create a truly unique medical resource of the State of Florida and the nation.

Florida State University has already received $30 million from the Florida legislature over the past two years for a new basic sciences building to be used for the College of Medicine. There is another $15 million requested in Governor Bush's budget pending with the legislature at this time. The estimated cost of the medical building is $60 million. We are requesting the remaining funding, $15 million, to

be secured from HRSA, which will allow us move forward with the building of this facility, and will ultimately allow FSU's new College of Medicine to becomes a reality. This investment will have lasting results that will greatly benefit both Florida and the nation.

Mr. Chairman, these are just a few of the many exciting activities going on at Florida State University that will make important contributions to solving some key problems and concerns our Nation faces today. Your support would be appreciated, and, again, thank you for an opportunity to present these views for your consideration.

PREPARED STATEMENT OF THE NATIONAL MILITARY FAMILY ASSOCIATION, INC.

Mr. Chairman, the National Military Family Association and the families we represent are grateful to this Subcommittee and to the United States Senate for its actions on behalf of military children and the Impact Aid Program. We thank all Congressional supporters of Impact Aid, especially the Members of the House and Senate Impact Aid Coalitions, for securing another increased appropriation for the program for fiscal year 2001. Your continued support of this program translates into better education for approximately 550,000 military children and several million of their civilian classmates in school districts across the country.

THE MILITARY CHILD

NMFA presents this statement on behalf of military families, or more specifically on behalf of military children:

—Military families move an average of every 2.9 years, three times the rate of their civilian counterparts. Military children attend an average of six different schools during their K–12 education. Less than 20 percent of these children attend Department of Defense schools; the overwhelming majority of military children attend civilian schools dependent on Impact Aid.

—Military children bring a wealth of cultural experiences gained from living in many parts of the world to their new schools. They also frequently come with gaps in their education that their new teachers must quickly fill while moving the rest of the class ahead. Sometimes they are far ahead of their new classmates, adding boredom to the list of reasons why they hate moving to yet another new school.

—Because of varying course standards, school schedules, and state graduation requirements, military children sometimes lose credits needed for graduation. Currently 18 states have graduation requirements linked to performance on state exit exams; 6 more states are developing exit exams. With the rise of exit exams and increased graduation requirements, transfers in the last year or two of high school are becoming more problematic. A change of schools at any time is traumatic, but a change in the middle of the school year is especially so. A midyear transfer can place some children so far behind that they cannot catch up the rest of the school year.

—Because of the high operations tempo of today's military, the military child often has to adjust to the new school, face that week of standardized tests, fight for the spot on the newspaper staff, and play the basketball game before a crowd of strangers, all without the support of their military parent. Worry about the safety of a parent in a place far from home where people are shooting at each other makes for a powerful distraction from the business of education.

Today's military force is an educated force and military members have high expectations for their children's education. More are accepting or rejecting assignments, or even deciding to leave the military, based on perceptions about the quality of education their children will receive at prospective duty stations.

WHY IMPACT AID? THE FEDERAL RESPONSIBILITY

Military families understand that the Impact Aid program supports basic education services provided by their local school districts. They understand the impact the federal presence has on the tax base of these local districts and their states. They understand the impact their children and the transient military lifestyle can have on their local schools. What they do not understand is that Impact Aid funds fall short of the levels intended by the creators of the program or of the amount needed by their children's schools.

Military families hold the Government, and the citizens they have sworn to serve and protect, accountable for living up to their promise to provide a quality education for their children. The districts have accepted the responsibility to educate military

children; the Federal Government must provide the resources it has promised to support that education. The intent of the original Impact Aid legislation (Public Law 81–874) was "to provide financial assistance for those local educational agencies upon which the United States has placed the financial burden." It originally provided an "in-lieu-of-tax" payment equal to the local per-pupil costs for students whose military parent both lived and worked on a federal installation (these students were termed "military A" students) and one-half of the local per-pupil cost for students whose military parent worked on a federal installation but lived in the civilian community (termed "military B" students).

NMFA thanks this Subcommittee and the Congress for its continued funding of Impact Aid for the military children who live off the installation, the military Bs. Two-thirds of military families live off-base. Although military families living in the civilian community pay property taxes to help support local schools, they often do not contribute to other sources of education funding. States provide an increasingly larger share of local districts' funding. Many military members pay no state tax on their military income. They also shop in military exchanges and commissaries, thus paying no sales tax. Under the provisions of the Soldiers' and Sailors' Relief Act, they are often exempt from paying personal property taxes or license fees for automobiles if they are on military orders away from their home state. Military children, whether living on- or off-base, impose costs on the district as they move in and out: records must be prepared, evaluations and testing must be done for special programs, transition labs or remedial programs may be needed.

NMFA is grateful to the Congress for recognizing the costs imposed on school districts by the military B students and the inadequacy of the B's weighting at only one-tenth of the payment made for on-base students. The increased weight to two-tenths of the on-base payment included in last year's reauthorization of the Impact Aid program was an important step in providing districts that serve these children with the funding necessary to meet their responsibility for educating them. Funding for these children will become even more crucial for school districts as the military Services increasingly look to the civilian community to provide more housing for military families. Funding for military Bs will also be important to districts serving installations building privatized housing in civilian communities off-base rather than on the installations. Although developers may be paying some taxes, these revenues may be inadequate, especially during the early years of the privatization contracts.

The administration's fiscal year 2002 budget proposal included a request for Impact Aid basic support at the fiscal year 2001 funding level rather than the smaller request we had come to expect from previous administrations. We note, however, that the increased weight now provided for off-base students will result in smaller payments for some districts unless more money is provided for basic support. We would hate to see that a much-needed change to help districts educating many off-base children would be paid for by districts supporting large numbers of on-base military children.

A well-funded Impact Aid program enables districts serving large numbers of military children to approach the level of educational opportunity available in neighboring, non-impacted school districts even though they do not have access to the same kind of tax base. Impact Aid dollars are targeted to districts where the Federal responsibility is the greatest under the law. The dollars go directly to school districts with no strings attached. The local community, the people with the greatest stake in the quality of education in their schools, decides how Impact Aid funds will best serve the basic education needs of all students.

FAMILY HOUSING PRIVATIZATION: A CAUTIONARY NOTE ON EDUCATION FUNDING

NMFA has supported the concept of privatization of military family housing as essential for increasing the amount of capital available to eliminate the backlog in substandard housing. However, we caution installation leaders and wish to inform policymakers of privatization's unintended consequences on both family budgets and school district funding. The law requires that servicemembers living in privatized housing be paid Basic Allowance for Housing (BAH), which is then turned over to the developer as rent. Eligibility for safety net programs administered by the U.S. Department of Agriculture such as food stamps; the Women, Infants, and Children (WIC) nutrition program; and free and reduced price school lunches is based on a family's total income. When an installation's housing is privatized and servicemembers start receiving BAH—which is immediately passed to the developer via an allotment—the total income as indicated on the member's Leave and Earnings Statement (LES) seems to have increased. Many servicemembers then lose eligibility for safety net programs. Press reports state, for example, that two-thirds of

the families receiving food stamps on Fort Carson, CO, lost their eligibility once the housing was privatized. When families lose eligibility for free and reduced school lunches, their local school can also lose other funding. Federal Title 1 and E-rate technology funding as well as some state funding is based on a school's poverty rate, which in turn is based on the percentage of children receiving free and reduced lunches. Fountain-Fort Carson District 8, a district of approximately 4,900 children, reports that it received $400,000 less in funding from these sources in the year after installation housing was privatized and servicemembers on Fort Carson began receiving BAH. NMFA urges the Departments of Defense, Agriculture, and Education to examine how school funding can be protected during the implementation of privatization projects.

FIX THE SCHOOLHOUSE

For a newly-arrived family in a military community, the sight of a well-maintained, safe, child-friendly school building can calm many anxieties about the latest move. Unfortunately, too many military children must deal with those anxieties in a school facility that has seen better days. Their military parents see the deteriorating school building as perhaps a symbol of a deteriorating respect for their service to the country. Although Impact Aid provides much of a heavily-impacted district's working capital, a district's payment cannot usually be stretched to fund the facility maintenance and improvements old school buildings need. Military families at many installations voice concerns about the repairs needed for these buildings and the lack of available funds. Obtaining funding to construct and renovate school buildings is a challenge for school districts across the country, not just districts receiving Impact Aid; many U.S. school buildings were built in the fifties and sixties and need major work to meet handicapped accessibility standards and to be able to handle modern technology. The reduced tax base of districts dependent on Impact Aid often makes it difficult for these districts to float the necessary bond issues to construct new schools or renovate existing buildings.

NMFA remains concerned about the inadequate funding to upgrade and maintain buildings owned by the Department of Education. The co-terminous districts—those civilian districts whose boundaries are the same as the military installations they serve—have received funds in recent years out of the Department of Defense budget to help with repair and renovation projects. Some of these districts have school buildings owned by the Department of Education. Even with the DOD funding, these districts still face difficult prioritization decisions on how to address facility shortfalls. Randolph Independent School District, serving Randolph Air Force Base in San Antonio, TX, estimates that it needs $14 million to meet the facility needs in its Department of Education-owned buildings. The district must address safety and structural needs before addressing a priority of many military families: renovating a room that is too small to accommodate the district's award-winning band.

Other districts, with a mix of schools owned by the district and by the Department of Education, have not received the funding they have needed to take care of these buildings. They have been forced to use district funds to bring the Department of Education-owned buildings up to district standards so that the military children attending these schools will not fall behind their peers in district-owned buildings. NMFA is pleased to note the increased amount requested for construction in the administration's budget proposal and urges Congress to allocate adequate construction funding in the Impact Aid budget for districts that do not have other funding alternatives available.

ONE CHILD, MANY SCHOOLS

The education of a military child is a continuum. As the military child moves from school district to district—from a school receiving Impact Aid in California, to another Impact Aid school in Texas, to a Department of Defense school in Japan, to an Impact Aid school in Kansas—the quality of education she receives in one school may well affect the education she and her classmates receive in the next. Children whose schools are unable to provide the necessary educational services could easily fall behind their peers in other districts. Schools serving these children could face difficulties in maintaining accreditation as tough new standards are implemented in many states. A smooth transition into their next school, whether across the state or around the world, benefits military children, their classmates, and their communities. The Impact Aid program enables districts affected by the presence of a military installation to offer not only a quality basic education program, but also the support services needed by military children as they transition from school to school.

Recognizing that servicemembers view quality education as an important quality of life factor and a retention issue, the military services have stepped up their ef-

forts to establish partnership programs with local schools, to train installation school liaison officers, to provide better information to families about local schools, and to study the problems faced by military children as they move. The Services are adopting proposals to facilitate parent involvement in schools, such as the policy at Fort Hood, TX and other installations that states a servicemember's place of duty is the scheduled parent-teacher conference. The Army has addressed the difficulties students' face when moving in their senior year by recently instituting a Senior Stabilization Policy that enables the soldier to request a delay in PCS orders so that a rising senior can finish high school at the current location. Personnel are working across the Services on common issues and are reaching out to military-related and education organizations. NMFA applauds DOD's creation of the Educational Opportunities Directorate to address the needs of all military children wherever they go to school. The Directorate has established a Special Needs Website (www.mfrc.calib.com/snn) as a resource for military as well as for schools and service providers. The Directorate is currently conducting a series of roundtables in states with high military populations to raise awareness of issues affecting the mobile child among parents, state and local education policymakers, and installation officials.

School districts are responding to military families' concerns about quality education and to the military Services' desire to develop partnerships by devoting resources to training their personnel on transition issues and to setting up more transition programs. They recognize their interdependence and their shared responsibility for the education of military children and are increasing their communication with each other to ease children's transition in and out of different school systems.

Military parents view the partnerships between their schools and the military Services—from the unit adopting the local elementary school to the presence of Service and DOD leadership at educational conferences on the military child—as progress toward relieving some of the anxieties about their children's education. The educational focus of these efforts is a legacy of a successful, well-funded Impact Aid program. When the Federal Government fulfills its responsibility to provide funding for basic education to districts serving military children, the schools can concentrate on providing a high-quality education program for all students. We thank you, the Members of this Subcommittee, for your leadership in this partnership for the education of military children. We ask you to continue this role by meeting the Federal obligation to fully fund Impact Aid.

PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

SUMMARY OF REQUEST

For 32 years United Tribes Technical College[1] (UTTC) has been providing postsecondary vocational education, job training and family services to Indian students from the Great Plains and throughout the nation. Our request for fiscal year 2002 funding for tribally controlled postsecondary vocational institutions as authorized under Carl Perkins Vocational and Applied Technology Act is:

—$6 million, or $400,000 over the fiscal year 2001 enacted level. This funding is essential to our survival as we receive no state-appropriated vocational education monies.

In addition we request:

—Funding for renovation of our facilities, many of which are original to the Fort Abraham Lincoln army installation and are on the National Register of Historic Places. A recent study commissioned by the Department of Education and submitted to Congress shows a facility need for UTTC of $49 million.

FUNDING AUTHORITY

Section 117 of the Carl Perkins Vocational Education and Applied Technology Education Act Amendments of 1998 authorizes funding for tribally controlled postsecondary vocational technical institutions. Under this authority funding is currently provided to UTTC and one other tribally controlled postsecondary vocational institution, the Crownpoint Institute of Technology. We do not receive funding through the Tribally Controlled Community Colleges Act.

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[1] The college is owned and operated by five federally-recognized tribes situated wholly or in part in North Dakota—Spirit Lake Sioux Tribe, Sisseton-Wahpeton Sioux Tribe, Standing Rock Sioux Tribe, Three Affiliated Tribes of the Fort Berthold Reservation, and Turtle Mountain Band of Chippewa. Control of the institution is vested in a ten-member board of directors comprised of elected Tribal Chairpersons and Tribal council members.

A UNIQUE INTER-TRIBAL EDUCATIONAL ORGANIZATION

United Tribes Technical College is the only inter-tribally controlled, campus-based, postsecondary vocational institution for Indian people. Our campus is the site of the Fort Lincoln Amy Post, an 110-acre area near Bismarck, North Dakota. We currently enroll 371 students from 32 tribes and 14 states. And we serve 155 children in our pre-school programs and 175 children in our elementary school, for a direct services population of 701.

EDUCATING STUDENTS AND CONTRIBUTING TO THE ECONOMY

We are proud of the education, skills and services provided by UTTC for our students and their families. And we are proud that this education is taking place in a setting they where can maintain and strengthen their tribal heritage. The average age of our students is 28. 68 percent of our students are female, and 45 percent of student are single parents with an average number of dependents of 2.5. We have had a sustained job placement rate exceeding 80 percent over the last 10 years. This success is all the more gratifying in light of the background of our students, most of whom come from tribal areas where poverty and unemployment are the norm. Many of our students are from the 14 tribes in the Dakotas, where unemployment among Indian people is chronic. BIA Labor Force data reports the percentage of potential Indian labor force on and near reservations in the Aberdeen Area who are jobless is 71 percent. Of those persons who are employed 33 percent are still living below the poverty guidelines. (Source: Interior Department 1999 Labor Market Information On the Indian Labor Force.)

We believe that a primary reason for UTTC student success is that we serve the students' social, academic and cultural needs. Many of our students are the first generation in their family to attend college, and for many it is their first experience in living away from home. Many students are on public assistance and many have families of their own. Some of our services are:

—Early childhood services for 145 children, ages birth to 5 years and an additional 12 elementary children for extended care.
—Theodore Jamerson Elementary School serving 148 Indian students;
—A health clinic whose services includes immunization, health education, eye and dental exams, and referrals to other health care providers;
—Family housing and dormitories for solo parents and for students without children;
—A local transportation system for students for school activities and necessary appointment e.g., (doctor appointments) outside the campus. Most UTTC students do not have cars.

UTTC is a major business contributor to the state of North Dakota. We undertook a study of the economic impact for 1999 of our institution on the state of North Dakota, and found, using only four key dollar impact areas, the economic impact created by UTTC was $34 million. This study did not encompass all the meetings and conferences that UTTC was directly or indirectly responsible for bringing to Bismarck. Thus, the economic impact in 1999 was even greater than indicated in our study ("Economic Impact by United Tribes Technical College on the Bismarck-Mandan Community and North Dakota—January 2001")

UTTC NEW COURSE OFFERINGS

We offer 9 Certificate and 15 Associate of Applied Science degree programs. We are very excited about the recent additions to our course offerings, and the particular relevance they hold for Indian communities. The modest increases in our Department of Education funding has helped make these new programs possible. These new programs are:

—Injury Prevention
—Food and Nutrition
—Tribal management, including gaming management
—Computer Support Technician
—Distance Learning programs

Food and Nutrition/Diabetes.—UTTC will meet the challenge of fighting diabetes through education. As this Subcommittee knows, the rate of diabetes is very high in Indian county, and with some tribal areas experiencing the highest incidence of diabetes in the world. About half of Indian adults have diabetes ("Diabetes in American Indians and Alaska Natives, NIH Publication 99–4567, October, 1999).

The College currently offers a Food and Nutrition Associates to increase the number of American Indians with expertise in human nutrition and dietetics. Currently, there are only a handful of Indian professionals in the country with training in

these areas. Future improvement plans include offering a Nutrition and Dietary Management degree with a strong emphasis on diabetes education and traditional food preparation.

United Tribes Technical College has also established the United Tribes Diabetes Education Center to assist local Tribal communities and UTTC students and staff in decreasing the prevalence of diabetes by providing diabetes educational programs, materials, and training.

Injury Prevention.—Through our Injury Prevention Program we are addressing the injury death rate among Indians which is 2.8 times that of the U.S. population (Source: IHS fiscal year 1999 Budget Justification). We received assistance through the IHS to establish the only degree-granting Injury Prevention program in the nation.

Computer Support Technician.—High demand exists for computer technicians. In the first year of implementation, the program is at maximum student capacity. In order to keep up with student demand, UTTC will need more classroom space, computers and associated equipment, and instructors. Our program includes all of the Microsoft Systems certifications which translates into high income potential.

Distance Learning.—We are bridging the "digital divide" by providing web-based education from our North Dakota campus to American Indians residing at other remote sites, including the Denver Indian community. Training is currently provided in the areas of Early Childhood Education and Computer Literacy. By the year 2005, students will be able to access full degree programs in Computer Technology, Injury Prevention, Health Information Technology, Early Childhood Education, and Office Technology, and others from these remote sites. Online education allows all American Indians an opportunity to overcome barriers such as geographic isolation and access to culturally relevant education. Through partnership programs, UTTC is meeting the challenge of providing technology skills and training to Indian country.

In addition, UTTC has been a member of the Interactive Video Network of North Dakota's colleges, universities, and tribal colleges. This allows for collaborative arrangements with other colleges and universities, expanding the educational opportunities for our students.

OTHER UTTC INITIATIVES

Northern Plains Bison Research.—UTTC is coordinating reservation-based field research under the Northern Plains 1862/1994 Land Grant Institutions Bison Research Collaborative. The overall project goal is to enhance the quality of prairie rangeland conditions that will sustain the spiritual and physical well being of Tribal bison herds. Research activities are focused on the habitat and nutrition needs of bison herds on North and South Dakota reservations.

Job Training and Economic Development.—UTTC is a designated Indian Minority Business Center serving Montana and the Dakotas. We also administer a Workforce Investment Act program and an internship program with private employers. And we are assisting tribes and tribal members in the Aberdeen Area with rebuilding their economies and buffalo herds.

Coordination with State Welfare-to-Work Efforts.—UTTC is working in cooperation with the state of North Dakota and Tribal JOBS programs on addressing the effects of welfare reform. The campus Child Development Center provides early childhood services for 91 families. This includes an Extended Care program so that students are able to complete TANF work requirements, complete Cooperative Education internships with private employers, and complete other work activities.

In North Dakota, only 33 percent of state TANF recipients are allowed schooling as a work activity. The 12-month statutory limit on length of time a TANF recipient can be enrolled in a vocational education course of study presents additional barriers for single parent families. This limits TANF recipients to taking 1-year certificate courses at UTTC. Our experience shows that the students who graduate from a 2-year, rather than a 1-year, course of study have significantly higher earning power. Many of our students come to UTTC planning to take a 1-year course, and then, finding themselves in a supportive environment and seeing the economic benefit of the longer course, decide to work for the 2-year degree.

NEW STUDY DOCUMENTS OUR FACILITY NEEDS

The 1998 Perkins Act required the Department of Education to study the facilities, housing and training needs our institution. That report, conducted for the Department of Education by the American Institutes for Research, was published in November 2000 ("Assessment of Training and Housing needs within Tribally Controlled Postsecondary Vocational Institutions, November 2000, American Institute of

Research") The report identified the need for $16,575,300 for the renovation of existing housing and instructional buildings ($8 million if some existing facilities are converted to student housing) and $30,475,000 for the construction of housing and instructional facilities. Our core facilities range from 90 to 100 years in age. Originally the site was a military post built as Fort Abraham Lincoln. UTTC acquired its use and eventual ownership in 1968.

If not adequately addressed, these costs will inevitably continue to grow as the buildings age and inflation rises. The following needs must be addressed if the College is to remain in existence and increase its capacity.

Housing.—UTTC continues to identify housing as its greatest need. UTTC has a huge waiting list of students—some wait from one to 3 years for arrival. New housing must be built to accommodate those on the waiting list as well as to increase enrollment. Existing housing must be renovated to meet local, state, and federal safety codes. In the very near future, some homes will have to be condemned which will mean lower enrollments and fewer opportunities for those seeking a quality education. Single student housing must also be built and expanded to meet the College's needs.

Classrooms & Offices.—This type of space is at a premium. The College has literally run out of space. This means that the UTTC cannot expand its course offerings to keep up with job market demands. Most offices and classrooms that are being used are quite old and are not adequate for student learning and success.

OTHER AREAS OF NEED

Devastating Utility Increases.—Utility costs have skyrocketed due to increases in natural gas. UTTC's utility costs have increased by 65 percent. This has put a major added burden on the school and is causing a funding dilemma, since we do not have the option of relying on state appropriated resources or other fixed cost revenues.

Inadequate Salaries.—We were able to provide a cost-of-living increase for our employees last year. However, our faculty and staff still receive salaries that are lower than any state college system in the 50 states. (Source: Integrated Postsecondary Education Data Systems Report of the U.S. Bureau of the Census and the Department of Education Office of Education Statistics.)

Course Offerings/Student Services.—We hope to change some of our courses to better meet new market demands, e.g. training to increase the number of students in the allied health professions, updating of technology. We also need to expand our diagnostic capabilities in tribal-specific areas and in the areas of literacy and math-science background. And, we want to make improvements in our student follow up, career development, and job market research efforts.

Thank you for your consideration of our request.

PREPARED STATEMENT OF THE UNIVERSITY OF TULSA

It is proposed that the Department of Education support an information technology center for the University of Tulsa. We are seeking $13 million for building and equipment needs.

THE UNIVERSITY OF TULSA CENTER FOR INFORMATION TECHNOLOGY

It is a reality that economies are increasingly linked to technology. In February 2000, Oklahoma Governor Keating hosted a round table discussion of technology, educational, and commerce leaders in Tulsa. As a result of that meeting, a Center of Excellence in Information Technology and Telecommunications was formed. Participants in the Center include the University of Tulsa, Oklahoma State University-Tulsa, the University of Oklahoma's Tulsa operations, Oral Roberts University, Tulsa Community College and Tulsa Technology Center.

The University of Tulsa is poised to help ensure that the Center of Excellence in Information Technology and Telecommunications meets the needs of industry and fulfills its mission of advancing the industry through research and educational programs. However, we are in need of a state of the art technology center to optimize our educational and research opportunities.

There are a number of significant benefits that will flow to the State of Oklahoma and the Tulsa community from an investment in a TU Center for Information Technology (IT). These include:

—Attracting and retaining quality students
—Enhanced educational opportunities
—Research opportunities for both faculty and students

Attracting and Retaining Quality Students

TU is committed to quality education. The University of Tulsa faculty is nationally recognized. For example, last year the Carnegie Foundation honored two University of Tulsa professors for the Advancement of Teaching and Learning. One was named a Carnegie Professor of the Year and one was named a Pew Scholar. In the past five years, The University of Tulsa, MIT and Stanford produced an equal number of Goldwater Scholars, tying for seventh place in the nation. The TU Center for IT would provide the infrastructure to maximize the potential of integrating these quality students with quality faculty. However, the Center would prove beneficial even before students arrive on campus. The recruiting competition for quality students is fierce. Students judge the technology infrastructure of a college or university when selecting an institution of higher learning. Students often make the decision to stay at a college or university based on opportunities for access to state of the art technology. TU wants to educate the technology knowledge workers to enter the digital economy work force and the Center would allow us to nationally recruit quality students to Oklahoma.

Enhanced Educational Opportunities

The TU Center for Information Technology will enhance educational opportunities in three areas:

—by providing tools/resources to enhance learning in all academic areas and disciplines,

—by providing an infrastructure for technology based program students (such as management information systems, computer information systems, and computer science) students to complement in class learning by applying their classroom learning, and

—by enabling TU to deliver education to a broader range of constituents—students in divers geographic regions. It will also enable TU to reinforce the lifelong learning we encourage our alumni to pursue.

Research Opportunities

The TU Center for Information Technology will provide resource opportunities for both University of Tulsa faculty, and graduate/undergraduate students. Due to the number of industry leaders located in Tulsa, TU researchers have access to a significant volume of relevant subjects and data. TU's research program for undergraduate students (known as TURC—the Tulsa Undergraduate Research Challenge) is nationally recognized and acclaimed. Students have won a variety of national scholarships and grants from prestigious organizations such as the National Science Foundation and the Department of Energy. The enhanced research labs available in the TU Center for IT would further enhance the success of this program.

In summary, the combination of quality professor, students, and technology infrastructure will result in a win-win proposition for students of higher education in Oklahoma and the Oklahoma economy.

PREPARED STATEMENT OF THE CROWNPOINT INSTITUTE OF TECHNOLOGY

This testimony addresses appropriations under The Carl D. Perkins Vocational Education Act, Section 117 "Tribally Controlled Vocational and Technical Institutions." On behalf of the Crownpoint Institute of Technology, (CIT), I thank this Subcommittee for providing very necessary and deeply appreciated appropriations to Section 117 for tribally controlled vocational educational institutions. CIT is aware of only two such institutions in the nation. Funding to the U.S. Department of Education by this Appropriations Subcommittee for Section 117 has enabled CIT to provide vocational and technical education and training to over 400 students annually. CIT graduates enter our nation's workforce with highly marketable employment skills.

While this appropriation has been greatly appreciated and extremely well-utilized for the education of Native American young adults, CIT believes the most significant situation relevant to Section 117 appropriations is that on March 27, 2001 the U.S. Department of Education unexpectedly issued new regulations and application guidelines that drastically redirect this appropriation. The Department ruled that minor changes in the 1998 reauthorization to Section 117 constituted a "substantial revision," and therefore expanded eligibility to tribal institutions already supported under other statutes. CIT does not agree that Section 117 of the reauthorization law was revised. Attached with this testimony is a side-by-side comparison of the 1990 and 1998 "Tribally Controlled Postsecondary Vocational Institutions" definitions demonstrating that there are no substantial revisions to the definitions of eligible

institutions. Our most important request to this Subcommittee is for assistance and intervention in ensuring that the intent of the Congress is carried out in the Department's awarding of funds under Section 117 beginning with fiscal year 2001 appropriations which this Department of Education March 27, 2001 Notice redirects effective May 29, 2001.

The Title for Tribally Controlled Postsecondary Vocational Institutions was enacted to create a stable base of operational support for those tribal colleges that were not eligible for the "Tribally-controlled Community Colleges Assistance Act." That 1978 act followed the U.S. Congress policy of Indian Self-Determination, which allowed tribes to manage their own institutions, and provides basic operational support for tribal colleges through Interior appropriations into the present time. The Tribal Colleges Act supports all but two of the nation's tribally controlled colleges. The Crownpoint Institute of Technology (CIT) is one of these two excluded tribal colleges. The reason for the exclusion is a provision in the Tribal Colleges Act that limits each Tribe to one college. On its surface this statutory limitation may seem reasonable. The average population of tribes having tribal colleges ranges between 3,000 and 10,000 members. The Navajo tribe is a population anomaly among Indian tribes with 225,298 members as verified by the most recent U.S. Census. Dine College, Tsaile, Arizona, is the Navajo Tribal College funded under Interior's Tribal Colleges Act. Founded in 1969, Dine is the first of the nation's tribal colleges. CIT was founded in 1979, one year after enactment of the Tribal Colleges Act and even then was originally created as a job skills center. The ensuing decade saw CIT's evolution from a job-training center to a full-fledged vocational technical college. Skilled employment opportunities expanded for students graduating with credentialed degrees, and CIT earned full institutional accreditation from North Central Association of Colleges and Schools in 1987. CIT's outstanding success at providing its students with highly marketable career skills has enabled over 4,000 Navajo adults to leave the welfare roles behind forever. This is how the Navajo Nation came to have a second college.

The size of the Navajo population warrants a second college. Throughout our nation, colleges are created to serve population bases. The number of tribes is irrelevant. There are sixteen Indian tribes in the three States of Montana, North Dakota and South Dakota. Each of these tribes has a tribal college supported by Congressional appropriations. Yet the combined population of on-reservation, all-ages of these sixteen tribes is 72,835. An enrollment base establishes the need for any educational institution. It is illogical by any standard to erect sixteen colleges for a 73,000 population, while simultaneously limiting a 225,000 population to only one college. However inadvertently, this is exactly what the Congress did in 1978 with enactment of Public Law 95–471, "The Tribally Controlled Community Colleges Act."

Geographic access to postsecondary education is another significant factor in establishing the need for a college, and was a primary consideration for most tribes in founding their own colleges. The Navajo Nation is 26,897 square miles extending into three States: Arizona, New Mexico and Utah. The Navajo Nation reservation is 2,810 square miles larger than the State of West Virginia, and only slightly smaller than the five New England States of Vermont, New Hampshire, Massachusetts, Connecticut and Rhode Island combined. The driving distance across this reservation is approximately nine hours. In the remote vastness of this reservation in America's Southwest, geographic access to postsecondary education for Native people would not exist for most citizens without these two tribal colleges.

The existing tribal colleges adamantly opposed many years of CIT's efforts to amend the Tribal Colleges Act to allow a second college in a situation of exceptional population. In 1990, Congress enacted the "Tribally Controlled Postsecondary Vocational Institutions" provisions to provide federal assistance to tribal colleges not eligible for Interior appropriations under the Tribal Colleges Act. At that time there were only two such colleges in the nation, and their primary mission was and remains vocational/technical education. Thus, the provision was included in the Carl D. Perkins Vocational Education Act. The second of these anomaly tribal vocational colleges is United Tribes Technical College (UTTC) located in Bismarck, North Dakota. The four tribes of North Dakota charter UTTC that each already had an on-reservation tribal college funded under the Tribal Colleges Act. More than two decades after their founding, there remain only two tribal vocational colleges in the nation, although during these same years several new tribal community colleges have been added under the Tribal Colleges Act. Each of those colleges is the only college that the sponsoring tribe has chartered. The vast majority of tribes have never founded a first tribal college. Due to the small populations of most tribes, it is highly unlikely that any tribe other than the Navajo will ever found a second tribal college. In the situation of the Navajo people, remote geography and population

uniquely combined to predicate this unusual need for a second postsecondary institution.

The 1998 Reauthorization of the Carl D. Perkins Vocational Education Act saw some major revision, but the Tribally Controlled Postsecondary Vocational and Technical Institutions provision remained essentially intact because the situation it addressed remained essentially the same. Because Section 117 contained only minor changes, Congressional sponsors did not accompany enactment with a statement of the intent of the Congress. The absence of such statement of the intent of Congress served as the Department of Education's justification to abruptly proclaim on March 27, 2001, more than two and one half years after 1998 enactment, that Section 117 definition of eligibility was "substantially revised." In response, a colloquy by the authorizers reiterating the intent of the Congress as to this provision was published in the April 26, 2001 Congressional Record and provided to the Department. Upon receipt of the requested clarification, the Department declined to withdraw the competition, which expands eligibility for appropriations to all tribal colleges, which already receive their basic operational support under Interior's Tribal Colleges Act. A technical amendment is in process. However, it is unlikely that this amendment can be enacted in time to affect awards under fiscal year 2001 appropriation because the Department's unretracted grant application deadline is May 29, 2001 with the fiscal year 2001 program year beginning the following month. This Subcommittee increased the fiscal year 2001 appropriation from $4.6 to $5.6 Million, under which CIT's student count allocation is desperately needed to remain in operation. Under the Department's new guidelines, CIT would lose at least 70 percent of its operational funding, and in a worst case, would not even be one of the institutions selected in the competition by the Department at all. In either case, CIT would not be able to open its doors for classes in August 2001, and will be forced to furlough employees beginning June 2001. Presently, CIT is only able to renew faculty contracts provisionally, subject to continued Section 117 funding. The potential loss of faculty to other more secure employment would have a devastating effect on CIT. We urge this Subcommittee to do all in its power to intervene and ensure that its fiscal year 2001 Section 117 appropriation is spent according to the law and the intent of the United States Congress.

CIT believes it has established its merit as a tribal institution worthy of federal assistance. CIT has an eight-year average student retention rate of 95 percent, and an average job placement rate of 86 percent over the same period. CIT's current enrollment is 492 headcount or 423 Full Time Equivalency/Indian Student Count, an increase of thirty students over academic year 1999–2000. Through tribal HUD assistance, CIT has expanded married/family on-campus housing to accommodate those students possibly most in need of jobs, students with dependant children. CIT is a dormitory-based institution and off-campus housing in scarce. Each year, student applications continue to surpass capacity and CIT has a waiting list of over 200 otherwise qualified applicants.

CIT offers fully-accredited two year Associate of Applied Science degrees and/or one year certificates in high employment demand fields including Accounting, Administrative Assistant, Applied Computer Technology, Automotive Technology, Building Maintenance, Carpentry, Culinary Arts, Electrical Trades, Environmental Technology and Natural Resources, Law Advocate, Legal Assistant, Nursing Assistant and Veterinary Assistant. For academic year 2001–2002, CIT has prepared to offer Dental Assistant and Health Technician in response to a high employment demand and shortage of skilled workers in these fields. CIT has already secured donated dental training equipment enabling it to maximize its use of federal assistance in this program.

Over 10,000 young adults graduate from Navajo area high schools each year. The decennial Indian population increase is 14 percent as compared to only 8 percent for mainstream America. Median Native American population age is now 27.4 years, 8 years younger than the median age for mainstream America. CIT's average student age is 26, although the actual range has been 18–64. CIT is open to and welcomes all qualified Indian and non-Indian applicants, and as just one example has retrained displaced non-Indian uranium workers from neighboring towns. However, the primary mission for this institution is to rectify the joblessness and hopelessness so prevalent among too many of the more than 200,000 on-reservation people. CIT graduates earn an average $15,075 average entry-level annual wage upon graduation. Each employed graduate pays an average of $2,261 of their earnings to federal taxes in the first year of employment alone. While tax contributions vary according to number of dependents and other factors, in general wages and tax contributions over an average thirty years of employment and tax paying. CIT lacks institutional resources to track all of its more than 4,000 graduates of the past two decades, but of those tracked, 61 percent are employed in private industry and do not rely on

federal appropriations for jobs. In an average lifetime of employment, CIT graduates will return to the federal government the cost of its investment many times over through tax contributions as well as through remaining off the welfare rolls.

It will have been a tragic loss of the investment of two decades that brought CIT to the educational institution it is today if federal operational assistance is so abruptly withdrawn. Over the past decade, a significant investment of tribal and federal funding has brought CIT facilities up to the standards that ultimately result in CIT graduates' abilities to succeed in the mainstream American economy. CIT opened its state-of-the art Veterinary teaching clinic last year. This teaching clinic will greatly enhance the way of life that remains traditional for most Navajo people, which relies on livestock yield. Over three years, a more than $4 Million EDA grant enabled the replacement of trailers with actual classrooms. In addition, this same EDA funding repaired dormitories damaged by years of soil contraction, an unforeseen construction problem endemic to the Southwest when CIT was originally built by the Federal Government. CIT Administrative buildings, also damaged beyond repair by this same problem, were replaced with new mobile units in order steer maximum facilities improvements directly to the students. The Navajo Nation invested their HUD funding to increase housing capacity for students with dependent children. Sixteen of a projected thirty-two units now have resident student families on their way to acquiring life-long employment skills to support these families. The Navajo Nation sacrificed much to ensure that CIT provides education equal to that provided in mainstream America so that our graduates can compete on a level playing field. It will be a tragic waste of this investment if federal assistance to CIT is withdrawn by the Department's radical new funding interpretations. We deeply thank this Subcommittee for all its assistance and urge that it take all action possible to ensure that its appropriations reach the recipients that the law specifies and that the Congress intended.

PREPARED STATEMENT OF THE ALPHA ONE FOUNDATION

Mr. Chairman and members of the Committee thank you for the opportunity to submit testimony for the record on behalf of the Alpha One Foundation.

THE ALPHA ONE FOUNDATION

The Alpha One Foundation is a national not-for-profit organization dedicated to providing the leadership and resources that will result in increased research, improved health, worldwide detection and a cure for $Alpha_1$-Antitrypsin (Alpha-1) Deficiency.

ALPHA-1 IS SERIOUS AND LIFE THREATENING

Alpha-1 is a genetic disorder that can result in devastating and fatal lung and or liver disease that is often misdiagnosed as asthma or Chronic Obstructive Pulmonary Disease (COPD). Alpha-1 afflicts an estimated 100,000 individuals in the United States with fewer than 6,000 accurately diagnosed. Alpha-1 is a major cause for lung transplantation in adults.

The pulmonary impairment of Alpha-1 causes disability and loss of employment during the prime of life, frequent hospitalizations, family disorganization, and the suffering known only to those unable to catch their breath. Lung transplantation, with all its associated risks and costs, is the most common final therapeutic option. Alpha-1 is the primary cause of liver transplantation in infants and an increasing cause in adults. Untreated individuals can have their life expectancy reduced by 20 or more years.

Alpha-1 is a progressive and devastating disorder that in the absence of proper diagnosis and therapy leads to premature death; in spite of the availability of therapeutics and preventative health measures that can be life prolonging.

THE MEDICAL NEEDS OF THE ALPHA-1 COMMUNITY HAVE GONE UNMET

$Alpha_1$-Antitrypsin Deficiency is a hidden killer that desperately needs new therapies. It masquerades as asthma, chronic usual obstructive lung disease and bronchiectasis. There is a lack of awareness of the insidious nature of the early symptoms of the lung disease associated with this genetic condition by both medical care providers and the public.

Currently, the only specific therapy for Alpha-1 is intravenous augmentation therapy produced from pooled human plasma at an average annual cost of $50,000.00. This single source therapy, initially marketed through the Orphan Drug Act, increases the plasma levels of the deficient protein and appears to slow or halt the

progression of the pulmonary disease described above. Unfortunately, this therapy has been in short supply over the past several years. During prolonged shortages, individuals on therapy were forced to reduce the dosage of drug being administered or prolong the duration of time between treatments. No data is available concerning the potential efficacy of these untested treatment regimens. As new patients were identified, they were unable to obtain drug during these periods.

SUPPORT FOR RESEARCH

The Alpha One Foundation believes that significant federal investments in medical research are critical to improving the health of the American people and specifically those affected with Alpha-1. The Foundation is supportive of the goal set by Congress of doubling the National Institutes of Health (NIH) budget by fiscal year 2003. At the proposed funding level NIH will be able to support the highest level of new and competing research project grants, and the highest level of total grants in NIH history.

It is fair to state that the support of this Subcommittee has made a substantial difference in improving the public's health and well-being. The Foundation requests that the increase in the NIH budget will reflect an increase in the $Alpha_1$-Antitrypsin Deficiency research portfolio to achieve the following goals:

—The Promotion of basic science and clinical research related to the AAT protein and AAT Deficiency.

—The funding to attract and train the best young clinicians for the care of individuals with AAT Deficiency.

—The support for outstanding established scientists to work on problems within the field of AAT research.

—The Development of effective therapies for the clinical manifestations of AAT Deficiency.

10 SPECIFIC AREAS OF CONCERN

1. *Increase the level of funding for investigator-initiated research.*—Our best ideas to cure and prevent Alpha-1 come from individual scientists working in the laboratory and with patients. We recommend that the NIH budget be increased to allow an increased number of scientifically meritorious grant proposals that are investigator initiated be funded.

2. *Provide significant increases in federal funding to attract, educate, and train more clinical and translational researchers.*—We need continued replenishment of leaders to bring findings from the laboratory bench to the bedside. We must recruit new clinicians to become involved in clinical research. This is becoming more and more difficult as managed care tightens budgets and allows little if any time for physicians to engage in research. We must address this issue if we are to have the trained personnel needed to prevent and cure Alpha-1 in the next 5 to 10 years.

3. *Increase individual grants for scientific conferences and workshops.*—Increase the number and amount of grants available to sponsor scientific conferences and workshops in order to increase the promotion and participation in these forums.

4. *Fund targeted screening and detection.*—In 1989 the HHS National Commission on Orphan Diseases estimated that only 30 percent of the 25 million patients suffering with rare diseases receive a diagnosis in three to five years after the onset of symptoms. That works out to about 7.5 million patients who are shuffled from specialist to specialist, year after year. Fifteen percent, or 3.7 million people, wait seven years or more. The average patient with Alpha-1 sees 5 physicians over 7 years before they are properly diagnosed. In addition only 6 percent of those estimated to have Alpha-1 have been identified. A targeted screening and detection plan should follow the recommendations of the World Health Organization's report on Alpha-1 and promote appropriate treatment and positive health interventions. Research has shown that early diagnosis and treatment leads to fewer long term health complications and a better quality of life.

5. *Establish "centers of excellence" to support proactive initiatives in Alpha-1 treatment.*—We must focus our efforts to further reduce smoking, understand and improve dietary habits and undertake a national effort to identify and test potential Alpha-1 patients in an effort to offer the best therapies and life prolonging preventative health strategies.

6. *Initiate health surveillance for frequent plasma recipients.*—Blood carries inherent risks that increase for life-long recipients. Although all plasma-derived products are virally inactivated, there are concerns about new and emerging pathogens and their ability to be transmitted through blood. Targeted surveillance of the Alpha-1 community would allow for an early warning system should such a threat be present in the blood supply. Specifically, the Foundation welcomes an evaluation of

the experience of this long term and frequent recipient cohort of pooled plasma derivatives.

7. *Capitalize on the unprecedented number of opportunities to create new therapeutics through increased funding and public-private partnerships.*—The medical needs of the Alpha-1 community will go unmet without the development of new therapies. The final delivery of new therapies depends on the overall process of drug development and clinical trials, and in the case of therapies for orphan disease this process is often burdensome and prohibitively expensive. Academic institutions and the private sector carry out these expensive processes. To fully leverage the strengths of these sectors and validate new therapies there must be resources to fund the expedited development of unprecedented and novel public-private partnerships.

8. *Fund programs to improve the quality of life.*—Alpha-1 is a tragic disease that extracts a great deal in terms of human suffering from its victims and their families. We must provide programs that address critical issues such as pain and fatigue and end-of-life issues for patients and families. Preventative measures, environmental effects, psychosocial, economic and ethical issues related to Alpha-1 should be fully explored.

9. *Fund initiatives that will address research questions dealing with disparities in minority, and underserved populations, and accelerate programs to ensure early detection, and treatment.*—We must make every effort to reduce and equalize disease rates across all populations. The Foundation supports increased funding for programs that ensure that all populations receive the benefit of research and that health disparities do not continue among minority populations.

10. *Adequately fund the Office of Rare Diseases.*—Finally, the NIH needs to ensure that all Americans, not just a select few, have access to the incredible work being done at the NIH. Today, only ten cents for each and every person suffering with a rare disease is dedicated to ORD. We request a significant increase in this funding amount.

CONCLUSION

The Alpha One Foundation supports an increase of $3.4 billion for fiscal year 2002, in the hope that this increased investment in the National Institutes of Health will translate into an increase in the resources dedicate to research and awareness of the devastating disorder: $Alpha_1$ Antitrypsin Deficiency.

PREPARED STATEMENT OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH

The Association of Schools of Public Health (ASPH) is the only national organization representing the deans, faculty, and students of this nation's 29 accredited schools of public health and graduate programs seeking accreditation as schools of public health in the United States and Puerto Rico. These schools have a combined faculty of over 2,500 and educate more than 15,000 students annually from every state in the U.S. and most countries throughout the world. The schools graduate approximately 5,000 professionals each year. The 29 schools of public health constitute a primary source of comprehensively trained public health professionals and specialists in short supply to serve the Federal Government, the 50 states and the private sector. Yet according to the DHHS, public health professionals are in short supply.

On behalf of the 29 graduate schools of public health in the U.S. and Puerto Rico, the Association of Schools of Public Health (ASPH) hereby submits a statement for the hearing record on the association's fiscal year 2002 appropriations requests for programs of primary concern in the U.S. Public Health Service. There is a chart on page five that outlines these recommendations. Consideration of these requests by the Subcommittee is appreciated.

PREVENTION RESEARCH CENTERS (CDC)

The Congress established the CDC prevention research centers program in 1985 to provide grants to academic institutions to fund applied research programs designed to develop new and innovative strategies in health promotion and disease prevention. Through this program, faculty expertise of schools of public health is made available to federal, state and local health officials, community-based organizations and nonprofit organizations. Additionally, the centers serve as sources of education and training for America's next generation of public health professionals. Unfortunately, the funding level for the program has never reached the level that Congress intended when authorizing the program.

ASPH REQUEST

CDC currently funds 24 prevention research centers at schools of public health and schools of medicine across the country. Each center has a specific prevention research focus, based largely upon its faculty expertise and geographic location. However, core funding for prevention centers has been decreasing since the program was first funded in 1986 from an average of approximately $800,000 per center to the current year average of approximately $715,000 per center. ASPH requests that the Congress increase the funding for this important program from the current year level of $25 million to $40 million. These funds will be used for the following purposes: to increase the core funding of centers such that the average core award is $1 million (as intended by the Congress) which would allow CDC the flexibility to provide additional funding to centers which have undertaken a more aggressive program; to provide sufficient resources to permit not more than six new, competitively-selected centers; and to provide the necessary resources for administration of an expanded program at CDC.

Each prevention research center (PRCs) taps into the long-standing links that schools of public health have with their communities and regions. Schools of public health faculty work closely with community leaders in designing and applying prevention strategies and programs that address the public health challenges facing these communities.

From Appalachia, Harlem, the Deep South, the Midwest, the Northwest and the Southwest, the PRCs link diverse and geographically distinct areas through a national network that tracks and translates prevention research and best practices to applications in community-based public health and disease prevention programs. Increasing funds for prevention research centers in fiscal year 2002 will enable them to expand community-based interventions further into communities, allowing wider access to lifesaving research and interventions.

HEALTH PROFESSIONS TRAINING (HRSA/BHPR)

The Association of Schools of Public Health respectfully requests that Congress provide at least $20 million for public health training programs and preventive medicine residencies in the fiscal year 2002 appropriations bill. Of this amount, $10 million should support public health traineeships and preventive medicine residencies and $10 million should be dedicated to public health training centers at schools of public health.

The Pew Health Professions Commission, in its 1995 report entitled Critical Challenges: Revitalizing the Health Professions for the Twenty-First Century, concluded that the demand-driven system in health care will result in increased demand for public health professionals as managed care organizations seek to hold health care costs down by employing public health solutions to community problems.

Several public health workforce experts in both government and academia estimate that as many as 80 percent of individuals currently working in state or local health departments have no formal education in pubic health. Furthermore, those same experts estimate that less than 50 percent of the directors of the local health departments, many of whom are MDs, have no public health training. There is a critical need to provide these professionals with the most up-to-date public health training available.

DHHS has listed personnel shortages in several public health occupations.[1] Many state/local health department directors have reported that the lack of practical knowledge and skills in the core sciences of public health and preventive medicine have restricted the effectiveness of their agencies. In order to improve the quality

[1] There is a large under-trained public health workforce of more than 400,000 who have no public health degree, certificate, or education in public health. This represents roughly four of every five employees in public health. Without well-trained public health professionals in various shortage disciplines, communities are left vulnerable to increased infectious diseases, toxic environmental situations, contaminated food, and other threats to public health. Training for public health professionals is critically important in medically underserved communities, where serving disadvantaged populations is critical. There are only 2,755 physicians trained in general preventive medicine and public health in the nation. The number of physicians completing a preventive medicine residency has declined by 25 percent during the last 5 years leading to major gaps in preventive medicine expertise need for clinical prevention, community public health, and health services organization/delivery. DHHS programs are designed to address the problems identified above. The public health traineeships provide support for students in shortage disciplines including epidemiology, biostatistics, environmental health, toxicology, public health nursing, public health nutrition, preventive medicine, behavioral sciences and mental health. The preventive medicine and dental public health programs support planning, development or maintenance of residency programs and provide financial assistance to residency trainees enrolled in these programs.

of the American public health infrastructure, we must provide adequate training, education and continuing education to the public health workforce.

Many national health groups—especially the maternal and child health agencies and state/local health officials—agree that regional shortages of adequately trained professionals present the most significant barrier to providing population-based prevention initiatives, in general, and ensuring the delivery of quality health care to underserved individuals and underrepresented populations, in particular. Health professionals trained to handle the unique demands of rural and inner-city public health issues are in the shortest supply.

ASPH REQUEST

The Association of Schools of Public Health (ASPH) is requesting that the fiscal year 2002 HRSA budget include $20 million for public health workforce training. Specifically, funding should be targeted to:

—Make public health/preventive medicine education more accessible;
—Create links between public health/preventive medicine education and future trends in the practice of public health;
—Continued efforts to promote diversity in student populations;
—Provide education or training for students and preventive medicine residents in practice-based sites instead of solely in the classroom; and
—Develop educational methods and distance-based learning technologies that ensure the ability of public health workers to reach underserved populations.

RESPONDING TO BIOTERRORIST ATTACK

Public Health Preparedness Centers

Building upon an fiscal year 2000 investment of $2 million and report language urging continuation of the program in fiscal year 2001 to conduct training for current state and local health department employees, the Congress should include $10 million in CDC's budget to continue public health education programs using distributed learning technologies with the goal of training employees of state and local departments of public health and community-based organizations to detect, contain and respond to a bioterrorist attack. Such an action would also provide critically needed training in the area of infectious diseases as well.

The recent focus on a bioterrorist attack on the United States has led many to question the ability of the current public health workforce to deal with such an emergency. There has not been a case of smallpox, for example, since the early 1970s—and few public health professionals are trained to recognize the symptoms of this deadly disease. This lack of formal training in infectious diseases extends to other biological agents such as anthrax, tularemia, botulinin toxin and plague. In order to detect and respond to a bioterrorist attack, the U.S. needs public health professionals who:

—Can conduct epidemiological surveillance;
—Can design and use the tools to detect terrorist biological attacks; and
—Understand the principles of containment.

ASPH REQUEST

We respectfully request that the Subcommittee include a total of $10 million in the fiscal year 2002 CDC budget to provide for professional workforce development services to public health and community-based organization employees in order to detect and respond to a bioterrorist attack. It is proposed that CDC select not more than ten public health preparedness centers based at accredited schools of public health to conduct distance learning and professional workforce development activities. Outcomes of these programs would include:

—Offering high-level, in-depth biodefense and infectious disease training to approximately 500 public health professionals in state and local leadership positions (including large cities and state departments of health) using the Internet and other distance learning technologies;
—Offering basic biodefense and infectious disease training to roughly 1,000 staff-level public health officers (such as surveillance officers) through distance learning;
—Assessing the skills and readiness of public health workers to respond to bioterrorist and other public health threats;
—Developing a comprehensive public health training curriculum focused on detection and response to bioterrorist attacks to be delivered through the Internet, or other appropriate mass communication technology.

PREVENTION RESEARCH INITIATIVE (PRI)

Prevention research plays a critical role in reducing the human and economic costs of disease. For example, the CDC has estimated that the annual cost of cardiovascular disease in the U.S. is approximately $259 billion, cancer is estimated to cost $104 billion, diabetes is estimated at $92 billion, Alzheimer's disease—approximately $80 billion, and arthritis about $65 billion. However, these costs can be reduced through prevention.

The benefits of population-based prevention are astounding. The Journal of the American Medical Association published a widely accepted article in 1993 that estimates that ten percent of all early deaths in this country can be prevented by medical treatment. By contrast, the study found that population-wide public health approaches have the potential to prevent up to 70 percent of these early deaths through measures that target underlying risks, such as tobacco, drug and alcohol use, diet and sedentary lifestyle, and environmental factors.

ASPH REQUEST

The Association of Schools of Public Health respectfully requests that the Congress increase the funding for the CDC prevention research initiative to $25 million in the fiscal year 2002 Labor, HHS and Education appropriations bill. Such a program should focus on conducting priority research in the following areas:

—Investigations into the epidemiology of disease, including identification of social and behavioral determinants of illness;
—Studies of means to ameliorate personal, social and environmental factors contributing to disease onset or exacerbation;
—Investigations into the disproportionate disease burden among underserved populations;
—Studies of vulnerable populations with a high disease burden;
—Studies on immunization strategies and of methods for and the cost-effectiveness of population screening programs; and
—Studies into the means by which further decline in physical or social functioning can be prevented in people already ill.

Finally, the program would serve to expand the capacity of CDC to bring the benefits of prevention to the millions of Americans at risk for unnecessary early death.

SUMMARY

In closing, we are spending billions of dollars on treatment of chronic diseases and/or research to find cures for such diseases, while at the same time using pennies of our health care dollars to find ways to prevent them. For example, the U.S. Government spends approximately $50,000 per year/per capita to train medical graduates; by contrast, the federal share per year to train graduate public health students in the United States is less than ten dollars per student.

Our training programs in schools of public health are focused on prevention of disease and disability; our programs are steeped in the basic public health sciences of epidemiology and biostatistics; and our curricula have a population-based perspective. In short, our graduates will be more likely to approach their jobs with a better understanding of disease in populations and with keener sense of a whole spectrum of interventions aimed at the environment, human behavior and lifestyle. Federal support of these programs is a wise investment in the health of the American people.

In addition to our requests, the ASPH wishes to go on record in support of the fiscal year 2002 appropriations recommendations of the following groups and coalitions that have or will submit testimony before the Subcommittee:

—Ad Hoc Group for Medical Research Funding
—CDC Coalition
—Coalition for Health Funding
—Friends of AHRQ
—Friends of NIOSH
—Friends of Title V (MCH Block Grant)
—Health Professions and Nursing Education Coalition
—Injury Control and Research Centers Coalition
—Friends of NCHS

In addition, we want to express the support of ASPH for providing $250 million to upgrade laboratory facilities at CDC. These facilities are in desperate need of renovation.

ASPH requests, and those outlined by these coalitions, represent needs assessments that were derived from the views and expert opinions of this country's most

respected administrators, scholars, scientists and leaders in the public health sector. We know that the Subcommittee members will take them into serious consideration when marking-up the fiscal year 2002 appropriations bill.

Listed below are the ASPH fiscal year 2002 funding recommendations for programs of primary concern to the academic public health community:

[In millions of dollars]

CENTERS FOR DISEASE CONTROL AND PREVENTION:	
Prevention Research Centers (PRCs)	40
Prevention Research Initiative (PRI)	25
Preparedness Centers (PHPCs)	10
HEALTH RESOURCES AND SERVICES ADMINISTRATION:	
Public Health Training Centers, Traineeships, Preventive Medicine and Dental Public Health	20

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT OF THE UNIVERSITY OF CINCINNATI

Mr. Chairman and Members of the Subcommittee, my name is Dr. Donald Harrison, and I am the Senior Vice President and Provost for Health Affairs at the University of Cincinnati. As CEO of the Medical Center, I am also administratively responsible for the University's participation in the Health Alliance of Greater Cincinnati and for the academic programs of the Colleges of Medicine, Nursing, Pharmacy, and Allied Health Sciences. I am a practicing cardiologist with an international patient base, and I have served as national president of the American Heart Association and Vice President of the American College of Cardiology.

I am here today on behalf of a coalition of 20 academic health centers across the nation to highlight issues of concern to all academic health centers in the United States. We are the institutions which conduct a significant portion of the extramural biomedical and behavioral research funded through the National Institutes of Health, and I welcome this opportunity to comment on the programs and policies which seek to strengthen the nation's extramural research enterprise.

First, I would like to thank all of the Members of this Subcommittee for the outstanding support provided to the NIH over the past several years. The additional funds clearly have a significant impact the causes, prevention and treatment of health problems which afflict the citizens of our nation and the world.

Second, I would like to thank the Subcommittee for successfully raising the salary cap imposed on extramural NIH researchers to Level One of the Executive Pay Scale, or $161,200 per year. This higher salary level allows academic medical centers to attract and retain the most talented individuals to biomedical and behavioral research, especially clinician-investigators. Further, the higher salary cap assures equity between intramural and extramural scientists. Because of your leadership, extramural salaries will now be equal to the maximum salary level which the NIH can pay its own senior scientists under the Senior Biomedical Research Service.

I would like to take this opportunity to request your support for further enhancing the extraordinary partnership that was established with great foresight years ago between academic institutions and the Federal Government. This partnership has spawned remarkable scientific developments over decades. These advances position us—academia, industry, and the government—to work together to exploit the golden era of biology. Academic institutions across the nation are proud to be major players in this partnership.

INCREASED FUNDING FOR NIH

As we look ahead to fiscal year 2002, I would like to begin by expressing the support of academic medical centers, and the extramural research community, to seek a $3.4 billion or 16.5 percent increase for the NIH this year to bring the agency's budget to $23.7 billion for fiscal year 2002. This level of support will keep efforts on track to double the NIH's budget by fiscal year 2003. This is an incredible time in biomedical history as the mapping of the human genome has been successfully completed just last month. This extraordinary accomplishment presents an exponential number of additional opportunities to investigate the causes of disease and will lead to new roads of inquiry to developing cures. In addition—and I will repeat a statistic that I am sure you are all very aware—the NIH currently funds fewer than four of every 10 approved research grants. All of these are judged by peer-review to merit funding because of their potential for biomedical advance. For these

reasons, I urge you to continue efforts to increase the NIH's budget toward the goal of doubling the agency's budget by fiscal year 2003.

Having raised the need to continue to increase funding for the NIH, I would like to bring to your attention several factors that impact the ability of our institutions to carry out the extramural component of our nation's expanding and thriving biomedical research enterprise. Our institutions bear certain costs for conducting NIH research that are not supported by the federal research dollar. In fact, all institutions, either public or private, bear a portion of the research expense. I am here today to advocate that we further strengthen the academic/federal partnership so that the extramural biomedical and behavioral research community can operate at optimal capacity and efficiency: Specifically, I urge you to:

—Increase extramural construction funding so that NIH investigators can utilize state-of-the-art facilities to carry out the increasing volume of federally-supported biomedical and behavioral research; and

—Provide resources to research institutions in order to comply with the increasing costs of federal regulation.

In addition, I seek your support for increased funding through the Agency for Healthcare Research and Quality for technological support to combat medical errors. This problem has been highlighted in a review by the Institute of Medicine and in numerous media reports.

INCREASE FUNDING FOR FACILITIES CONSTRUCTION, RENOVATION, AND EQUIPMENT

For the past two years, the NIH has included $75 million in extramural construction funding through the NIH's National Center for Research Resources (NCRR). These funds are necessary for extramural researchers to have adequate laboratories in which to conduct this important research. It is vitally important that we have the facilities and equipment to fully exploit research opportunities and utilize the increased project grant funding. Exciting developments in genomics, chemical biology, neurosciences, cancer, and many other fields require new kinds of equipment and facilities. Even the best minds cannot compensate for outdated equipment and facilities.

The National Science Foundation (NSF) completed a study in 1998 on the status of scientific research facilities at U.S. colleges and universities. This analysis generated an estimate of $11.4 billion in deferred biomedical research construction and repair or renovation projects. In a March 1998 report, the Association of American Medical College (AAMC) stated that "The government should reestablish and fund an NIH construction authority, consistent with the general recommendations of the Wyngaarden Committee report of 1988, which projected at that time the need for a 10-year spending plan of $5 billion for new facilities and renovation." In June 1998, the Federation of American Societies of Experimental Biology (FASEB) reported that "Laboratories must be built and equipped for the science of the 21st Century. Infrastructure investments should include renovation of existing space as well as new construction, where appropriate." We have reached a period where the useful life of our research facilities fail to meet the needs of modern technology and in many instances do not meet regulatory standards.

While the research community commends the Subcommittee for providing $75 million for extramural facility construction last year, there is a clear and documented need for several billion dollars to rectify this situation. For this reason, we urge the Subcommittee to provide a funding level of $250 million for extramural construction in fiscal year 2002. The funds would be awarded on a peer-reviewed, competitive basis—requiring institutional matching funds to leverage NIH resources.

INCREASING COSTS OF COMPLYING WITH FEDERAL REGULATIONS

Another issue of significant concern to academic medical centers is the increased costs to research institutions for complying with research-related federal regulations. While extramural researchers have always been subjected to certain federal regulations, the increasing number of administrative requirements imposed on institutions has resulted in escalating costs. In recent years, institutions have been required to take additional measures to comply with more frequent institutional review boards, privacy regulations, human subject and animal protections—to name just a few. Let me reiterate that researchers are not opposed to providing these safeguards and do not question the necessity of these measures. We are, however, concerned about the costs of complying with these mandates, many of which are constantly changing. Last year the nonprofit RAND institute published a report titled "Paying for University Research Facilities and Administration." The report notes that compliance costs affect both facilities and administrative components, and fur-

ther states "increasingly sophisticated regulations have required new specialized personnel." The RAND report further provided the following impact on an unnamed institution:

". . . compliance with facilities requirements necessitates so many improvement projects for existing facilities that is infeasible to undertake them all at once. This university has committed $1.2 million per year, indefinitely, for facilities improvements to enhance compliance with hazardous waste, occupational safety, animal care, and other facilities regulations . . . This is only a partial estimate of the costs of compliance. This estimate does not include the costs of compliance associated with major building renewal of new construction projects that the university undertakes. Neither does it include the costs of administrative oversight each year to track compliance, train people, and make reports".

FASEB, in its recommendations for federal funding for biomedical and related life sciences funding for fiscal year 2002, specifically advocates "that NIH, other federal agencies and the biomedical research community address growing administrative costs associated with increased regulation, such as for human subjects protection and animal care. These costs should be fully funded by the sponsoring agency."

Researchers at academic medical centers join reiterate the concern raised by our colleagues in FASEB that federal agencies sponsoring biomedical and behavioral research should provide adequate funds for institutions to comply with the necessary regulations associated with conducting federal research. In my own institution, we have had to add more than five new staff to meet recently enacted regulations. Our interaction with federal agencies responsible for these has increased several-fold.

TECHNOLOGICAL INFRASTRUCTURE TO ADDRESS MEDICAL ERRORS

Lastly, I would like to commend the Subcommittee for providing $50 million in last year's Labor/HHS Appropriations bill through the Agency for Healthcare Research and Quality to determine ways to reduce medical errors. This funding was provided consistent with S. 2038, the medical Error Reduction Act of 2000, which was introduced by Senators Arlen Specter, Tom Harkin and Daniel Inouye. This legislation sought to establish a competitive demonstration program for health care facilities and organizations to test best practices for reducing errors. As institutions with large clinical programs, we are, of course, interested in reducing the incidents of medical errors within our institutions. We seek additional funding for this program to provide our institutions with adequate resources to utilize or upgrade technological infrastructure to reduce the incidence of medical errors.

CONCLUDING REMARKS

Mr. Chairman, polls conducted by Research!America—including polls in my State of Ohio—reflect the fact that the American public strongly supports our federal investments in biomedical and behavioral research. We believe that NIH's extramural research enterprise would significantly benefit if institutions were provided with additional resources, including $250 million to upgrade extramural laboratory space and instrumentation, and additional funding to address the increased administrative costs associated with regulatory compliance. In addition, we support additional funding through the Agency for Healthcare Research and Quality for technological infrastructure so that our institutions can reduce medical errors.

Each of these steps will increase the productivity and efficiency of the academic/government partnership in biomedical and behavioral research and research training. On behalf of academic health centers across the nation, I thank you for your attention to these needs and recommendations. Best wishes to each of you.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 93,000 member American Academy of Family Physicians is pleased to submit this statement for the record on three issues of critical importance to family physicians in the United States: (1) funding for family medicine training in Section 747 of the Public Health Service Act; (2) funding for the Agency for Healthcare Research and Quality (AHRQ); and (3) funding for rural health programs. The Academy is the professional organization representing practicing family physicians, residents and medical students.

FAMILY MEDICINE TRAINING PROGRAMS

Recommendation

The American Academy of Family Physicians supports appropriations of $158 million for Section 747 of Title VII of the Public Health Service Act for fiscal year 2002. Section 747 authorizes the Primary Care and Dentistry cluster, which includes support for family medicine, general internal medicine and general pediatrics, physician assistants and general and pediatric dentistry. This figure includes $96 million for family medicine programs. In fiscal year 2001, Section 747 received $91 million, a 17 percent increase over last year's funding level of $78.3 million.

Section 747 is the only program at the federal level that supports four family medicine training programs at both the undergraduate and graduate level: residency training; academic departments; predoctoral programs and faculty development. Section 747 is crucial to training the physicians that America needs most; it is the engine that powers the growth of this nation's supply of family physicians.

Title VII Grants to Medical Schools Induces Physicians to go into Primary Care

A recent, unpublished study by the Robert Graham Policy Center for Policy Studies showed that the receipt of Section 747 family medicine funds by a medical school made a significant difference on whether medical students ultimately (1) practiced in family medicine or primary care (defined as family physicians, general practitioners, general internists or general pediatricians), (2) practiced in a rural area, or (3) practiced in a whole county primary care health professions shortage area.

—All three types of grants (departments of family medicine, predoctoral medical education programs, and faculty development programs) made a difference in producing more family physicians, and more primary care doctors.

—Predoctoral and department development grants made a difference in producing more primary care doctors serving in rural areas, and more primary care doctors serving in primary care health professional shortage areas.

—Sustained funding during the years of medical school training had more positive impact than intermittent funding.

Due to Section 747 funding, thousands of physicians are making career choices to go into primary care and family medicine and to serve millions of patients. Without Section 747 funding, fewer students would be making these career choices.

The United States Relies on Family Physicians Unlike any other Physicians

Another recent study by the Robert Graham Center showed that the United States relies on family physicians more than any other physician specialty. Specifically, the study looked at counties designated as Primary Care Health Professions Shortage Areas, those counties that have inadequate numbers of family physicians, general pediatricians, general internists or obstetrician/gynecologists. Currently, there are 3,082 counties in the United States; 784 qualify as Primary Care HPSAs. The study found that:

—If family physicians were to be withdrawn from all 3,082 counties, an additional 1,332 counties would become Primary Care HPSAs.

—In contrast, if all internists, pediatricians and obstetrician-gynecologists were to be taken out of the nation's counties, only another 176 would become shortage areas.

Without family physicians, counties around the United States would not receive essential primary care services.

Turning Around the Shortage of Family Physicians

There is a shortage of family physicians and other primary care physicians (general internists and general pediatricians) in the United States. Numerous experts, including the Physician Payment Review Commission; the Council on Graduate Medical Education; the Robert Wood Johnson Foundation; the Pew Health Professions Commission; the American Medical Association and the Association of American Medical Colleges have called for increasing the supply of primary care physicians for quality, access and cost reasons. Most experts believe a physician workforce with a 50/50 ratio between primary care physicians and subspecialists would best meet America's health care needs; the ratio is currently approximately 30/70.

Section 747 family medicine grants have helped establish an infrastructure throughout the country that has reversed the downward trend in primary care. While at one time, the United States physician workforce was comprised of more than 50 percent primary care physicians, it declined after World War II to approximately 30 percent today. The Section 747 family medicine training programs provided funds to establish family medicine departments in medical schools; to increase the number of faculty to both teach and act as role models, and to set up new residencies throughout the country.

Market Demand for More Family Physicians

The demand for family physicians in the market is greater than our nation's current training capacity. Medicare payment policies have contributed to the increase in subspecialist physicians and have fundamentally skewed the market. These policies have promoted training in the expensive inpatient specialties—rather than in family medicine and other primary care fields. Moreover, NIH grants, totaling billions of dollars, go primarily to subspecialist research in the nation's medical education complexes.

Primary Care Doctors are Cost Effective

Numerous studies show that primary care physicians are more cost-effective due to their prudent use of hospital services, tests and procedures. A September, 1995, study conducted by KPMG Peat Marwick, The Role of Primary Care Physicians in Controlling Health Care Costs: Evidence and Effects, indicated that Medicare spending could be cut by at least $48.9 billion and as much as $271.5 billion over the next six years if primary care physicians were 50 percent of the total physician workforce.

Community Training Requires Support

In contrast to other specialties, 80 percent of family practice residencies are located in community settings rather than in major tertiary care teaching hospitals. These residencies provide more ambulatory training than any other residencies. As a result, family practice programs do not have access to the considerable resources that flow to teaching hospitals. Further, 25 percent of family practice residencies are located in public hospitals. These hospitals receive a low reimbursement for patient care services, and treat fewer Medicare patients. As a result, they do not receive substantial Medicare graduate medical education dollars.

Acute Shortage of Faculty

There is an acute shortage of faculty for family medicine residency programs and family medicine departments. The discipline has been successful at placing its graduates in practice settings serving communities of need rather than in full-time faculty positions. Without adequate funding, there is a risk that even the progress that has been made so far will be compromised for lack of faculty.

Title VII and Graduate Medical Education

Title VII health professions programs are separate and distinct from graduate medical education (GME). Title VII is a Public Health Service program and funding goes to medical schools, universities and residency programs to develop a primary care infrastructure. Graduate medical education is part of the Medicare program and funds go primarily to hospitals to support residency training.

The Academy has had a long-standing interest in graduate medical education because of our commitment to a rational physician workforce policy that both discourages an oversupply of physicians and encourages increased training of those physician specialties in short supply. Our organization has produced and updated a number of policies on physician workforce issues, as well as specific GME recommendations. However, without a major overhaul of the physician workforce in the United States that would address the primary care issues targeted by Title VII funding, it is imperative to support these programs.

Innovative Programs

Title VII funds are used to support innovative new programs that help training and teaching programs simply get better, a goal that often involves new technologies. Innovative programs can include web-based technologies to evaluate training programs, or even establish links to primary care research networks. Grant recipients are using Title VII dollars to leverage dollars not only to meet the traditional goals of diversity, outreach to the underserved and rural populations, but also to new programs that use key technologies.

Additional Outcomes Data

There have been several articles that have specifically described the value of Title VII family medicine programs.

—An October, 1994 General Accounting Office (GAO) report indicated that "students who attended medical schools with family medicine departments were 57 percent more likely to pursue all three primary care disciplines (italics added)." In addition, the 1994 GAO report indicated that "students who attended schools requiring a third-year family practice clerkship were 18 percent more likely to pursue primary care."

—A November/December, 1997, article in the Archives of Family Medicine found a strong relationship between continued Title VII funding and the presence of family medicine departments, which is associated with greater rates of primary care production. (The Impact of Title VII Departmental and Predoctoral Support on the Production of Generalist Physicians in Private Medical Schools, Robert M. Politzer, ScD, et. al.)

—Family physicians have deep roots in rural communities, where 25 percent of all Americans live. About one-quarter of family physicians locate there, as well. The February, 1998, Tenth Report of the Council on Graduate Medical Education (COGME) stated that, "Programs authorized under Title VII of the Public Health Service Act support family medicine programs with a successful record of training physicians who choose to practice in rural and underserved areas. These efforts should be continued and increased."

The goals stipulated by Congress in the Title VII reauthorization bill emphasize both the delivery of health services to underserved populations and the geographic distribution of health professionals to underserved, particularly rural, areas. These congressionally mandated goals are fully addressed by the Title VII programs, and for family medicine, all four program areas have been extremely successful.

In addition, another Congressional priority is to enhance the diversity of our medical workforce. In 1978, the first year for which we have data, the number of minority residents in training in family practice residency programs was 9.5 percent. By 1997, that rate had increased to 24 percent.

Finally, over 90 percent of physicians who complete family practice residency programs work in direct primary patient care and are able to handle a high percentage of their patient's problems.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Recommendation

The American Academy of Family Physicians recommends appropriations of $400 million for the Agency for Healthcare Research and Quality (ARHQ) in fiscal year 2002. We strongly support the Agency because of its emphasis on primary care and practice-oriented research. It is the only federal agency with this charge. In fiscal year 2001, the Agency for Healthcare Research and Quality (AHRQ), received $269.9 million, a 36 percent increase above the current funding level of $198.76 million.

What is Primary Care Research?

Primary care research includes (1) research on the conditions that affect the majority of the population, and (2) translating biomedical research into practice.

Additional research is needed on conditions that affect most Americans. Most medical care is provided in outpatient settings. However, ambulatory medicine is the least researched mode of patient care. While over 95 percent of all medical conditions have been evaluated and treated outside of hospitals over the last 30 years, physicians are educated and trained using research that has been derived mainly from hospitalized patients, or patients with rare conditions. Primary care physicians who diagnose and treat patients before they need hospital care operate without the level of research available to their subspecialist colleagues.

It is not enough to develop new treatments; they must also be implemented and result in better patient outcomes. American medicine is praised worldwide for its excellence in biomedical research. However, while we have invested heavily in new technologies, drugs and procedures, they are seen increasingly as costly advances for potentially modest gains. Greater gains may be possible if we can invest more heavily in finding ways to bring state-of-the art medicine to community medical practices.

Primary Care Research Agenda

A primary care research agenda should include at least six basic categories for study. (The agenda is further described in the AHRQ report, Putting Research into Practice: Report of the Task Force on Building Capacity in Primary Care, 1993.) Included in this agenda should be research on:

—the origin of disease and the loss of health;
—improvements in diagnostic accuracy;
—appropriate treatments;
—improvements in the physician-patient relationship;
—improvements in health care delivery;
—improvements in patient satisfaction.

Examples of Primary Care Research Needs

Primary care research is needed to provide information to physicians on the most effective treatment plans for patients with numerous, serious conditions. An example of this situation is a single patient with diabetes, hypertension, depression, low back pain and heart disease. Traditional, disease-specific treatment is not useful in this situation; treatment for one disease may exacerbate the other conditions.

Research is also needed on differentiating the common headache that affects 20 million Americans from one with serious implications. While headaches afflict millions of individuals, the primary care physician has little information on how to identify the few who suffer from life-threatening illness.

IOM Recommendation on Funding Needed for Primary Care Research

According to the 1996 Institute of Medicine (IOM) report on primary care, Primary Care: America's Health in a New Era, federal investments in primary care research today total between $15 and $20 million annually. The IOM report recommended an immediate fourfold increase in primary care research.

RURAL HEALTH PROGRAMS

Finally, the Academy supports continued funding for several rural health programs. In particular, we support the programs of the Federal Office of Rural Health Policy; Area Health Education Centers, two programs that are equally important to health care in rural areas and in our inner cities; the Community and Migrant Health Center Program and the National Health Services Corps. State rural health offices, funded through the National Health Services Corps budget, help States implement such programs so that they benefit rural residents as much as urban dwellers. Continued funding for these rural programs is vital if we wish to provide adequate health care services to America's rural citizens.

CONCLUSION

Thank you for your consideration of these important requests.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

On behalf of the 41,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to submit comments on fiscal year 2002 appropriations for Physician Assistant (PA) education programs that are authorized through Title VII of the Public Health Service Act.

A member of the Coalition for Health Funding (CHF), the American Academy of Physician Assistants supports the CHF recommendation to appropriate $44.285 billion for the Public Health Service in fiscal year 2002. The Academy is also a member of the Health Professions and Nursing Coalition (HPNEC) and supports the HPNEC recommendation to provide at least $440 million to support the Titles VII and VIII programs in fiscal year 2002. The Academy believes that the recommended increase in funding for the Title VII health professions programs is well justified. The programs are essential to the development and training of primary health care professionals and contribute to the nation's overall efforts to increase access to care by promoting health care delivery in medically underserved communities.

The Academy is very concerned with the Administration's proposal to reduce fiscal year 2002 funding for the Titles VII and VIII programs. As Members of the Subcommittee are aware, these programs are designed to help meet the health care delivery needs of the nation's Health Professional Shortage Areas (HPSAs). By definition, the nation's 2,800 HPSAs experience shortages in the primary care workforce that the market alone can't address. We wish to thank the Members of this Subcommittee for your historical role in supporting funding for the health professions programs, and we hope that we can count on your support for these important programs in fiscal year 2002.

OVERVIEW OF PHYSICIAN ASSISTANT (PA) EDUCATION

PA programs provide students with a primary care education that prepares them to practice medicine with physician supervision. Physician assistant programs are located at schools of medicine or health sciences, universities, teaching hospitals, and the Armed Services. All PA educational programs are intensive education programs that are accredited by the Accreditation Review Commission on Education for the Physician Assistant.

The typical PA program consists of 111 weeks of instruction. The first phase of the program consists of intensive classroom and laboratory study, providing stu-

dents with an in-depth understanding of the medical sciences. More than 400 hours in classroom and laboratory instruction are devoted to the basic sciences, with over 70 hours in pharmacology, more than 149 hours in behavioral sciences, and more than 535 hours of clinical medicine.

The second year of PA education consists of clinical rotations. On average, students devote more than 2,000 hours or 50–55 weeks to clinical education, divided between primary care medicine and various specialties, including family medicine, internal medicine, pediatrics, obstetrics and gynecology, surgery and surgical specialties, internal medicine subspecialties, emergency medicine, and psychiatry. During clinical rotations, PA students work directly under the supervision of physician preceptors, participating in the full range of patient care activities, including patient assessment and diagnosis, development of treatment plans, patient education, and counseling.

Physician assistant education is competency based. After graduation from an accredited PA program, the physician assistant must pass a national certifying examination jointly developed by the National Board of Medical Examiners and the independent National Commission on Certification of Physician Assistants. To maintain certification, PAs must log 100 continuing medical education credits over a 2-year cycle and reregister every two years. Also to maintain certification, PAs must take a recertification exam every six years.

PHYSICIAN ASSISTANT PRACTICE

Physician assistants are licensed health care professionals educated to practice medicine as delegated by and with the supervision of a physician. In all states, physicians may delegate to PAs those medical duties that are within the physician's scope of practice and the PA's training and experience, and are allowed by law. Forty-seven States, the District of Columbia, and Guam authorize physicians to delegate prescriptive privileges to the PAs they supervise.

PAs are located in almost all health care settings and in every medical and surgical specialty. Fourteen percent of all PAs practice in rural areas where they may be the only full-time providers of care (state laws stipulate the conditions for remote supervision by a physician). Approximately twenty percent of PAs work in urban and inner city areas. The majority of PAs are in primary care. Nearly one-quarter practice in surgical specialties. Seventy percent of PAs practice in outpatient settings. In 2000, an estimated 161 million patient visits were made to PAs and approximately 202 million medications were prescribed or recommended by PAs.

CRITICAL ROLE OF THE TITLE VII, PUBLIC HEALTH SERVICE ACT, PROGRAMS

A growing number of Americans lack access to primary care, either because they are uninsured, underinsured, or they live in a community with an inadequate supply or distribution of providers. The growth in the uninsured U.S. population increased from approximately 32 million in the early 1990s to over 42 million today. Simultaneously, the number of medically underserved communities continues to rise, from 1,949 in 1986 to 2,800 today.

The role of the Title VII programs is to alleviate these problems by supporting access to quality, affordable, and cost-effective care in areas of our country that are most in need of health care services, specifically rural and urban underserved communities. This is accomplished through the support of educational programs that train more health professionals in fields experiencing shortages, improve the geographic distribution of health professionals, and increase access to care in underserved communities.

The Title VII programs are the only federal education programs that are designed to address the supply and distribution imbalances in the health professions. Since the establishment of Medicare, the costs of physician residencies, nurses and some allied health professions training has been paid through Graduate Medical Education (GME) funding. However, GME has never been available to support PA education. More importantly, GME was not intended to generate a supply of providers who are willing to work in the nation's medically underserved communities. That is the purpose of the Title VII Public Health Service Act Programs, which support such initiatives as loans and scholarships for disadvantaged students, scholarships for students with exceptional financial need, centers of excellence to recruit and train minority and disadvantaged students, and interdisciplinary initiatives in geriatric care and rural health care.

TITLE VII SUPPORT OF PA EDUCATION PROGRAMS

Targeted federal support for PA education programs is currently authorized through section 747 of the Public Health Service Act. The program was reauthorized

in the 105th Congress through the Health Professions Education Partnerships Act of 1998, Public Law 105–392, which streamlined and consolidated the federal health professions education programs. Support for PA education is now considered within the broader context of training in primary care medicine and dentistry.

Public Law 105–392 reauthorized awards and grants to schools of medicine and osteopathic medicine, as well as colleges and universities, to plan, develop, and operate accredited programs for the education of physician assistants and faculty, with priority given to training individuals from disadvantaged communities. The funds ensure that PA students from all backgrounds have continued access to an affordable education and encourage PAs, upon graduation, to practice in underserved communities. These goals are accomplished by funding PA education programs that have a demonstrated track record of: (1) placing PA students in health professional shortage areas; (2) exposing PA students to medically underserved communities during the clinical rotation portion of their training; and (3) recruiting and retaining students who are indigenous to communities with unmet health care needs.

The program works. A review of PA graduates from 1991–1999 reveals that 16.5 percent of students graduating from PA programs supported by Title VII are from underrepresented minorities, compared to 7.7 percent of graduates from programs that did not receive Title VII support. Similarly, 13.5 percent of the graduates who attended PA programs receiving Title VII support during the 8-year period practice in underserved communities, compared to 10.1 percent of graduates of programs not receiving such support during the same period.

The PA programs' success in recruiting and retaining underrepresented minority and disadvantaged students is linked to their ability to creatively use Title VII funds to enhance existing educational programs. For example, a PA educational program in Iowa uses Title VII funds to target recruitment efforts to disadvantaged students, providing shadowing and mentoring opportunities for prospective students, increasing training in cultural competency, and identifying new family medicine preceptors in underserved areas. PA programs in Texas use Title VII funds to create new clinical rotation sites in rural and undersered areas, including new sites in border communities, and to establish non-clinical rural rotations to help students understand the challenges faced by rural communities. A PA program in Kansas has used Title VII funds to provide a significant portion of the training for 500 PA students in remote, medically underserved communities in the state. Several other PA programs have been able to use Title VII grants to leverage additional resources to assist students with the added costs of housing and travel that occur during relocation to rural areas for clinical training.

Without Title VII funding, many of these special PA training initiatives would not be possible. Institutional budgets and student tuition fees simply do not provide sufficient funding to meet the special, unmet needs of medically underserved areas or disadvantaged students. Nevertheless, the need is very real, and Title VII is critical in meeting it.

NEED FOR INCREASED TITLE VII SUPPORT FOR PA EDUCATION PROGRAMS

Increased Title VII support for educating PAs to practice in underserved communities is particularly important given the market demand for physician assistants. Without the Title VII funding to expose students to underserved sites during their training, PA students are far more likely to practice in the communities where they were raised or the communities in which they attended school. Title VII funding is a critical link in addressing the natural geographic maldistribution of health care providers by exposing students to underserved sites during their training, where they frequently choose to practice following graduation.

The supply of physician assistants is inadequate to meet the needs of society, and the demand for PAs is expected to increase. A 1994 report of a workgroup of the Council on Graduate Medical Education (COGME), "Physician Assistants in the Health Workforce," estimated that the anticipated medical market demand and the estimated workforce requirements for PAs would exceed demand. Additionally, the Bureau of Labor Statistics projects that the number of available PA jobs will increase 48 percent between 1998 and 2008.

Despite the increased demand for PAs, funding has not proportionately increased for the Title VII programs that are designed to educate and place physician assistants in underserved communities. Nor has the Title VII support for PA education kept pace with increases in the cost of educating PAs. A review of PA program budgets from 1984 through 1999 indicates an average annual increase of 7.2 percent, a total increase of 173 percent over the past sixteen years; yet, federal support has remained relatively static. The fiscal year 2001 increase in appropriations for Title VII's Cluster on Training in Primary Care Medicine and Dentistry, which includes

funding for PA education, represented the first real increase in funding in nearly a decade.

RECOMMENDATIONS ON FISCAL YEAR 2002 FUNDING

The American Academy of Physician Assistants urges members of the Appropriations Committee to consider the inter-dependency of all the public health agencies and programs when determining funding for fiscal year 2002. For instance, while it is important to fund clinical research at the National Institutes of Health (NIH) and to have an infrastructure at the Centers for Disease Control (CDC) that ensures a prompt response to an infectious disease outbreak, the good work of both of these agencies will go unrealized if the Health Resources and Services Administration (HRSA) is inadequately funded. HRSA administers the "people" programs, such as Title VII, that bring the cutting edge research discovered at NIH to the patients—through providers such as PAs who have been educated in Title VII-funded programs. Likewise, CDC is heavily dependent upon an adequate supply of health care providers to be sure that disease outbreaks are reported, tracked, and contained.

The critically important programs administered by NIH, HRSA, and CDC are integral components within the nation's public health continuum. One component is not more important than another, and no one component can succeed without adequate support from each of the other elements. The Academy is particularly concerned that any increase for the NIH not be made at the expense of the health professions education program or other public health programs, as recommended this year by the Senate Budget Committee.

The American Academy of Physician Assistants is particularly appreciative of the increase in funding for PA education programs that was appropriated for fiscal year 2001. Yet, the increase is not sufficient to meet the increasing demand for PA graduates in the growing number of medically underserved communities. Accordingly, the Academy respectfully requests that the Title VII health professions programs receive a 15 percent funding increase in fiscal year 2002, including $10 million to support PA educational programs.

Thank you for the opportunity to present the American Academy of Physician Assistants' views on fiscal year 2002 appropriations.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

The American Association for Geriatric Psychiatry (AAGP) appreciates this opportunity to present its recommendations on issues related to fiscal year 2002 appropriations for mental health research and services. AAGP is a professional membership organization dedicated to promoting the mental health and well being of older Americans and improving the care of those with late-life mental disorders. AAGP's membership consists of over 2000 geriatric psychiatrists as well as other health professionals who focus on the mental health problems faced by senior citizens.

AAGP would like to thank the Subcommittee for its continued strong support for increased funding for the National Institutes of Health (NIH) over the last several years, particularly the additional funding you have provided for the National Institute of Mental Health (NIMH) and the National Institute on Aging (NIA). Although we generally agree with others in the mental health community about the importance of sustained and adequate Federal funding for mental health research and treatment, AAGP brings a somewhat unique perspective to these issues because of the aged patient population served by our members.

There are serious concerns, shared by AAGP and researchers, clinicians, and consumers that there exists a critical disparity between appropriations for research, training, and health services and the projected mental health needs of older Americans. This disparity is evident in the convergence of several key factors:

—demographic projections inform us that, with the aging of the U.S. population, there will be an unprecedented increase in burden of mental illness among aging persons, especially among the baby boom generation;

—this growth in the proportion of older adults and the prevalence of mental illness is expected to have a major direct and indirect impact on general health service use and costs;

—despite the fact that effective treatment exists, the mental health needs of many older adults remain unmet;

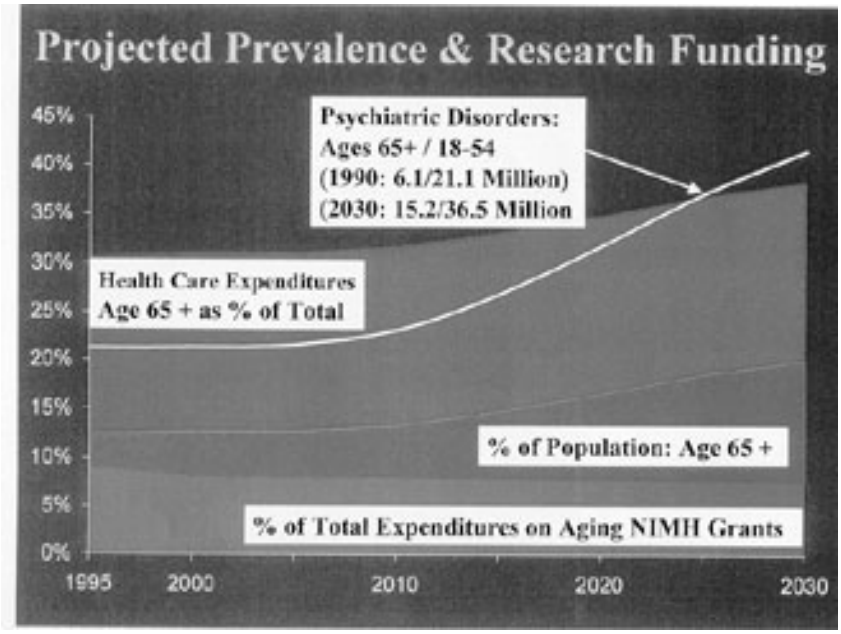
—a major gap exists between research and service delivery; and

—despite recent significant increases in appropriations for support of research in mental health, the allocation of NIMH and the Center for Mental Health Services (CMHS) funds for research that focuses on mental health and aging is dis-

proportionately low, and woefully inadequate to deal with the impending crisis of mental health in older Americans.

DEMOGRAPHIC PROJECTIONS AND THE DISPARITY IN RESEARCH FUNDING FOR MENTAL DISORDERS OF AGING

As shown in Figure 1 (attached), the increase in the number of people over 65 years of age, combined with the increasing prevalence of psychiatric problems in that segment of the U.S. population, will dramatically increase the proportion of older adults with mental health disorders relative to younger adults. Furthermore, older adults account for health care costs that are disproportionately greater than their numbers. This figure also illustrates that the projected proportion of NIMH funding for aging research (based on current funding trends) is drastically below what will be needed to address the projected increase in mental health problems among older persons over the coming decades.



With the "baby boom" generation nearing retirement, the number of older Americans experiencing mental problems is certain to increase in the future. By the year 2010, there will be approximately 40 million people in the United States over the age of 65. Over 20 percent of those people will experience mental disorders. A national crisis in geriatric mental health care is emerging and has received recent attention in the medical literature. Action must be taken now to avert serious problems in the near future. While many forms of mental and behavioral disorders can occur late in life, they are not an inevitable part of the aging process, and continued research holds the promise of improving the mental health and quality of life for older Americans.

Current and projected economic costs of mental disorders alone are staggering. For example, the direct medical costs of caring for patients with Alzheimer's disease (many of whom are treated by geriatric psychiatrists) ranges from $18,000 to $36,000 a year per patient, depending on the severity of the disease. In addition, there are other expenses associated with caring for an Alzheimer's disease patient including social support, care giving, and often nursing home care. It is estimated that total costs associated with caring for patients with Alzheimer's disease is over $100 billion per year. Psychiatric symptoms (including depression, agitation, and psychotic symptoms affect 30 to 40 percent of people with Alzheimer's and are associated with increased hospitalization, nursing home placement, family burden, and over 20 percent greater costs over and above Alzheimer's alone. Although NIA has supported extensive research on the cause and treatment of Alzheimer's, treatment

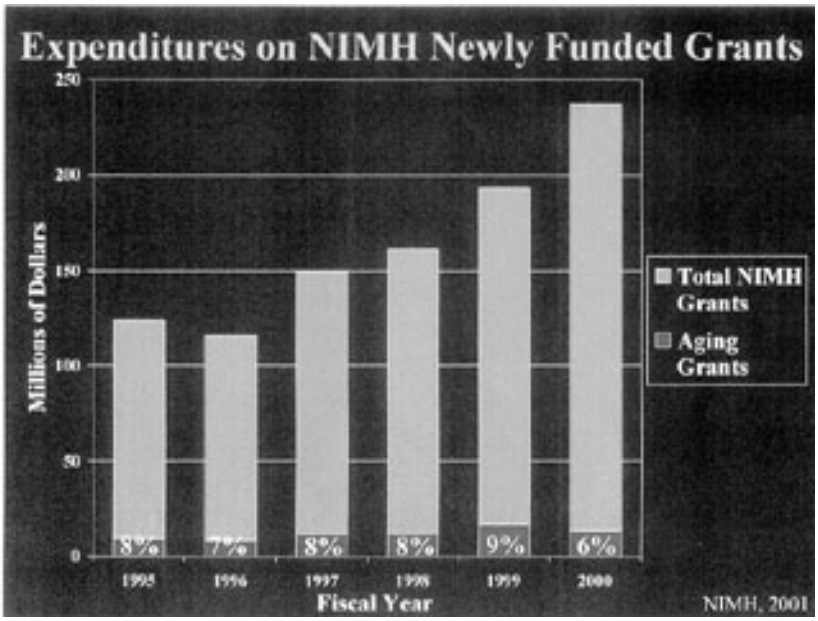
of these behavioral and psychiatric symptoms has been neglected and should be supported through NIMH.

Depression is another example of a common problem among older persons. Of the approximately 32 million Americans who have attained age 65, about five million suffer from depression, resulting in increased disability, general health care service use and costs, and increased risk of suicide. Approximately 30 percent of older persons in primary care settings have significant symptoms of depression; and depression is associated with greater health care costs, poorer health outcomes, and increased mortality. Older adults have the highest rate of suicide rate compared to any other age group.

The enormous and widely underestimated costs of late life mental illnesses justifies major new investments. The personal and societal costs of mental illness and addictive disorders are high, but advances in research and treatment will help save lives, strengthen families, and save taxpayer dollars. While the funding increases supported by this Subcommittee in recent years have been essential first steps to a better future, a serious and sustained investment in research is necessary to allow continuous progress on the many research advances we made to date. Toward that end, we support the professional judgment of the mental health research advocacy community that a 16.5 percent across-the-board increase in fiscal year 2002 funding for NIH is warranted.

Commendable as recent funding increases for NIH and NIMH have been, AAGP would like to call the Subcommittee's attention to the fact that these increases have not always translated into comparable increases in funding for extramural research on mental health of the elderly. Data supplied to AAGP by NIMH indicates that while extramural research grants by NIMH increased 59 percent during the 5-year period from fiscal year 1995 through fiscal year 2000 (from $485,140,000 in fiscal year 1995 to $771,765,000 in fiscal year 2000), NIMH grants for aging research increased at less than half that rate: only 27.2 percent during the same period (from $46,989,000 to $59,771,000).

Figure 2 (attached) shows that funding for aging mental health research is not keeping pace with that of other adult mental health research, and is actually decreasing proportionally when considered in the context of anticipated projections in growth of mental disorders in older persons. For example, the proportion of total NIMH newly funded extramural research grant funding devoted to aging research declined from an average of eight percent from fiscal years 1995 to 1999 to a low of six percent in fiscal year 2000. It is likely that one reason for the decline in funding of new grants is due to the lack of grant review committees at NIMH with specific expertise in aging. Grant review committees with specialized expertise in geriatrics are needed to assure fair review of research proposals that take into account knowledge of the unique biological factors associated with the aging brain, the universal presence of co-occurring medical disorders, and different nature of financing and health service delivery for older Americans.



THE BENEFITS OF RESEARCH ON PUBLIC HEALTH

The U.S. Surgeon General's Report on Mental Health (1999) and the Administration on Aging Report on Older Adults and Mental Health (2001) underscore the prevalence of mental disorders in older persons and provide evidence that research supports the development of effective treatments. These publications by the Federal Government recognize the increasing importance of late life mental illness on our society. In addition, these reports summarize research findings showing that treatments are being developed and tested that are effective in relieving symptoms, improving functioning, enhancing quality of life, including preliminary findings suggesting that these interventions reduce the need for expensive and intensive acute and long-term services. However, it is also well demonstrated that there is a pronounced gap between research findings on the most effective treatment interventions and implementation by health care providers. These reports stress the need for translational and health services research focusing on identifying the most cost-effective interventions, as well as creating effective methods for improving the quality of health care practice in usual care settings. A major priority (neglected to date) is the development of a research agenda focusing on health services research on mental health and aging that examines the effectiveness and costs of effective models of mental health service delivery for older persons.

Special attention also needs to be paid to investigations of inadequate, or poorly studied, serious late-life mental disorders since illnesses such as schizophrenia, anxiety disorders, alcohol dependence and personality disorders have been largely ignored by both the research community and the funding agencies despite the fact that these conditions take a major toll on patients, their care givers, and society at large. Many of AAGP's members are at the forefront of groundbreaking research on Alzheimer's disease, depression, and psychosis among the elderly, and we strongly believe that more research funds must be focused in these areas. Improving the treatment of late-life mental health problems will benefit not only the elderly, but also their children, whose lives are often profoundly affected by those of their parents.

Perhaps one of the greatest costs of late-life mental illness is the physical and emotional toll on family members, caregivers, and friends. AAGP would like to express its appreciation to Congress for a new program established and funded for the first time this year: the Family Care Givers Program of the Older Americans Act. This new program provides funding to the States so that they may assist family care givers in obtaining the best, most appropriate care for their loved ones, as well as offering care givers limited, but badly needed respite from their care-giving re-

sponsibilities. First year funding of $125,000,000 was authorized and appropriated for fiscal year 2001. AAGP expects the need for these services to grow rapidly in the future and urges the members of the Subcommittee to be responsive to this need as it develops. In addition to caregiver programs and support services, research is needed to fill in the gaps in our understanding of the psychiatric responses of caregivers to the chronic stresses of taking care of older adults with mental illnesses.

In addition to supporting research activities at the NIMH, AAGP supports increased funding for the other institutes at the NIH that have some jurisdiction over geriatric mental health, including the NIA and the National Institute of Neurological Disorders and Stroke.

It is also critical that there be adequate funding increases for the mental health initiatives under the jurisdiction of the CMHS within the Substance Abuse and Mental Health Services Administration (SAMHSA). While research is of critical importance to a better future, the patients of today must also receive appropriate treatment for their mental health problems. SAMHSA provides funding to State and local mental health departments, which in turn provide community-based mental health services to Americans of all ages, without regard to the ability to pay. The Labor-HHS conference agreement for fiscal year 2001 increased funding for SAMHSA by about 11.5 percent (from $2,651,342,000 to $2,958,001). AAGP urges the Subcommittee to increase the funds available to SAMHSA for these purposes to keep pace with this demand.

Furthermore, a top priority should be funding for the dissemination and implementation of evidence-based practices in "real world" usual care settings. Despite significant advances in research on the causes and treatment of mental disorders in older persons, there is a major gap between these research advances and clinical practice in usual care settings. The greatest challenge for the future of mental health care for older Americans is to bridge this gap between established research findings and clinical practice in the community. A specific geriatric mental health services initiative is needed to disseminate and implement evidence-based practices in routine clinical settings across the states.

CONCLUSION

Based on AAGP's assessment of the current need and future challenges of late life mental disorders, we submit the following recommendations:

—The current rate of funding for aging grants at NIMH and CMHS is inadequate. Funding for NIMH and CMHS aging research grants should be increased to be commensurate with current need (approximately three times the current funding level). In addition, the anticipated projected future increase in mental disorders among our aging population in terms of dollar amount of grants and absolute number of new grants should be built into the budget process;

—A fair grant review process will be enhanced by committees with specific expertise and dedication to mental health and aging; and

—Infrastructure within NIMH and CMHS is needed that supports the development of initiatives in aging research, monitors the quality and number of applicants for aging research grants, and management of those grants. Specifically, AAGP believes that individuals should be designated in the Office of the Director of NIMH and in the Office of the Director of CMHS to oversee the aging research agendas and initiatives for these two agencies.

AAGP strongly believes that the present research infrastructure, health care financing, and healthcare personnel with appropriate geriatric training, and the mental health delivery systems are grossly inadequate to meet the challenges posed by the expected increase in the number of elderly with mental disorders. The economic impact of the aging baby boom generation on the Medicare and Social Security systems has already become a focus of national dialogue, but that there is another challenge that has not received attention. Because of reduced mortality in older adults with chronic medical disorders, we can expect an unprecedented explosion in the number of people over age 65 with potentially disabling chronic mental illnesses. Congress must continue to support funding for research that addresses the identification, diagnosis, and treatment of mental illnesses, as well as support programs that increase the quality of life for those with late life mental illness.

The American Association for Geriatric Psychiatry looks forward to working with the members of this Subcommittee and others in Congress to establish aging research as a priority at NIMH and at CMHS.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists (AAI) is a professional association of six thousand research scientists and physicians dedicated to understanding the immune system, resulting in the prevention, treatment, and cure of disease. We appreciate this opportunity to submit written testimony for the Hearing Record regarding the fiscal year 2002 appropriations bill for the Departments of Labor, Health and Human Services, and Education. Our comments will be confined to issues involving the Department of Health and Human Services, and specifically, the National Institutes of Health (NIH).

FISCAL YEAR 2002 APPROPRIATIONS FOR THE NATIONAL INSTITUTES OF HEALTH

AAI is grateful for this subcommittee's and the Congress's strong commitment to biomedical research through the ongoing effort to double the budget of the National Institutes of Health. In addition to the sheer purchasing power of the increased appropriations—allowing for the funding of more quality research grants, better lab equipment, and training for the next generation of scientists—this national commitment has energized researchers around the world who realize that many of the scientific achievements and discoveries of recent years—including the sequencing of the human genome—are just the first essential steps toward unraveling the mysteries of the human body and the treatments that may prevent or even cure deadly diseases. We urge this subcommittee, therefore, to support rapidly unfolding biological discoveries by continuing the process of doubling the NIH budget with additional appropriations of $3.4 billion for fiscal year 2002, for a total budget of $23.7 billion.

IMMUNOLOGY AND ITS PROMISING RESEARCH

While "immunology" may not be a discipline that Americans contemplate in their daily lives, AAI's members' life's work affects every person throughout the world every day. Immunologists study both the immune system that helps protect the body from harm and the maladies—from the common cold or flu to cancer and AIDS—which can invade it. Many of us work to discover the cause of a particular immune response—which can range from successfully destroying an invading virus or bacteria to fighting one's own body tissues (resulting in an "autoimmune" response and possibly causing an autoimmune disease). Others work to find a way to prevent an undesirable immune response, i.e., an allergic response to a vaccine or drug treatment. And others of us work to find a treatment for a known immune response that leads to illness or disease (such as diabetes). So when you read the newspaper and see stories about scientists working to develop effective vaccines for HIV/AIDS and influenza; to discover new defenses against re-emerging infections such as tuberculosis and drug-resistant bacterial infections; to regulate autoimmune diseases such as diabetes and lupus; to develop treatments to prevent the rejection of transplanted organs and bone marrow; and to discover the causes of cancer and promising new treatments, you are reading about immunology and the budget of the National Institutes of Health.

To give you an example of the type of research conducted by immunologists, let us cite a few examples of some exciting work now being done.

—On March 9, 2001, the Washington Post reported on a new study by immunologists that supports the prospect of an AIDS vaccine. According to the article, "[i]n a study offering new evidence that AIDS can be controlled by vaccine, inoculated monkeys stayed healthy despite exposure to high levels of virus. . . . The new vaccine is being fast-tracked toward human testing." The study was reported in the March 9 issue of the journal Science.

—Immunologists are studying responses of the fortunate few people who are repeatedly exposed to HIV but don't get the virus, to determine how their immune system appears to fend off active infection of HIV-crucial information for the design of an effective vaccine.

—Immunologists are also working at understanding how the immune system can recognize cells infected with viruses. Here mice, genetically modified to have only a very simple immune system—but one which can recognize a lethal virus infection—are critical to understanding how an immune response is initiated, how the immune system remembers past infection, and therefore how it will respond to future infection. These studies, originally made for a virus infection in mice, have led to clinical trials in cancer immunotherapy (see Time Magazine, January 15, 2001).

—Immunologists are studying the role of cytokines (hormone-like substances made by cells that regulate immune and other biological functions) in mice to discover their role in protecting their hosts from intestinal parasites such as

worms and also to determine their deleterious role in asthma, allergy, rheumatoid arthritis, and lupus. This research might help determine the best way to reduce or prevent the overproduction of cytokines, to prevent these diseases, and to identify and reduce side effects from potential treatments. Earlier research by this same team of scientists helped to determine that cytokines play a critical role in causing asthma.

—Immunologists are studying how cytokines affect the immune response to self-antigens (molecules already in the body) in the insulin secreting cells in the pancreas. Understanding the immune response is critical because we know that autoimmune destruction of the pancreas is the cause of Type I diabetes, a disease which classically attacks young people. A recent paper has shown that by changing the way the self-antigen is exposed to the immune system, the disease can be prevented in mice genetically predisposed to develop diabetes.

—Immunologists are studying periodontal disease (gum disease), which is the major cause of tooth loss in the United States. Current work is seeking to understand how the two major bacterial species cause this disease. This involves cloning the bacterial genes necessary for allowing the bacteria to cause disease, and understanding the body's response to the bacteria. Both the bacteria and the response are necessary to cause tooth loss.

—Immunologists are studying the effect of aging and environmental factors on the development of autoimmune disorders, with a special focus on myasthenia gravis—a disease that causes muscle weakness. In this disease, the immune system responds to a critical molecule necessary for nerve signal conduction. Because this molecule is present only in very low amounts, people (and animals) are able to develop an immune response since immune tolerance was never produced. Immunologists have created a transgenic mouse in which this tolerance does occur. This allows the identification of the major mechanisms of disease to be discovered and ultimately controlled.

—Immunologists have identified a novel DNA binding protein that is produced only in the thymus and appears to play a role the production of the antigen receptor gene rearrangement. Because aberrant rearrangement of certain genes (oncogenes) has been seen in many lymphomas and leukemias, immunologists are studying the regulatory processes involved. Such studies may offer critical insight into both diseases.

—Immunologists are studying systemic lupus erythematosus (lupus), an autoimmune rheumatic disorder which can cause arthritis, rashes, kidney failure, central nervous system disease, and other serious medical problems. In studying the antibodies that are made in the disease and the substances to which they bind, a team of immunologists has theorized that the Epstein Barr virus may play a role in causing this disease and is now testing this theory. These immunologists are also working to identify the genes which they believe may predispose people to develop lupus.

As the above examples show, the work of immunologists is varied and relevant to the everyday lives of many American families. Our members devote their professional lives to painstaking work that may one day cure a disease or contribute on some smaller but significant level to better scientific understanding of complex human physiological reaction.

MAKING SCARCE DOLLARS GO FURTHER

As this subcommittee struggles with difficult decisions regarding the funding level for NIH and other important government agencies and programs for fiscal year 2002, we would like to suggest two ways that we believe that dollars allocated to biomedical research could be stretched further. First, our researchers have found an increasing regulatory burden placed on them by various rules and regulations promulgated by a variety of government agencies. While our scientists appreciate that their work is funded by taxpayer dollars and respect their duty to account for the use of those funds, they have often found these regulations burdensome and lacking any measurable benefit, taking valuable time (and money) away from the research at hand.

Reducing paperwork and streamlining and simplifying rules would certainly help obtain the greatest value from every research dollar.

Second, as our work described above makes clear, immunologists depend heavily on the use of animal models in their research. Without the use of animals, theories about immune system function and treatments that might cure or prevent disease would have to be tested first on human subjects, something our society—and our scientists—would never countenance. Despite the clear necessity for animal research, people and organizations that oppose such research are threatening sci-

entists who use animal models. The legal and extra-legal methods used by these groups to further an animal-rights/anti-medical research agenda is diverting precious resources from our work, threatening the personal safety and security of scientists, and delaying the progress of important research that is already underway. Addressing this ongoing problem is an additional cost that—were it relieved—would enable NIH dollars to go further.

NIH BUDGET PLANS FOR SUPPORTING YOUNG SCIENTISTS

AAI would like to call to the subcommittee's attention NIH's announced plans to increase the level of stipends for post-doctoral recipients. AAI has been deeply concerned about the future supply of biomedical researchers, and in particular, the plight of post-doctoral fellows who are significantly underpaid and under-compensated for their work. In early March, the National Academy of Sciences (NAS) held a Convocation on Enhancing the Postdoctoral Experience For Scientists and Engineers to discuss post-doctoral issues and a report recently issued by its Committee on Science, Engineering, and Public Policy (COSEPUP). Among the many recommendations of the COSEPUP committee was the need for better compensation and employment benefits for post-doctoral fellows. NIH responded by releasing on March 22 a statement in response to the NAS report (Notice NOT–OD–01–027), in which it indicates its plans to increase the stipends for National Research Service Award (NRSA) recipients over a period of five years. While AAI believes that the urgency of the situation requires a phase-in of higher stipends and the offering of basic employment benefits in considerably less than five years, AAI applauds NIH for responding to the COSEPUP report promptly and greatly appreciates NIH's leadership in beginning to address the need for better compensation for post-doctoral fellows. We urge this subcommittee and the Congress to support efforts to address the immediate need for better compensation and benefits for our nation's future biomedical research leaders.

NIH BUDGET ON RESEARCH MANAGEMENT AND SUPPORT (RMS) FUNDING

Current funding for management and oversight at NIH is $693 million, or 3.3 percent of the NIH budget. As funding for NIH has increased, allowing for large new numbers of increasingly complex grants, there has been an inadequate increase in support for oversight to ensure that the funds are used wisely and well. As Congress has increasingly asked questions—rightfully so—about what NIH and the nation's researchers are doing with these additional funds, NIH is hampered by insufficient staff to either answer those questions or to ensure fully the proper management and oversight of existing grants.

Between 1984 and 2000, there was little if any increase in RMS funding. In fiscal year 2000 and fiscal year 2001, there were increases of 8 percent and 10 percent respectively, raising the RMS to its current level. But if NIH is to properly manage taxpayer dollars, ensure the continuation of its excellent and highly regarded peer review process, provide professional development to staff, manage its facilities, provide public education, and undertake the multitude of activities supported by the RMS budget, AAI believes that an increase in the RMS budget to 4.5 percent of the NIH budget—a level that is the historical average—is required. We urge this subcommittee to review this important budget category again this year, recognizing that for NIH to use well—and account for—the generous funding increases you have provided, the RMS budget needs your active support.

On behalf of AAI, may I express our appreciation for having this opportunity to submit our remarks and invite any members of the subcommittee who have questions to feel free to contact me for further information.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

The American Association of Colleges of Nursing (AACN) respectfully submits this testimony to the Subcommittee with our requested funding priorities for nursing research and education programs. This federal support will be a critical piece in the nation's effort to overcome the nursing shortage. AACN represents over 550 baccalaureate and graduate nursing education programs in senior colleges and universities across the United States.

The country is in the midst of an emerging nursing shortage unlike any that the nation has experienced over the past 30 years. Since 1994, AACN has noted declining enrollments in baccalaureate nursing programs. Increasingly, employers are reporting dramatic and crisis level shortages of nurses in their health care settings. Hospitals are forced to close entire patient care units; ambulances are being di-

verted to other overcrowded facilities; and surgeries are being canceled due to the lack of appropriately educated and skilled registered nurses (RNs). Nurse vacancy rates are noted in all practice settings including long-term care, home care, and public health. In addition, an aging workforce, with the average age of RNs up to 45.2 years, compounds the shortage.

Although employers are seeking a more highly educated nursing workforce for today's complex health care environment, only 41 percent of nurses have a baccalaureate or higher degree. The growing shortage and the decline in enrollments are accompanied by a number of other factors that will affect the ability of the nursing profession to meet the demand for professional nursing care. The longitudinal American Freshman Study indicates that an extremely small percentage of freshman college students are choosing a nursing career. A recent national assessment of children's career aspirations by the J. W. Thompson Company has found that young children, particularly those who plan to seek a college education, also do not see nursing as an attractive career option.

A lack of nursing faculty has had an impact on the shortage. The majority of AACN member nursing programs report great difficulty filling budgeted faculty positions. The small one percent of doctorally prepared nurses in this country and the lengthy completion time of a doctoral degree have limited the availability of nurses prepared to function in a faculty role. Doctoral nursing students also are more often part-time students and have maintained their full-time clinical or other positions. Expansion of doctoral enrollments as full-time students would facilitate greatly the production of available faculty. AACN members also report difficulty recruiting master's prepared nursing personnel for faculty roles because of the great disparity between clinical salaries and the salaries available as a faculty member. Schools would benefit from support initiatives that provide resources to augment salaries for specialized faculty needed to support the entire program.

AACN recognizes that strategies to meet the growing nursing shortage must encompass private and public sector initiatives. Local communities and health care employers are utilizing creative programs to recruit middle school students into the nursing profession. States are introducing legislation funding scholarships and studies to assess statewide workforce need. We are asking the Subcommittee to graciously consider these requests and the effect that an unresolved RN shortage of this magnitude will have on the future of health care in America.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

We thank you and respectfully request a fiscal year 2002 funding level of $144.37 million, which reflects an increase of $40 million for the National Institute of Nursing Research. At this funding level, NINR will support significant new research on health disparities in diseases such as diabetes and cardiovascular disease, self management of chronic pain, end-of-life research to address weight loss, muscle wasting, fatigue, and caregiver issues. Most critical to enhancing research within the nursing profession is infrastructure development that increases the pool of nurse investigators, expands programs to develop partnerships between research-intensive environments and smaller colleges and universities, and promotes career development for minority researchers.

In an effort to develop the pool of nurse faculty and researchers, NINR directs 8 percent of its budget to research training. Research training dollars supported approximately 190 pre-doctoral nurse researchers and 70 post-doctoral researchers this year. These numbers must be increased in the future to address recent recommendations of the National Research Council. Additionally, AACN's 2000 Survey of Institutional Data Systems claims 3,338 nurses in doctoral programs, indicating that NINR supports less than 6 percent of those nurses in doctoral study. In view of the national nurse faculty shortage of 500 unfilled positions in teaching and research, we recommend this significant increase in appropriations for additional stipends and training for pre- and post-doctoral researchers.

NINR provides research findings for the nation's largest profession of health care providers: 2.7 million RNs. In light of the increasing shortage of qualified professional nurses, the NINR requires a significant funding increase for the following reasons:

—To provide clinically-based research findings that make a difference in the lives of all Americans, from our youth whose health needs must be addressed to our nation's aging population of which many experience chronic, debilitating diseases.

—To establish the role of nurse researcher, which attracts bright young women and men into a field that provides opportunities to both conduct meaningful re-

search and use important research findings that make a difference in people's lives.

NINR's fiscal year 2001 funding is at $104.37 million. This is $14.83 million or 16.6 percent more than the fiscal year 2000 level. Nurses from across the nation are thankful for this increase. It has provided resources for 81 new multi-year research grants beginning in fiscal year 2000 and an estimated 60 new studies, which begin in fiscal year 2001.

The increase in appropriation for fiscal year 2000 enabled NINR's success rate to reach the NIH mean success rate of 32 percent for competing research projects for the first time in its 15-year history. This is a significant improvement over fiscal year 1999 when the success rate was only 14.4 percent. Because of NINR's ability to attract important applications for research studies, the success rate for fiscal year 2001, despite a good increase in appropriation, is estimated to be only 20 percent.

The fiscal year 2000 research findings from NINR-funded studies include 17 reports related to aging, long-term care, or Alzheimer's and care giving. More studies are reported in dozens of scientific articles in: HIV/AIDS patient care, cardiovascular disease prevention and care, child and adolescent health, critical care, diabetes, mental health, and the utilization of nurses in the health care system. In addition, NINR-funded investigators across the country produced scientific advances in maternal-infant care, pain and other symptom management, and women's health. These findings together form the research base to establish evidence-based practice for registered nurses providing direct patient care 24-hours a day, seven days a week, all across the country.

In addition, NINR is the lead institute at NIH to coordinate research on end-of-life care, addressing the public's disappointment with the current status of care at the end of life. Other groups such as the Institute of Medicine, the Robert Wood Johnson Foundation, and the Hartford Foundation recognizing this need especially in light of our aging population. End-of-life care utilizes many of the skills of nurses such as pain and other symptom management, clinical management to promote quality of life, and family teaching and counseling. This focus helps families to identify and use resources to better cope with the stresses at this critical time.

The Subcommittee investment in NINR is well justified as nursing research contributes extensively to wellness and health choices that prevent disease. The NINR supports investigators who conduct a broad range of clinical research, developing and testing interventions to improve patient care, treat disease, manage chronic conditions and address the physical and emotional concerns that are important to the diverse American public. There is growing evidence of advances made possible by NINR research, but I will highlight just four recent success stories. AACN believes that based on these and numerous other examples, it is clear that nursing research is making a difference in health outcomes. For example, NINR research has made a difference by identifying interventions or other studies to:

—Enhance the independence and reduce signs of distress among severely cognitively impaired nursing home residents.

—Develop new methodologies for investigating ways to reduce breast cancer risk in women who have a genetic predisposition.

—Reduce the extremely high stress levels experienced by family members who were involved with decisions to stop life-sustaining support for a terminally ill loved.

—Reduce the risk of cardiovascular disease in children from minority backgrounds who are living in rural areas.

THE NURSE EDUCATION ACT (NEA)

We also ask for increased funding of $25 million for the Nurse Education Act and additional funding for the nursing student loan programs. AACN recommends an increase in the NEA for fiscal year 2002 to $103.1 million for the NEA and $an additional $20 million directed to student loan programs. NEA appropriations for fiscal year 2001 were $78.1 million. Central to increasing the availability of a well-trained nursing workforce is the availability of educational grants and scholarships. Current demand for nursing student loan support exceeds significantly the resources available. In addition, scholarship support is a major incentive to enter the profession and facilitates full-time study.

Title VIII of the Public Health Service Act (PHSA), the NEA, is the major federal statute providing authority for the Department of Health and Human Services to fund initiatives to expand or improve nursing education. Authorities under Title VIII provide for support of advanced practice nursing education, special initiatives for nursing clinics, support of innovations in the delivery of nursing care, expansion of enrollments in baccalaureate nursing programs, and development of initiatives to

expand minority nursing enrollments. Several of the programs assist schools with their efforts to bring more students into baccalaureate nursing programs. In addition, the program for loans to nursing students allows students to acquire low interest rate loans that can be repaid through service in high need areas.

—*Advanced Education Nursing Grants (Sec. 811)*.—The initiative provides grants to schools to train advanced practice primary care nurse practitioners and nurse midwives. It also provides grants to educate master's and doctoral students as clinical nurse specialists, public health nurses, nurse administrators, faculty, nurse anesthetists, and non-primary care nurse practitioners. It includes traineeships for master's and doctoral students with a limit of 10 percent of appropriations for doctoral traineeships.

—*Nursing Workforce Diversity Grants (Sec. 821)*.—To increase opportunities for nursing education for disadvantaged students, including underrepresented minorities, this initiative furnishes scholarships, stipends, pre-entry preparation, and retention activities. Grantees are responsible for accomplishing the objectives of their grants.

—*Basic Nurse Education and Practice Grants (Sec. 831)*.—This initiative disseminates grants to schools of nursing to strengthen basic nurse education and practice with seven priority areas. The areas are: expanding nursing practice in non-institutional settings to increase access to primary health care, training for care of underserved and high risk populations, education for managed care, developing cultural competency, expanding baccalaureate enrollments, increasing nursing career mobility, and nursing education in informatics and use of distance learning.

—*Nursing Student Loan Program (NSLP) (Sec. 836)*.—AACN recommends an appropriation of at least $10.3 million for the NSLP for fiscal year 2002. Administered by the Division of Student Assistance, this program was created to address nursing workforce shortages. Academic institutions select students enrolled in nursing programs for participation in the program based on financial need. The program operates on revolving funds received through student loan paybacks and returned funding received from nursing schools that closedown. In fiscal year 2001, only 291 out of 1,500 eligible collegiate schools of nursing participate in the program because of reluctance to compete for the limited funding. This loan program has received no new funding since 1983.

—*Nursing Education Loan Repayment Program (NELRP) (Sec. 846)*.—AACN requests at least an additional $10 million for this program in fiscal year 2002. The NELRP, administered by the Bureau of Primary Health Care, provides loans to registered nurses, nurse anesthetists, and nurse practitioners in exchange for practicing in designated Health Profession Shortage Areas. Due to funding limitations in fiscal year 2000, the Bureau provided loans of 60 percent of the amount authorized to only 50 percent of the nurses applying for program participation. The NELRP has $2 million in fiscal year 2001 funding.

SCHOLARSHIPS FOR DISADVANTAGED STUDENTS (SDS)

AACN recommends that SDS be funded at $55.63 million for fiscal year 2002, a 25 percent increase. Fiscal year 2001 funding is at $44.5 million. Scholarships for Disadvantaged Students is a PHSA Title VII Program (Sec .737) that provides funds to disadvantaged and minority health professions students. The statute directs 16 percent of the funds appropriated to nursing students. This program is the major federal scholarship source for undergraduate nursing students and eliminates or reduces the financial barriers that may prevent these students from enrolling. The majority of SDS recipients are minority students.

NATIONAL HEALTH SERVICE CORPS (NHSC)

AACN recommends maintaining the 10 percent set aside and increasing funds for the NHSC to $300 million. The National Health Service Corps Scholarship and Loan Repayment programs (PHSA Title III) seek to attract health professionals to practice in Health Professional Shortage Areas that lack such providers. Many of those areas are rural, and have difficulty attracting and retaining caregivers. Nursing has a 10 percent set aside that provides funding for certified nurse midwives, nurse practitioners, and psychiatric clinical nurses specialists.

CONCLUSION

In summary, AACN respectfully recommends the following appropriations for fiscal year 2002:

[In millions of dollars]

	Amount
National Institute of Nursing Research	144.37
Nurse Education Act	103.1
Nursing Student Loan Program	10.3
Nursing Education Loan Repayment Program	12
Scholarships for Disadvantaged Students	55.63
National Health Service Corps Scholarship/Loan	300

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

As President of the Philadelphia College of Osteopathic Medicine and Chairman of the Board of Governors of the American Association of Colleges of Osteopathic Medicine (AACOM), I am pleased to present the views of our nineteen colleges on fiscal year 2002 appropriations for health professions education assistance programs under Titles VII and VIII of the Public Health Service Act. First, I would like to express the American Association of Colleges of Osteopathic Medicine's appreciation for the past efforts of this Subcommittee to maintain a commitment to health professions education. The Subcommittee's vision has enabled health professions schools in general and colleges of osteopathic medicine in particular to address the physician workforce needs dictated by a rapidly changing health care delivery system.

However, we are not yet able to say we are in a position to completely meet these workforce needs. "Healthy People 2010," a document that serves as a blueprint for health care delivery, has articulated two overarching goals: Increase Quality and Years of Healthy Life; and Eliminate Health Disparities. To achieve these goals by 2010, we must begin now to train health professionals who have the necessary skills and commitment. More than ever, institutions need the support of Titles VII and VIII programs to develop the kind of workforce consistent with "Healthy People 2010."

At the same time we recognize the responsibility of the Subcommittee to examine all programs in light of their cost effectiveness in meeting the health care needs of all Americans. We believe colleges of osteopathic medicine measure particularly well under such scrutiny. By training and by tradition, osteopathic physicians practice "hands on," holistic medicine and value the highly close and interactive physician-patient relationship that is characteristic of our profession. This philosophy has driven a unique educational model in our medical schools. The American Association of Colleges of Osteopathic Medicine is especially proud that the model of osteopathic medical education is entirely consistent with the Federal objectives of addressing physician geographic maldistribution in the United States and increasing access to primary care services. Mr. Chairman and Members of the Subcommittee, it is important to note that this model has not been developed recently in response to Federal funding requirements. Rather, it has been at the core of our osteopathic medical education for over 100 years.

The principal vehicle for addressing the specialty and geographic maldistribution of physicians has been through primary care education and training. The American Association of Colleges of Osteopathic Medicine member schools have a long history of dedication to training primary care physicians to work in America's smaller communities, rural areas and underserved urban areas. Osteopathic physicians represent 5.5 percent of the U.S. physician workforce, but constitute 15 percent of the physicians practicing in communities of fewer than 2,500 population.

The mission statement of my own institution reflects this commitment: " Philadelphia College of Osteopathic Medicine is dedicated to providing programs of study to educate skilled professionals in health and science fields and competent and caring osteopathic physicians. The programs of study are built on the foundations of primary care, an orientation to the needs of the community and are guided by osteopathic tradition, concept and practice. The college is committed to the advancement of knowledge and encouragement of intellectual growth through research and leadership and to the advancement of the community through health promotion, education and service."

Mr. Chairman and Members of the Subcommittee, all of our osteopathic medical schools share similar missions. These missions are reflected in the profile of our medical students. Our latest data show that over 40 percent of our entering students come from small towns and rural areas (i.e. towns of fewer than 50,000).

The health professions assistance programs under Titles VII and VIII of the Public Health Service Act have been valuable in our efforts to continue to ensure this

commitment. In Public Law 105–392, the Health Professions Education Partnership Act of 1998, 44 different Federal health professions training programs were consolidated into seven clusters. These clusters provide support for training of underrepresented minority and disadvantaged students; training of primary care and dental providers; the establishment and operation of interdisciplinary community-based training activities; health professions workforce and analysis; public health workforce development; nursing education; and student financial assistance. These programs are designed to meet the health care delivery needs of the over 2,800 Health Professions Shortage Areas in the country. Many rural and disadvantaged populations depend on the health professionals trained by these programs as their only source of health care. For example, without the practicing family physicians who are currently in place, an additional 1,332 of the United States' 3,082 urban and rural counties would qualify for designation as primary care Health Professions Shortage Areas.

Titles VII and VIII programs have had a significant impact in reducing the nation's Health Professions Shortage Areas. Indeed, a recent study estimated that if funding for Title VII programs were doubled the effect would be to eliminate the nation's Health Professions Shortage Areas in as little as 6 years (Politzer, RM, Hardwick KS, Cultice JM, Bazell, C. Eliminating Primary Care Health Professions Shortage Areas: The Impact of Title VII Generalist Physician Education, The Journal of Rural Health, 1999: 15(1): 11–19).

A study by the Robert Graham Center showed that the receipt of Title VII family medicine grants by medical schools produced more family physicians and more primary care doctors serving in rural areas and health professionals shortage areas. Over 69 percent of Title VII funded internal medical graduates practice primary care after graduation. This rate is nearly twice that of programs not receiving Title VII funding.

Among the programs within these clusters that have been especially important to enhancing osteopathic medical schools' ability to train the highest quality physicians are: General Internal Medicine residencies; General Pediatric Residencies; Family Medicine Training; Preventive Medicine Residencies; Area Health Education Centers; Health Education and Training Centers; Health Careers Opportunities Programs; Centers of Excellence Programs; and Geriatric Training Authority.

Let me give you examples of how Title VII programs have benefited not only the osteopathic medical schools receiving the support, but also the citizens in the communities and states they serve.

The Philadelphia College of Osteopathic Medicine (PCOM) received a 3 year grant, now in its final year, from the Health Resources and Services Administration to develop a predoctoral curriculum which places significant emphasis on a comprehensive and integrative approach to providing health care to medically underserved persons. The three major curriculum goals are:

—To develop, implement and evaluate a teaching module which focuses on preventive medicine for the medically underserved in a managed care environment.

—To develop, implement and evaluate a teaching module which focuses on understanding the roles of family and community in health care delivery.

—To develop, implement and evaluate a teaching module which focuses on the application of evidence-based medicine in patient care and on becoming a self-directed learner.

This program will serve as a model for medical institutions that, like the Philadelphia College of Osteopathic Medicine, are interested in reaching out to medically underserved populations by training doctors to understand the socioeconomic aspects of patients' lives in order to provide them with the most appropriate, comprehensive, and integrative health care.

Nova Southeastern University College of Osteopathic Medicine has a Model Area Health Education Center (AHEC) Program Grant that serves underserved rural and inner-city communities throughout South and Central Florida. Nearly 500,000 people reside in the many Health Professions Shortage Areas in this nineteen county region served by this AHEC program. Among the many special initiatives have been an active AHEC Rural Medicine Program, an AHEC Health Careers Camp, a Library Without Walls Program, A Practice Opportunities Program, and Distance Learning Teleconferences. This AHEC Program has also worked closely with three other medical schools in Florida to develop a Statewide Florida AHEC Network to cultivate and leverage additional state support to maximize overall program scope and effectiveness. In 1997, this Florida AHEC Network was recognized by its peers across the nation for its program excellence in developing an innovative and collaborative statewide network of community/academic partnerships, and for significantly improving the supply and distribution of primary care health professionals in underserved communities of Florida.

The Chicago College of Osteopathic Medicine of Midwestern University is in their third year of funding with an Establishment of Family Medicine grant. This grant has allowed for the establishment of a new course "Topics in Family Medicine" for MSII students. The Chicago College of Osteopathic Medicine took material that was historically taught the last eight week of the MSII year and developed it into a full year course focusing on topics in medicine normally seen by primary care physicians and including issues in managed care and practice management. A simulated patient program has been incorporated that allows students to practice dealing with difficult patient situations such as death and dying. Community medicine sites have been enhanced and approximately 50 new preceptors have been added. This spring, the Chicago College of Osteopathic Medicine will sponsor a faculty development program for all new preceptors. There have also been great strides in the area of technology and on-line capabilities for things such as distance learning with the students.

Title VII also authorizes student assistance programs that are especially important to osteopathic medical students. Our students have the highest average debt upon graduation among health professions. Congress should be concerned with minimizing the debt load of graduates of health professions schools, if they, in turn, can be expected to hold down medical costs, practice in primary care, and locate in underserved areas.

Title VII grants have been a crucial factor in the establishment and growth of primary care departments and have enabled them to develop innovative curricula. These grants represent the only Federal initiative that has specifically encouraged students to consider careers in primary care, a clearly identified national priority. With the exception of fiscal year 2001, appropriations for Titles VII and VIII programs have remained relatively flat for a number of years. Thus, the ability to meet the workforce needs mentioned earlier becomes more difficult.

Accordingly, Mr. Chairman and Members of the Subcommittee, AACOM recommends that the fiscal year 2002 funding level for Titles VII and VIII be $440 million. These figures do not include funding for the children's hospitals graduate medical education program, which is an amount separate from Titles VII and VIII funding. This funding level would provide a much needed boost toward ensuring the training of a workforce who will be delivering the types of services and providing the full access to these services identified in Healthy People 2010.

Finally, Mr. Chairman and Members of the Subcommittee, the American Association of Colleges of Osteopathic Medicine supports the Ad Hoc Group for Medical Research Funding request of $23.7 billion for the National Institutes of Health for fiscal year 2002. This $3.4 billion (16.5 percent) increase represents the fourth step toward the bipartisan goal of doubling NIH funding over the 5-year period from fiscal year 1999 to fiscal year 2003. Although osteopathic medical schools in the past have not engaged in research activities nearly to the extent of our allopathic brethren, we have been steadily increasing the research capabilities of our institutions.

Again, I appreciate the opportunity to present our views to the Subcommittee. If I can provide you with any additional information, you may contact either me at the Philadelphia College of Osteopathic Medicine or Michael Dyer, Vice President for Government Relations at AACOM (301) 968–4152.

Prepared Statement of the American Association of Colleges of Pharmacy

RECOMMENDATIONS FOR FISCAL YEAR 2002

[In thousands of dollars]

Public Health Service Act Title VII Programs	Fiscal year	
	2001	2002 recommendation
Health Careers Opportunity Program	32,800	35,000
Scholarships for Disadvantaged Students	44,500	48,000
Faculty Loan Repayment	1,300	2,300
Health Professions Workforce Information and Analysis	826	1,200

Your past support of the Title VII of the Public Health Service Act programs means improved access to care for all Americans. The health professions students and schools supported by these programs are the mostly likely to offer their services to underserved communities and practice in sites like community health centers.

With Title VII programs facing substantial reductions in the President's fiscal year 2002 budget, your support for these programs is important again this year.

The leadership and faculty of our nation's colleges and schools of pharmacy are committed to educating professional pharmacists capable of and comfortable with providing comprehensive pharmacy services to the diverse populations they serve. A recent survey of the pharmacy services provided at community health centers, conducted by the University of Texas at Austin under a grant from the Health Resources and Services Administration's (HRSA) Bureau of Primary Care, found that the culturally diverse patient populations served by the CHCs benefit from improved health promotion counseling by pharmacists with similar cultural background.

Individuals considering pharmacy as a career choice and their teachers (pharmaceutical education faculty, and colleges and schools) all benefit from the Title VII programs such as:

—Health Career Opportunities Program (HCOP);
—scholarships for disadvantaged students (SLD);
—faculty loan repayment and faculty training fellowships (FLRP); and
—Centers of Excellence programs (COE).

Your support of critical Title VII programs is needed since the diversity of the current pharmacist workforce, or any other health professions workforce, does not mirror the diversity of our society in general.

The fact that we need to educate more pharmacists, in general, is supported by a congressionally mandated study that the Department of Health and Human Services (HHS) released last December. The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists indicates that the demand for pharmacists will remain strong for the foreseeable future. Improving the opportunity for students from culturally diverse backgrounds is more important than ever. In light of the study, targeting funds to pharmacy students and colleges and schools of pharmacy could prove beneficial. The health workforce data HRSA currently collects through the National Center for Health Workforce Information and Analysis (NCHWIA) within the Bureau of Health Professions is insufficient to assist policy makers to determine how many active pharmacists there are. With increased appropriations NCHWIA could establish a health professions database, including pharmacists, that is verifiable, reliable, indicative of health professions numbers at the state, county and local level, and not merely a repository of statistics from professional associations and societies. This database could also be used to improve the decision making process for placement of National Health Service Corps personnel.

Your consideration of our recommendations is greatly appreciated. Please do not hesitate to contact our office should you require additional information.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF PHARMACEUTICAL SCIENTISTS

SUMMARY OF FISCAL YEAR 2002 RECOMMENDATIONS

AAPS supports the continual efforts to double the National Institutes of Health (NIH) budget by providing a 16.5 percent increase for fiscal year 2002, to $23.7 billion.

Basic scientific research conducted at the National Institutes of Health or sponsored by NIH has resulted in a better understanding of new therapies for many diseases. The American Association of Pharmaceutical Scientists (AAPS) represents scientists in academia, industry and government. While NIH funding does not support all of our members, the impact of scientific discoveries derived from NIH sponsored research has broad implications for all who are developing new treatments. Pharmaceutical scientists trained in academic institutions under the auspices of NIH often become noted academic, industrial or governmental researchers. Many of these scientists create knowledge in the pharmaceutical sciences that forms the basis for new approaches in the treatment of the diseases that bedevil mankind. AAPS members develop new methods of drug discovery, drug delivery and related technologies, pharmaceutical analysis, new information regarding drug metabolism and disposition, clinical evaluation, pharmacoepidemiology, and pharmacoeconomics. All areas are important in ensuring the safety, efficacy, and availability of new therapeutic modalities.

Currently, pharmaceutical scientists advise the NIH in direct collaborations and by participating in many study section review boards. Many pharmaceutical scientists have been involved with "start-up" biotechnology companies. A few of these entities are enormously successful and have changed the way that some diseases are

treated. Others are involved in innovative research that may lead to the next big breakthrough in the treatment of a number of diseases. With the proposed reorganization of the NIH review process, this may be an appropriate time for our 11,000 members to expand their involvement in the evaluation of research related to the pharmaceutical sciences and we stand ready to do so. Because of the importance of the discoveries by NIH, AAPS urges Congressional support for funding at or above the proposed levels. Continued NIH funding is necessary to continue the leadership and reputation of the United States in the fields of biomedical research and pharmaceutical sciences. There has been an explosion of biomedical and pharmaceutical knowledge in the last few years and it is crucial that this knowledge now be used to develop new therapies for those in need.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF CARDIOLOGY

INTRODUCTION

The American College of Cardiology (ACC) is a 25,000-member, professional medical society and educational institution whose mission is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and guidelines and the formulation of health policy. The ACC submits for the record this statement in support of fiscal year 2002 funding for the National Heart, Lung, and Blood Institute (NHLBI).

Thanks to the research support of the NHLBI, patients have benefited from the emergence of advanced technologies, devices, and pharmaceuticals. Medical research has played a major role in a notable decline in the number of deaths from cardiovascular disease over the past three decades. Yet, cardiovascular disease continues to claim more lives each year than the next seven leading causes of death combined. This year, it is estimated that nearly one million Americans will die as a result of heart and blood vessel/vascular disease. More than 60 million Americans are living with one or more types of cardiovascular disease. Fortunately, many of these individuals are living better and more productive lives as a result of new drug and device therapies, surgical innovations, prevention initiatives, and educational programs—all made possible in part through NHLBI-sponsored research.

Because cardiovascular disease continues to affect the lives and productivity of millions of Americans, and because researchers are on the brink of many new and exciting medical discoveries, it is critical that the subcommittee maintain its longstanding support for the NHLBI, specifically heart-related research.

THE COST OF HEART DISEASE

In 1999, the total economic impact—direct and indirect costs—of heart disease was $183 billion, of which $81 billion is attributed to lost productivity—people unable to work or care for their families. According to the National Institutes of Health (NIH), 450,000 Americans age 65 and older require home or hospice care due to cardiovascular disease, and congestive heart failure is the largest cause of hospitalization for aging Americans. Investments in cardiovascular research today will result in future savings to the health care system and to society. According to a report issued in May 2000 by the congressional Joint Economic Committee, it is estimated that the average American has gained a value of $85,000 in increased longevity from medical advances in heart disease since 1950, at a cost of $35,000 per person in research spending—a gross investment return of about 240 percent of costs.

Last year, Congress demonstrated its commitment to medical research by providing a 15 percent increase in funding to the NIH. The ACC recognizes this commitment and hopes Congress will continue to work toward doubling the NIH's budget by 2003.

GROUND-BREAKING HEART RESEARCH ADVANCEMENTS

In 1991, the NIH launched the Human Genome Project. Innovative research in human genetics holds great promise for the prevention, diagnosis, and treatment of cardiovascular disease. Today, the NHLBI is a leader among other NIH institutes in gene research.

In September 2000, the NHLBI launched the Programs for Genomic Applications. This $37 million initiative is designed to advance genomic research in the areas of heart, lung, blood, and sleep disorders by deciphering individual genes and functions and then applying those findings to what is already known about the mapping and sequence of the human genome. The initiative will accelerate progress in heart, lung, blood, and sleep research by stimulating investigator-initiated research and by

making information immediately available to the research community, thereby allowing other scientists to develop separate relevant studies cost effectively. Ensuring investigators have the tools necessary to conduct genomic analysis expands the potential for medical discovery.

NHLBI-funded researchers recently grew heart valves in laboratories using new tissue-engineering techniques. More than 60,000 patients in the United States receive replacement heart valves each year. Although the valves' performance has been excellent, problems such as abnormal clotting or poor durability limit their effectiveness. Further research efforts are needed to improve these new tissue-engineering techniques so that heart valves of higher durability and quality can be produced. Scientists are hopeful that someday laboratory-grown implantable valves will last an entire lifetime, actually growing and maturing with the patient.

With the help of NHLBI research funding, scientists are seeking ways for patients to grow blood vessels in the heart to replace the ones they have lost as a result of a heart attack. During a heart attack, blockage in coronary arteries leaves a portion of the victim's heart tissue without oxygen. When this happens, part of the heart tissue begins to die. Research has indicated that it is possible to grow new blood vessels in the heart; however, this research is still in its infancy, necessitating continued funding. This research may yield hope that heart attack victims will someday be able to regenerate blood vessels and keep damaged tissue alive.

SUPPORT FOR CLINICAL TRIALS

All scientific developments in biomedicine must pass through clinical research before they can benefit patients. A critical component of clinical research is trials that allow physicians to apply the results of research in practice. Clinical trials can also be an important tool in identifying early on therapeutic strategies and pharmacological agents that have the potential to reduce health care costs.

To alter clinical practice, large-scale randomized trials are usually necessary to demonstrate unequivocally the effectiveness of a new drug or device or a new application for an existing drug or device. Some of these trials require thousands of patients to be studied over several years. For example, funding is needed to conduct large-scale clinical trials to study heart failure in the elderly. Large trials are also needed to examine ways in which heart disease can be treated once it is detected. While large-scale clinical trials require a significant financial commitment, they hold the potential to improve patient well-being and to reduce health care spending over time. The ACC believes that continued funding increases are needed to significantly increase clinical research overall, and large-scale clinical trials specifically, while also increasing funding levels for basic research. Funding for basic science and clinical trials must go hand-in-hand, and there cannot be increased funding for one at the expense of decreased funding for the other.

The ACC asks the subcommittee to ensure that increased funding be made available for the training of clinical investigators. Clinical investigators, or physician-scientists, are quickly becoming a "dying breed." Critical to the advancement of medical science, clinical investigators bridge scientific discoveries and their application at the patient bedside. Today, young physicians are being forced to choose between performing research or practicing medicine. The demands of managed care and other health insurance programs have further precluded physicians from performing basic research and supervising patient care at the same time. Incentives are needed to attract physicians to the important field of clinical investigation. Increased resources must also be dedicated to train a new generation of clinical investigators who are well trained in biostatistics, research protocol designs, bioethics, and outcomes analysis. So many of the advances in patient care in the last 30 years have come from the research efforts of these investigators who bridge the basic and clinical domains. They are a vital link in our battle against premature death and disability from heart and vascular disease, and their training must be supported.

HEART RESEARCH INITIATIVES AND OPPORTUNITIES

Congestive Heart Failure Clinical Network

It is estimated that 4.8 million Americans suffer from congestive heart failure and that approximately 400,000 new cases are diagnosed every year. Health care costs associated with heart failure are estimated at $40 billion annually. More effective treatments are needed to address this growing public health problem. The NHLBI plans to establish a collaborative network of clinical research centers and a data coordinating center to conduct clinical studies in heart failure. Clinical networks have been shown to be an effective method for translating promising basic research findings into clinical research and practice. This initiative will allow for investigations

focused on women and minorities and on programs to train physicians in clinical research.

Bone Formation and Calcification in Cardiovascular Disease

Evidence suggests that a relationship exists between bones and blood vessels. Research, however, is needed to determine whether there is a link between bone formation, repair, and breakdown (e.g., osteoporosis) and the development of cardiovascular disease. Scientists already know that patients who take statin drugs to lower cholesterol levels are at a decreased risk of bone fractures. Conversely, studies have found that people with low bone mass may have an increased risk of developing or dying from cardiovascular disease. Further research in this area may lead to strategies to prevent both cardiovascular disease and osteoporosis.

Lifestyle Intervention With Stress Management After Heart Attack

Mental stress has been shown to trigger myocardial ischemia. Patients with coronary artery disease who experienced myocardial ischemia following mental stress tests had higher than expected rates of subsequent cardiac events. Results from rehabilitation and prevention programs that included stress management interventions have shown that behavioral interventions may improve quality of life and reduce morbidity and mortality of patients with coronary artery disease. However, because those trials used small sample sizes, it has been difficult to accurately assess the effect of stress management interventions. The NHLBI has suggested the need for a pilot study of behavioral interventions to determine the feasibility of recruiting patients, delivering interventions, ascertaining the effects on adherence, and assessing the progression of coronary artery disease and other clinical outcomes.

Public Access to Defibrillation

About one fourth of the 300,000 annual deaths from sudden cardiac arrest occur outside the home—in public areas. In August 2000, the NHLBI launched a nationwide pilot program to test public access to automated external defibrillators (AEDs). AEDs are devices that automatically analyze heart rhythms and deliver an electric current to the heart of a cardiac arrest victim. Survival rates after cardiac arrest are low, averaging 4 percent. However, survival rates can be increased by shortening the time to defibrillation. The study will place AEDs in 24 communities across the Unites States and Canada. Researchers already know that AEDs save lives. The purpose of this study is to look at the life-saving potential and cost effectiveness of AEDs when used by trained lay-individuals. When the study, which will be conducted over 30 months, is complete, 1,000 sites will be equipped with AEDs. As of March, 850 of those sites had been approved for the placement of AEDs.

Recognizing the critical importance of early defibrillation, the ACC asks the subcommittee to support $12.5 million in funding for implementation of the Rural Access to Emergency Devices Act, Public Law 106–505, the Public Health Improvement Act. The funding will be used to help rural communities buy AEDs and to train rural emergency responders in the use of AEDs.

PREVENTION, EDUCATION, AND PRACTICE

Efforts must be strengthened to prevent the incidence of heart attacks, coronary heart disease, heart failure, and high blood pressure through increased patient and physician education if we are to win the war against heart disease. We know that heart disease is linked definitively to hypertension, high cholesterol, obesity, diabetes, smoking, and physical inactivity. The NHLBI's public education programs—the National High Blood Pressure Education Program, the National Cholesterol Education Program, the Obesity Education Initiative, and the National Heart Attack Alert Program—make information readily available to patients, families, and health professionals.

The earlier that heart disease is detected, the better it can be treated to prevent its development. In September 2000, the NHLBI launched a 10-year, multi-center study to find new ways of detecting heart disease early, before it produces symptoms. The $68 million Multi-Ethnic Study of Atherosclerosis involves six centers, which will recruit 6,500 participants. The hope is that the study will yield more specific predictors of heart disease and will determine which factors best predict heart disease in men and woman and in different ethnic groups.

One of the fastest growing public health problems in this country is adult and childhood obesity. People who are overweight or obese are at greater risk for several major diseases, including heart disease and stroke. More than 108 million adults in the United States are overweight or obese. Even more startling, an estimated 5 million children in this country between age six and 17 are considered overweight.

Just recently, the NHLBI unveiled a new tool for health care providers and the public to combat obesity. A "practical guide" is now available to physicians and other health care professionals. The guide includes a 10-step plan and a quick reference tool to help physicians assess, classify, and treat patients who are overweight and obese. The guide also includes information for patients on diet, physical activity, and tools for behavioral change.

The NHLBI has also funded research targeted at the prevention and treatment of obesity. NHLBI-funded researchers have found that in overweight individuals, high dietary sodium intake is strongly associated with an increased death rate, particularly from cardiovascular disease. The average adult in the United States consumes well above the recommended daily sodium level of 2,400 milligrams. Knowing this, physicians and other health care providers can suggest reducing sodium intake as a low-cost intervention for those who have difficulty losing weight as a way to help lower their risk of death from cardiovascular disease.

Another NHLBI study has shed new light on genetic predisposition to obesity. Additional research is needed to gain a better understanding of the leptin receptor gene, the gene linked to fat accumulation. Researchers have found that a variation in the leptin receptor gene is associated with higher fat levels in middle-age white males, but not in black males or in women of either race. This suggests that leptin therapy may be effective only in middle-age white males, and that other genetic factors influence excess fat accumulation in women and blacks. Understanding the leptin receptor gene will be an important step in developing effective preventive and therapeutic strategies to fight obesity.

There is much to be done to ensure that preventive and therapeutic measures proven effective in the fight against cardiovascular disease are adopted by physicians. Cardiovascular drugs, such as anti-hypertensives and beta-blockers, have played a key role in the decline of heart disease-related deaths. Beta-blockers, drugs that are used to slow the rate and force of the heart's contractions and to stabilize the heart's rhythm, are still underused in treating heart attack patients in the emergency room. Funding is needed to gather evidence-based information that can be used to improve health care practices by physicians and other health care providers. The ACC supports increased funding to the Agency for Healthcare Research and Quality for the purposes of improving health care quality.

CONCLUSION

Beyond better public awareness and the incorporation of research advances into practice, reducing the number of cardiovascular-related deaths is greatly dependent upon research sponsored by the NHLBI. We must intensify our cardiovascular disease research efforts now in an effort to prevent an increase in the prevalence of cardiovascular disease that will otherwise accompany the aging of the so-called "baby-boomer" generation. The ACC hopes the subcommittee shares its optimism about the unique opportunities scientists and clinical investigators now have to achieve their long-standing goal of conquering this nation's number-one killer. In summary, the ACC encourages the subcommittee to provide a funding level of at least $2.679 billion for the NHLBI in fiscal year 2002. Furthermore, the ACC asks that at least $1.650 billion of that amount be devoted to heart- and stroke-related research.

The ACC hopes the subcommittee will consider this request. It is a wise investment in the future health of our nation.

PREPARED STATEMENT OF THE AMERICAN DENTAL HYGIENISTS' ASSOCIATION

On behalf of the American Dental Hygienists' Association (ADHA), thank you for the opportunity to present testimony regarding fiscal year 2002 appropriations for the Department of Health and Human Services. I am Stan Peck, ADHA's Executive Director.

ADHA is the largest national organization representing the more than 100,000 dental hygienists across the country. Dental hygienists are preventive oral health professionals who are licensed in each of the fifty States. As prevention specialists, dental hygienists understand that recognizing the connection between oral health and total health can prevent disease, treat problems while they are still manageable, and conserve critical health care dollars. Dental hygienists are committed to improving the nation's oral health, a fundamental part of total health. Please visit the ADHA web site at <<www.adha.org>>.

U.S. SURGEON GENERAL'S MAY 2000 REPORT ON ORAL HEALTH IN AMERICA

Last May, U.S. Surgeon General David Satcher issued "Oral Health in America: A Report of the Surgeon General." This landmark report confirms what dental hygienists have long known: that oral health is an integral part of total health and that good oral health can be achieved. Key findings enumerated in the Report include:

—Oral diseases and disorders in and of themselves affect health and well-being throughout life.
—Safe and effective measures exist to prevent the most common dental diseases—dental caries (tooth decay) and periodontal diseases.
—Lifestyle behaviors that affect general health such as tobacco use, excessive alcohol use, and poor dietary choices affect oral and craniofacial health as well.
—There are profound and consequential oral health disparities within the U.S. population.
—More information is needed to improve America's oral health and eliminate health disparities.
—The mouth reflects general health and well-being.
—Oral diseases and conditions are associated with other health problems.
—Scientific research is key to further reduction in the burden of diseases and disorders that affect the face, mouth and teeth.

The Surgeon General's Report on Oral Health challenges all of us—in both the public and private sectors—to address the compelling evidence that not all Americans have achieved the same level of oral health and well-being. The Report describes a "silent epidemic" of oral diseases, which affect our most vulnerable citizens—poor children, the elderly and many members of racial and ethnic minority groups. The Surgeon General insists that additional steps be taken to address these disparities in oral health status.

ADHA suggests that one such step is to improve access to the preventive oral health care services provided by dental hygienists. This is important because unlike most medical conditions, the three most common oral diseases—dental caries (tooth decay), gingivitis (gum disease) and periodontitis (advanced gum and bone disease)—are proven to be preventable with the provision of regular oral health care. Despite this prevention capability, tooth decay—which is an infectious transmissible disease—still affects more than half of all children by second grade. Clearly, more must be done to increase children's access to oral health care services.

While the profession of dental hygiene was founded in 1923 as a school-based profession, today the provision of dental hygiene services is largely tied to the private dental office. Increased utilization of dental hygienists in schools, nursing homes, and other sites—with appropriate referral mechanisms in place to dentists—will improve access to needed preventive oral health services. This increased access to preventive oral health services will likely result in decreased oral health care costs per capita and, more importantly, improvements in oral and total health.

ADHA is committed to working with the Congress to improve access to oral health care services, particularly for children eligible for Medicaid and the State Children's Health Insurance Program (SCHIP).

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

As the Surgeon General's Report on Oral Health so clearly demonstrates, the nation's oral health can and must be further improved. The National Institute of Dental and Craniofacial Research (NIDCR) is the nation's focal point for oral health research and NIDCR's work has yielded significant advancements in oral health.

Moreover, NIDCR's work in dental research has not only resulted in better oral health for the nation, it has also helped curb increases in oral health care costs. Americans save nearly $4 billion annually in dental bills because of advances in dental research and an increased emphasis on preventive oral health care. To enable NIDCR to continue and to build upon its important research mission, ADHA joins with other groups in the oral health community to recommend $370 million for NIDCR.

ORAL HEALTH INITIATIVE

ADHA is pleased to see the increasing recognition among federal Policymakers of the importance of oral health to overall health and well-being. A primary illustration of this appreciation for the link between oral health and general health is the Oral Health Initiative at the Health Resources and Services Administration (HRSA). The goals of HRSA's Oral Health Initiative are to work toward the elimination of disparities in oral health status and to improve access to oral health services. Re-

gretfully, much work needs to be done in both of these areas to help assure that children enrolled in Medicaid and the State Children's Health Insurance Program (SCHIP) are provided access to necessary oral health services.

As the General Accounting Office (GAO) confirmed last year in two separate reports to Congress, "dental disease is a chronic problem among many low-income and vulnerable populations" and "poor children have five times more untreated dental caries (cavities) than children in higher-income families." The GAO further found that the major factor contributing to the low use of dental services among low-income persons who have coverage for dental services is "finding dentists to treat them." ADHA pledges to work with HRSA to achieve the goals of the Oral Health Initiative. Increased utilization of dental hygiene services—appropriately linked to the services of dentists—is critical to addressing the nation's crisis in access to oral health care for vulnerable populations.

Because access to preventive oral health services is vital to children's health and wellbeing, ADHA urges a minimum of $20 million for HRSA's Oral Health Initiative so that access to oral health services for Medicaid and SCHIP children will improve and disparities in oral health status will be lessened. A portion of these monies would be used to fund important children's health projects authorized in the "Children's Health Act of 2000."

ADHA further urges that the Oral Health Initiative receive a separate line item in the budget. This consolidation into a line item will vastly improve coordination of HRSA's various oral health activities.

CENTERS FOR DISEASE-CONTROL DIVISION OF ORAL HEALTH

ADHA would also like to lend its support to the Division of Oral Health within the Centers for Disease Control (CDC). Specifically, ADHA joins with other dental groups in urging a budget of $17 million for the Division of Oral Health at CDC. This funding level will enable the Division of Oral Health to continue its vital work to control and prevent oral disease, including its important work in the area of community water fluoridation and school-based dental sealant programs as authorized in the "Children's Health Act of 2000."

RYAN WHITE HIVAIDS DENTAL REIMBURSEMENT PROGRAM

Included in the Ryan White CARE Act is a dental reimbursement program that assists in meeting the oral health needs of people living with HIV/AIDS, most of whose care is not covered under existing federal and state assistance programs. The dental reimbursement program provides participating institutions with partial reimbursement for the cost of providing oral health care services to low income people living with HIV and AIDS. In 1999, oral health care was provided to more than 65,000 patients under the program.

The "Ryan White CARE Act Amendments of 2000" would—for the first time—render dental hygiene programs eligible for the dental reimbursement program. There are presently 255 accredited dental hygiene education programs in the United States. In fact, all States, with the exception of Montana, have at least one dental hygiene education program. Currently, there are 55 dental schools.

Federal support for the provision of oral health services through dental hygiene programs to HIV positive individuals will not only provide greatly needed oral health services, but will also afford dental hygiene students important education opportunities. ADHA joins with the American Dental Education Association in recommending $15 million for this important program.

CHIEF DENTAL OFFICER

ADHA further urges that the position of Chief Dental Officer at the Health Care Financing Administration (HCFA) be made permanent. While this vital position has historically received funding, it is not now permanent. Given the increasing recognition of the importance of oral health and the key role of HCFA's Chief Dental Officer, it is imperative that this position be institutionalized.

ALLIED HEALTH

ADHA joins the Allied Health Roundtable in supporting the important work of Title VII of the Public Health Service Act and recommends 521 million for Allied Health Project Grants. Allied health disciplines constitute fully 60 percent of the health care work force. With the acknowledged need for cost-effective health care providers, it is time to augment funding for and recognition of these important allied health programs. ADHA further encourages funding for federal programs in

HRSA's Minority and Disadvantaged Health Professionals Training Cluster. These important programs recruit and retain minority and disadvantaged students.

MATERNAL AND CHILD HEALTH PROGRAM

Title V Maternal and Child Health (MCH)/Children with Special Health Care Needs programs have had a history of supporting the public oral health infrastructure, for providing the population-based prevention programs, such as water fluoridation or dental screenings, and for providing direct and enabling oral health services when necessary. Despite this important work, the Maternal and Child Health program has not enjoyed the level of spending growth over the last ten years that many other public health programs have realized. ADHA strongly supports the MCH programs and urges $850 million for fiscal year 2002, which is full funding at the level authorized last year.

CLOSE

In closing, the American Dental Hygienists' Association appreciates the important contributions this Subcommittee has made in improving the quality and availability of oral health services throughout the country. ADHA is committed to working with this Subcommittee—and all Members of Congress—to improve the nation's oral health which, as Oral Health in America: A Report of the Surgeon General so rightly recognizes, is a vital part of overall health and well-being.

Thank you for this opportunity to submit the views of the American Dental Hygienists' Association.

PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION (ALA) AND THE AMERICAN THORACIC SOCIETY (ATS)

The American Lung Association (ALA) and the American Thoracic Society (ATS) are very pleased that President Bush has committed his Administration to doubling the NIH budget by fiscal year 2002. To keep the NIH budget on course towards doubling the budget in 2003 will require a 16.5 percent increase in fiscal year 2002. We look forward to working with this committee to bring the campaign pledges of President Bush to fruition. Mr. Chairman, while our comments today will focus on selected parts of the Public Health Service, the American Lung Association and the American Thoracic Society are firmly committed to appropriate funding for all parts of our nation's public health infrastructure.

There are 3 specific issues that ALA/ATS would like to bring to your attention.

SHORTAGE OF PHYSICIAN-INVESTIGATORS

Mr. Chairman while investments in biomedical research at NIH will make tremendous strides in the health of our nation, the ALA/ATS feel there is a fundamental flaw in the research enterprise. That flaw is the shortage of physician-investigators. Physician-investigators are MDs or MD/PhDs who devote a significant share of their time to conducting research.

Physician-investigators are essential to the research enterprise because they link the worlds of patient care and bench research. Physician-investigators are best equipped to translate the needs of the patients they serve into research questions. The active presence of physician-investigators is essential to keep biomedical research focused on the needs of the patient.

In recent years, the number of new physician-investigators applying for NIH grants has diminished. NIH must take action to ensure new physician-investigators are entering the field of research.

Last year, Congress enacted the Clinical Research Enhancement Act. This legislation will take a number of steps to address the shortage of physician-investigators involved in clinical research. While the legislation is an excellent first step, we feel the shortage of physician-investigators is not limited to just clinical research but extends to shortages of physician-investigators in all disciplines of biomedical research.

The ALA/ATS recommends Congress continue to support activities called for in the Clinical Research Enhancement Act, but consider extending the support mechanisms to all physician-investigators. We also recommend NIH raise the low training stipends paid to students. The $35,000 paid to fifth year post-doctoral students is extremely low considering the $95,000 average debt physicians have after medical school.

National Heart, Lung, and Blood Institute AIDS Budget

Last year, the Administration's budget proposed to flat fund the AIDS Budget at the National Heart, Lung, and Blood Institute. Mr. Chairman, as you may know, opportunistic pulmonary illnesses (like tuberculosis, pneumonia and influenza) are the leading cause of death for people with AIDS. Adequate funding is needed for the NHLBI to continue to study the interaction of these illnesses in the lungs of people with HIV. We are pleased to report that, with the good help of this subcommittee, the National Heart Lung and Blood Institute has increased its investment in investigating the interactions between tuberculosis and HIV.

The ALA/ATS want to thank the committee for its help in bringing attention to the valuable work done at NHLBI on tuberculosis and AIDS. We hope we can count on the Subcommittee to continue that interest in this small, but important program.

Fogarty International Center TB Training Programs

The Fogarty International Center at NIH provides training grants to U.S. universities to teach international physicians and researchers AIDS treatment and research techniques. The goal of the program is to develop a cadre of health professionals in the developing world to begin to control the global AIDS epidemic.

Because of the linkage between AIDS and TB infection, FIC has created supplemental TB training grants for these institutions to train international health care professionals in the area TB treatment and research. This supplemental program has been highly successful in beginning to create the human infrastructure to treat the nearly 2 billion people who have TB worldwide.

However, we believe TB training grants should not be offered exclusively to institutions that have received AIDS training grants. The TB grants program should be expanded and open to competition from all institutions. The ALA/ATS recommend Congress provide an additional $3 million for FIC to expand the TB training grant program from a supplemental grant to an open competition grant.

MAGNITUDE OF LUNG DISEASE

This year over 350,000 Americans will die of lung disease. Lung disease is third leading cause of death in the U.S., responsible for one in every seven deaths. More than 25 million Americans suffer from a chronic lung disease. Lung diseases cost the U.S. economy an estimated $89.1 billion annually.

Lung diseases represent a spectrum of chronic and acute conditions that interfere with the lung's ability to extract oxygen from the atmosphere, protect against environmental or biological challenges and regulate a number of metabolic processes. Lung diseases include: chronic obstructive pulmonary disease, lung cancers, tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, and asthma. While lung disease encompasses many illnesses, these comments will focus on two illness, asthma and tuberculosis.

ASTHMA

Asthma is a chronic lung disease in which the bronchial tubes of the lungs become swollen and constrict, preventing air from getting into or out of the lung. These obstructive spasms of the bronchi are caused by a broad range of environmental triggers that vary from one asthma-sufferer to another.

Asthma is on the rise. A 1998 survey found that an estimated 26 million Americans (8.6 million children under the age of 18) have been told by their doctor they have asthma. Rates are increasing for all ethnic groups and especially for African American and Hispanic children. While some children appear to out grow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition.

Asthma is expensive. The growth in the prevalence of asthma will have significant impact on our nation's health expenditures, especially Medicaid. Currently, asthma costs the United States over $8.1 billion in direct medical expenditures. Hospital inpatient visits account for $3.2 billion in asthma expenses. Asthma attacks bring 1.9 million people to the emergency room each year.

Asthma kills. In 1998, 5,438 people in the U.S. died as a result of an asthma attack. That is a 209 percent increase from 1979. A disproportionate share of these deaths occurred in African American families.

Federal Response to Asthma

The federal response to asthma has three components; research, programs and planning. We are pleased to report that, with support from the Subcommittee, we are making progress on all three fronts.

FEDERAL RESPONSE TO ASTHMA—RESEARCH

As the prevalence of asthma has grown, so has asthma research. Researchers are developing better ways to treat and manage chronic asthma. Research supported by National Heart, Lung and Blood Institute (NHLBI) has shown that using corticosteroids to treat children with mild to moderate asthma is safe and effective. For several years there had been concern that corticosteriods would stunt the growth of children who used them. The five-year study showed that children had a one-year small reduction in their growth rate. But they had normal growth rates compared with children who did not use corticosteriods for the following 4 years. Children who used corticosteroids did suffer fewer asthma attacks and fewer trips to the emergency room.

Genetic research is also providing insights into asthma. Physicians have noticed that while most people respond well to inhaled beta-agonists—a commonly prescribed drug to treat asthma—some patients do not response or have worse asthma using inhaled beta-agonists. Researchers in the NHLBI supported Asthma Clinical Research Network have discovered that a genetic variation in the beta-adrenegric receptor determines how well asthma patients will respond to inhaled beta-agonists. This discovery will enable physicians to better target the drugs they proscribe to treat asthma.

Basic research is also learning more about asthma. Researchers supported by NHLBI have developed better animal models to allow expression of selected asthmatic genetic traits. This will allow researchers to develop a greater understanding of how genes and environmental triggers influence asthma's onset, severity and long-term consequences.

FEDERAL RESPONSE TO ASTHMA—PROGRAMS

Last year, Congress provided approximately $27 million for CDC to conduct asthma program and tracking activities. CDC will use these funds to conduct asthma outreach, education and tracking activities. In Ohio, Case Western University and Rainbow Babies and Children's Hospital have been awarded funds to conduct an asthma intervention program. However, at the current level of funding, less than half the states have funds to respond to asthma. The ALA/ATS recommend that CDC be provided $50 million to expand its asthma programs.

FEDERAL RESPONSE TO ASTHMA—PLANNING

Last year, Congress enacted legislation that directs the National Asthma Education and Prevention Program (NAEPP) at NHBLI to develop a plan for the federal government to respond to the growing asthma epidemic in the U.S. The plan will include recommendations on research, public health, tracking, education and treatment activities. The ALA/ATS supports this planning process and looks forward sharing the recommendations of the NAEPP Federal Asthma Plan with this Subcommittee in the near future.

IOM Report: Ending Neglect—the Elimination of Tuberculosis in the United States

Mr. Chairman, tuberculosis has been with us since the dawn of time. Tuberculosis is an airborne infection caused by a bacterium, Mycobacterium tuberculosis (TB). TB primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine.

TB is spread through coughs, sneezes, speech and close proximity to someone with active tuberculosis. People with active tuberculosis are most likely to spread TB to others they spend a lot of time with, such as family members or coworkers. It cannot be spread by touch or sharing utensils used by an infected person.

There are an estimated 10 to 15 million Americans infected with latent TB, with the potential to develop active TB in the future. About 10 percent of these individuals will develop active TB disease at some point in their lives. In 1998, over 18,000 cases of active TB were reported in the United States.

The Institute of Medicine (IOM) recently published a report on how the United States has responded to tuberculosis. The IOM report documents the cycles of attention and progress toward TB elimination, the periods of insufficient funding and the re-emergence of TB. The ALA/ATS is pleased to report that, at the moment, TB rates in the U.S. are on the decline. From a high in 1992 of 26,673 new cases, we have seen 7 straight years of decline in TB rates.

While declining TB rates is good news, the emergence and spread of multi-drug resistant TB poses a significant threat to the public health of our nation. Continued support is need if the U.S. is going to continue progress toward the elimination of TB.

The IOM report provides the United States with a road map of recommendations on how to eliminate TB in the United States. The IOM report identifies needed detection, treatment, prevention and research activities. The American Lung Association and the American Thoracic Society endorse the IOM report and its recommendations. We estimate it will cost $528 million for the CDC Tuberculosis Elimination Program to implement the IOM report recommendations.

The National Institutes of Health also has a prominent role to play in the elimination of TB. Currently there is no highly effective vaccine to prevent TB transmission. However, the recent sequencing of the TB genome and other research advances have put the goal of an effective TB vaccine within reach. The National Institutes of Allergy and Infectious Disease have developed a Blueprint for Tuberculosis Vaccine Development. ALA/ATS encourage the Subcommittee to fully fund the TB vaccine effort.

NIOSH—Researching and Preventing Occupational Lung Disease

In 1998, approximately 66,000 Americans died from work-related injuries or illnesses; 392,000 newly diagnosed cases of occupational illnesses and 5.5 million nonfatal work injuries were reported. Workplace illness and injury will cost the U.S. economy $171 billion this year.

To protect the health of our nation's workforce will require research, training, tracking and new technologies. The ALA/ATS recommend that the Subcommittee provide a $50 million increase for the NIOSH budget including $25 million for the NIOSH National Occupational Research Agenda (NORA). NORA represents a partnership research plan for occupational disease. The NORA agenda was developed with input from labor, business and the health community.

A recent IOM Report—"Safe Work in the 21st Century: Education and Training Needs for the Next Decades Occupational Safety and Health Personnel," identified a growing shortage of trained occupational health professionals in the United States. Unlike the majority of medical subspecialties, occupational health professionals do not receive Medicare training support. We recommend $10 million to increase training opportunities for occupational health professionals. The ALA/ATS believe more funds are needed to track the incidence of serious work-related illnesses and injury. We recommend $10 million for surveillance data on workplace safety.

LUNG-DISEASE OPPORTUNITIES AND ADVANCES

Previously, the ALA/ATS reported that NHLBI-supported researchers found that retinoic acid can reverse the effects of emphysema in laboratory rats. The ALA/ATS is pleased to report that studies have gone from rats to non-human primates and that results continue to be encouraging. NHLBI is taking steps to test retinoic acid treatment in people. We appear to be one step closer to finding a way to reverse the effects of emphysema—what was once considered an irreversible, debilitating disease.

NHLBI and Medicare are continuing to investigate the efficacy of the Lung Volume Reduction surgery in the National Emphysema Trial (NET). This clinical trial will help evaluate the best combination of surgical and rehabilitation therapy for people with emphysema.

NHLBI is continuing its support for sleep-related research. It has been observed that people who suffer from inadequate sleep appear to recover more slowly from infections. NHLBI is supporting research to better understand the genetic basis of sleep-immune interactions.

NHLBI-supported researchers have made strides in understanding the health effects sleep apnea and have identified genes in dogs that cause narcolepsy. The discovery of the narcolepsy gene in dogs will help guide further research in humans.

Researchers have discovered a genetic defect that may cause familial primary pulmonary hypertension (PPH) in humans. PPH is a rare but serious disease in which blood pressure in the pulmonary artery becomes extremely high. Discovering the gene for familial PPH will help researchers discover the cause of this rare and fatal disease and should lead to improved treatments for PPH.

In conclusion, Mr. Chairman, lung disease is a growing problem in the United States. It is America's number three killer, responsible for one in seven deaths. The lung disease death rate continues to climb. Overall, lung disease and breathing problems constitute the number one killer of babies under the age of one year. Worldwide, TB kills 3 million people each year, more people than any other single infectious agent. Mr. Chairman, the level of support this committee approves for lung disease programs should reflect the urgency illustrated by these numbers.

PREPARED STATEMENT OF THE AMERICAN GASTROTENTEROLOGICAL ASSOCIATION

SUMMARY OF RECOMMENDATIONS

The American Gastroenterological Association ("AGA") urges Congress to increase funding for medical research on digestive diseases and disorders through budgetary increases to the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Agency for Healthcare Research and Quality ("AHRQ").

Specifically, AGA encourages Congress to provide at least a 16.5 percent increase over fiscal year 2001 for NIH, raising the funding levels from $20.3 billion to $23.7 billion, as recommended by the Ad Hoc Group for Medical Research Funding. Within NIH, AGA recommends at least a commensurate increase for the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), the National Cancer Institute ("NCI"), and the National Institute of Allergy and Infectious Diseases ("NIAID"), each of which support a considerable portfolio of gastrointestinal research. These increases would allow for further research on the diagnosis, treatment and cure for debilitating and devastating digestive diseases.

AGA also urges Congress to increase funding over fiscal year 2001 by 29 percent to $5.0 billion for the CDC as recommended by the CDC Coalition, and by 40 percent to $400 million for AHRQ as recommended by the Friends of AHRQ.

MEDICAL RESEARCH RECOMMENDATIONS

AGA is the nation's oldest, not-for-profit specialty medical society, consisting of over 11,000 gastroenterologic physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system. As the nation's leading voice on gastrointestinal research, AGA is uniquely qualified to advise Congress on the current status of federally-supported digestive disease research programs and the areas in need of further research.

Each year more than 62 million Americans are diagnosed with digestive disorders. Among the more common are obesity, gastrointestinal cancers, inflammatory bowel disease, motility disorders and foodborne illness. This testimony focuses on these serious health problems and makes recommendations on how Congress should allocate this country's precious medical research dollars to combat digestive diseases.

Nutrition and Obesity

110 million adults in this country are either overweight (61 million) or obese (49 million); 31.3 percent of men and 34.7 percent of women are considered to be clinically obese; one in five children are clinically obese. The number of obese adults in the United States has doubled in the last 25 years.

The costs to society are both direct and indirect, and include increased medical expenses, loss of productivity in the workplace, disability claims and job discrimination. Approximately 300,000 adult deaths in the United States each year are attributable to obesity.

Obesity is a major health problem in the United States because of its marked prevalence, causal relationship with serious medical diseases and considerable economic impact. Obesity is a major cause of gastrointestinal diseases such as gall bladder disease, liver disease (including cirrhosis of the liver), and colorectal cancer. Treatment of obesity and diseases directly related to it accounts for 5 percent to 7 percent of total health care costs annually.

Despite the fact that obesity is gaining more recent attention, a significant amount of ground must be covered before medical research catches up with the need to address the problem in a comprehensive manner. There are a growing, but inadequate, number of grants being funded to examine this disease.

AGA recommends that Congress urge NIDDK, the National Institute of Child Health and Human Development, the Office of Research on Women's Health and the Center for Research on Minority Health to increase RO1 funding for obesity research by 15 percent for fiscal year 2002 and to encourage the institutes to consider RFA's on the effects of obesity on gene expression, particularly as it relates to GI cancers, including colon cancer. Additionally, research into the effect of diet and nutrient intake on mucosal function, metabolism and gene function will provide insight into how nutrients affect gut function. Furthermore, the institutes should increase advanced research training at the basic level (KO8) and clinical level (K23) by 25 percent in fiscal year 2002.

Gastrointestinal Cancers

Approximately 226,600 new cases of gastrointestinal cancers will be diagnosed this year. Sadly, 129,800 Americans will die from these cancers. The most common cancers involve the colon/rectum, stomach/esophagus, and pancreas.

—*Colorectal cancer is the second leading cause of cancer-related deaths in the United States and ranks fourth as the most common cancer.*—70 percent to 80 percent of colorectal cancer cases involve average-risk individuals. If diagnosed early, this cancer is highly curable. As such, research and early detection through screening remains the key to preventing, treating, and curing this disease. We encourage Congress to require coverage for screening for all Americans. Further, we urge Congress to support additional research on colorectal cancer.

—*Pancreatic cancer will be diagnosed in 28,300 Americans in 2001 with 28,200 people projected to die from this disease.*—It is a highly lethal form of cancer with the lowest survival rate among all major malignancies.

—*Of increased concern to AGA are esophageal and stomach cancers. These are the second most common gastrointestinal cancers.*—It is projected that nearly 34,000 Americans will be diagnosed and more than 25,100 will die in 2001 from these cancers. Of heightened concern to AGA is Barrett's esophagus, a precursor to esophageal cancer, and the relationship between Barrett's and chronic gastroesophageal reflux disease ("GERD").

AGA applauds the NCI for its commitment to improving the understanding of, and seeking cures to, these and other gastrointestinal cancers. However, more research is needed. Congress should encourage the NCI to likewise establish a Progress Review Group on espohgeal and stomach cancers. Congress also should urge the NIDDK to augment its efforts in these areas, and to particularly focus resources on the genetic aspects of these cancers, diagnostic tests for genetic abnormalities and prevention of these cancers, the modulation and understanding of epithelial injury and repair the environmental factors relating to the development of these diseases, and the development and treatment of Barrett's Syndrome in patients with GERD.

Most cases of these cancers are detected too late to be effectively treated. However, CDC's National Colorectal Cancer Screening Awareness program is helping to inform the public that early detection through regular screening is important. Congress should support CDC's Colorectal Cancer Screening Awareness program with $15 million in fiscal year 2002, an increase of $6 million over fiscal year 2001.

Inflammatory Bowel Disease

It is estimated that 1 million Americans have inflammatory bowel disease ("IBD"). Although older and younger people may also develop this disease, IBD usually begins between the ages of 15 and 40 and persists throughout life with remissions. People with IBD experience abdominal pain, fever, bowel sores, intestinal bleeding, anorexia, weight loss, fullness, diarrhea, constipation, and vomiting. In severe cases, the patient can hemorrhage or contract sepsis/toxemia resulting in death.

Studies on the cause of IBD are desperately needed in order to have a better understanding of the disease and work towards more effective management and treatment. Specifically, AGA recommends that NIDDK support genomic research aimed at identifying abnormal genes in persons with IBD and finding the causes of IBD.

Motility Disorders

It is estimated that up to 30 percent of all Americans may be affected at some time during their lives by motility disorders. Irritable bowel syndrome ("IBS"), the most common motility disorder, is especially troubling because a patient does not present with any pathognomonic symptoms or laboratory findings of the disease, making diagnosis and treatment extremely difficult.

Further research is needed in this area both due to the high prevalence of this disease as well as the lack of knowledge on how to identify, diagnose, and cure the disease. AGA urges Congress to direct the NIDDK to focus additional resources on IBS. Specifically, AGA recommends that NIDDK support research into the development of physiologic tests to characterize the phenotypic subgroups of functional gastrointestinal disorders, including non-ulcer (functional) dyspepsia, functional constipation, and irritable bowel syndrome (motility). Additionally, AGA urges Congress to also encourage the Office of Research on Women's Health to devote more of its attention to these areas of research in light of the high incidence of IBS among women.

Foodborne Illness

Foodborne illnesses are estimated to cost annually $5 to $6 billion in direct medical costs and productivity losses. Due to poor reporting of foodborne incidents, experts vary on the number of Americans affected annually from a conservative 6 million to over 80 million.

AGA recommends that Congress encourage the NIH, including NIDDK and NIAID, and others conducting foodborne illness research like the United States De-

partment of Agriculture ("USDA") and the CDC to concentrate more intensively on research into treatments for foodborne illness. AGA thus urges NIDDK and NIAID to support research on (1) intestinal diseases caused by combination of luminal (including bacterial), environmental, and genetic factors with an emphasis on inflammatory bowel diseases, and (2) the reaction of the gut to foodborne pathogens, including research on the pathogenesis of the disease, the reaction of the gut to infections, the development of animal models to test therapies, and the invention of vaccines or substances that bind with the toxins to prevent the illness.

MEDICAL RESEARCH INFRASTRUCTURE

Digestive Disease Research Centers

Digestive Diseases Research Core Centers are key to establishing strong research networks and advancing medical knowledge. Currently, fourteen fully funded centers exist which conduct basic and clinical research on a variety of digestive disorders. They have been highly successful in expanding medical knowledge on a variety of GI diseases and disorders. AGA urges Congress to instruct NIDDK to expand the number of centers by adding one new 5-year center in each of the next 2 years such that sixteen centers are fully supported. These new centers should focus on genomic and proteomic approaches to gastrointestinal research. Moreover, NIDDK should maintain full funding for those centers already in existence.

Small Equipment Grants

As technology continues to evolve, laboratory research equipment is becoming more expensive to purchase and maintain. NIH's current Shared Instrumentation Grant Program offers equipment grants for which researchers can apply for equipment with a minimum cost of $100,000; appropriate for use in replacing pieces of large equipment. However, a similar grant program does not exist to assist researchers in replacing less expensive ($50,000–$100,000), often highly utilized, pieces of equipment. Researchers' small equipment needs are just as critical as larger pieces of equipment and the cost of replacing such instrumentation can be prohibitively expensive to support on a single grant application. Therefore, AGA urges Congress to suggest that NIH study the need for a small equipment grant program comparable to the existing Shared Instrumentation Grant Program.

Training of Physician-Scientists

While research has expanded our medical knowledge and enabled physicians and other providers to better prevent diseases, diagnose disorders, and treat people, there is growing concern that the number of physician-scientists (e.g., investigators who have medical degrees) is declining and that this decline will negatively impact many key future research endeavors. A recent study documenting this decline points to the tremendous debt incurred by medical school graduates who have more lucrative options outside of research as a primary cause. See Tamara R. Zemlo et al., The Physician-Scientist: Career Issues and Challenges at the Year 2000, 14 The FASEB Journal 221–230 (2000).

AGA views this problem as an immediate and serious threat to the future of biomedical research generally, and gastrointestinal research in particular. To alleviate this growing problem, AGA urges Congress to increase funding for the continued expansion of clinical research and clinical research training opportunities. To achieve this Congress should take the following steps: career support for established clinical investigators, especially to enable them to mentor new investigators; and appropriate funding to NIH for the implementation of the loan repayment provisions of the Clinical Research Enhancement Act.

NIH Budget Doubling Initiative

Medical research endeavors and America's patients have benefited tremendously from the 5-year effort to double the NIH budget. However, researchers recognize that there may be ramifications once the NIH budget has been doubled, and annual funding increases return to pre-initiative levels. It is imperative that Congress not permit NIH funding to stagnate upon achieving the goal doubling the NIH budget. Therefore, in order to prevent a funding crisis that results in a retreat from the significant progress that has been made, AGA recommends that Congress plan for the post-doubling period accordingly. Additionally, Congress should applaud NIH for working to develop a funding strategy for post-fiscal year 2003, encourage further budget modeling exercises at NIH, and afford NIH the maximum amount of flexibility to address post-budget doubling funding levels.

CONCLUSION

The diseases described above continue to take a huge toll on America's health and economy. Congress must keep up the momentum it has started, and in some cases, devote even more resources. AGA appreciates the opportunity to present its views on the fiscal year 2002 appropriations. Please call Michael Roberts, Vice President of Public and Government Relations at AGA, at (301) 941–2618 if you have further questions.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

It is highly likely that heart attack or stroke will cause your death or disability or that of a loved one. Heart attack, stroke and other cardiovascular diseases remain America's leading cause of death and a major cause of disability. Cardiovascular diseases account for nearly 1 of every 3 deaths in the United States.

The American Heart Association works to reduce death and disability from heart attack, stroke and other cardiovascular diseases. We commend this Committee for making fiscal year 2001 funding for the National Institutes of Health and for the Centers for Disease Control and Prevention a priority. But, we are concerned that our government is still not devoting sufficient resources for research and prevention to America's No. 1 killer—heart disease—and to our country's No. 3 killer and a leading disabler—stroke.

STILL NUMBER ONE

Heart attack, stroke and other cardiovascular diseases have been America's No. 1 killer since 1919. Nearly 61 million Americans—1 in 5—suffer from one or more of these diseases. Americans of all ages! Also, hundreds of millions of Americans have major risk factors for these diseases—about 50 million have high blood pressure, 41 million adults have elevated blood cholesterol (240 mg/dL), 49 million adults smoke, 107 million adults are overweight or obese and 10 million have physician-diagnosed diabetes. As the baby boomers age, the number of Americans afflicted by these lethal and disabling diseases will increase substantially. Cardiovascular disease costs Americans more than any other disease. Americans will pay an estimated $300 billion for cardiovascular-related medical costs and lost productivity in 2001. These diseases constitute 4 of the top 5 hospital costs for all payers, excluding childbirth and its complications, and 4 of the top 5 Medicare hospital costs. Heart disease is also the major cause of premature, permanent disability of American workers, accounting for nearly 20 percent of Social Security disability payments.

HOW YOU CAN MAKE A DIFFERENCE

Now is the time to capitalize on a century of progress in understanding heart attack, stroke and other cardiovascular diseases. According to an expert panel supported by this Committee, America's progress in reducing the death rate from cardiovascular disease has slowed, suggesting that new strategies against these killers are needed. The panel also reported that there are striking differences in cardiovascular death rates by race/ethnicity, socioeconomic status and geography. But promising, cost-effective breakthroughs in treatment and prevention are on the horizon. If you stay the course to double NIH funding by fiscal year 2003, the support of heart and stroke research and of the translation of that research into effective clinical and community initiatives will cut health care costs and improve the quality of life. For fiscal year 2002, we urge you to do the following:

—*Appropriate $23.7 billion (a 16.5 percent increase over fiscal year 2001 funding) for the NIH—the fourth step toward the bipartisan goal of doubling NIH's budget by fiscal year 2003.*—NIH research provides new treatment and prevention strategies, cuts health care costs, creates jobs and maintains America's status as the world leader in the biotechnology and pharmaceutical industries.

—*Provide at least a 16.5 percent increase over fiscal year 2001 funding for NIH heart and stroke research.*—Researchers are on the brink of advances to greatly enhance prevention and to provide new treatments so you and your loved ones can be spared the pain and suffering of heart disease and stroke.

—*Allot $50 million for CDC's Cardiovascular Health Program to expand this initiative to 35 states.*—Science must be made applicable through community programs that encourage Americans to make healthful lifestyle choices to prevent heart disease and stroke.

—*Support $12.5 million to continue to help rural communities buy automated external defibrillators (AEDs) and to train rural emergency responders, including*

police and fire personnel, to use them.—Rural Access to Emergency Devices Act is part of Public Law 106–505, Public Health Improvement Act.

HEART AND STROKE RESEARCH BENEFITS ALL AMERICANS

Thanks to advances in addressing risk factors and in treating cardiovascular diseases, more Americans are surviving heart disease and stroke. Heart disease and stroke research and prevention breakthroughs are saving and improving lives. Several examples follow.

—*Stents*.—Each year nearly 1 million Americans undergo angioplasty to widen their narrowed arteries to the heart. But, within six months, 35 percent of angioplasties must be repeated because the artery narrows again. In a major change in patient care, stents (wire mesh tubes used to prop open an artery) are now used in nearly 80 percent of angioplasties. The use of stents along with angioplasty has significantly reduced the incidence of artery renarrowing within six months.

—*Surgery to Reduce Risk for Stroke*.—In many cases, surgeons can prevent stroke by removing the buildup of plaque when one of the main arteries to the brain is severely narrowed. Research has better defined the group of patients in whom this surgery is most helpful. About 121,000 such procedures are performed each year.

—*State-of-the-Art Life-Extending Drugs*.—Research has produced amazing new drugs to help prevent and treat heart disease and stroke. Cutting-edge drugs to control blood pressure and cholesterol are more effective than ever in saving lives and enhancing life quality of millions of Americans. Some of these drugs can prevent both heart attack and stroke. When prevention fails, revolutionary "clotbuster" drugs, such as tPA, can reduce disability from heart attack by dissolving blood clots causing the attack. In stroke, the use of tPA, within 3 hours of the onset of symptoms, can restore blood flow and reduce chances of permanent disability by 33 percent, saving health care costs. TPA offers hope for the estimated 1.1 million Americans who will suffer a heart attack and the 450,000 who will have a clot-based stroke this year.

So Americans can continue to benefit from these types of breakthroughs, it is critical that we proceed toward doubling the overall NIH budget by fiscal year 2003. We advocate an fiscal year 2002 appropriation of $23.7 billion for the NIH, the fourth step toward the doubling goal. We have a particular interest in individual NIH components that relate directly to our mission of reducing heart attack, stroke and other cardiovascular diseases. Our funding recommendations for these institutes, centers and programs follow.

HEART RESEARCH CHALLENGES AND OPPORTUNITIES FOR NHLBI

The above and other advances have been made possible by more than 50 years of American Heart Association-sponsored research and more than a half-century of investment by Congress in the National Heart, Lung, and Blood Institute. Thanks to research, more of our patients, our families, and our friends survive their heart attack or stroke and with a better quality of life. However, while more Americans are surviving, heart attack and stroke are still our No. 1 and No. 3 killers, respectively, and can cause permanent disability, requiring costly medical care and loss of productivity and quality of life. Clearly more work is needed if we are to win the fight against heart disease and stroke.

We urge this Committee to double the NHLBI budget, including heart initiatives, by fiscal year 2003. As the next step toward reaching this goal, we advocate an fiscal year 2002 appropriation of $2.679 billion for the NHLBI, with $1.650 billion for heart and stroke-related research. A funding level of this amount will allow NHLBI to expand existing programs and invest in promising new initiatives. Several challenges and opportunities to advance the battle against heart disease are highlighted below.

—*Advanced Imaging*.—Research has revolutionized imaging technology to diagnose heart disease. About 1.3 million Americans in 1998 were hospitalized for an angiogram, an X-ray picture of blood vessels that can demonstrate narrowings in arteries that can lead to heart attacks or strokes. Because angiograms are associated with some discomfort, the risk of infection and bleeding, and in rare cases, heart attack or stroke; there is strong motivation to replace them with easier, safer and cheaper imaging procedures. Considerable progress has been made. The high speed CT scan takes pictures that produce a measure of blockages in arteries to the heart, and helps doctors better tailor treatments. Three-dimensional coronary magnetic resonance angiography uses strong magnets to provide detailed images of the arteries to the heart. In less

than an hour, an MRA evaluates heart anatomy and other heart functions, providing an accurate and thorough, non-invasive examination.

—*Bone Formation and Calcification in Cardiovascular Diseases*.—Calcium is an early marker of atherosclerosis involving the arterial wall. Evidence suggests an association between bone formation, repair and breakdown (e.g. osteoporosis) and development of heart disease and other cardiovascular diseases. For instance, patients who take statin drugs—effective in lowering cholesterol levels and in reducing cardiovascular disease risk—are at decreased risk for bone fractures. Conversely, several studies have reported that people with low bone mass may have an increased risk of developing or dying from cardiovascular diseases. These results indicate that basic research in this area may result in strategies to prevent osteoporosis and cardiovascular diseases.

—*Heart Attack, Stroke and Other Cardiovascular Diseases in Women*.—Cardiovascular diseases are a major cause of disability and the No. 1 killer of American women, killing more women than the next 14 causes of death combined. About 1 in 5 women live with effects of cardiovascular diseases. The clinical course of cardiovascular disease is different in women than in men and our diagnostic capabilities are less accurate in women than in men. After a woman develops cardiovascular disease, she is more likely than a man to have continuing health problems and is more likely to die. But these diseases are largely unrecognized by both women and their doctors. Extra funding is needed to allow NHLBI to expand cardiovascular disease research in women and to create more educational programs for patients and health care providers on cardiovascular diseases risk factors, as authorized under Public Law 105–340, Women's Health Research and Prevention Amendments.

—*Resuscitation Research*.—Some 1,000 Americans die each day from unsuccessful cardiopulmonary and trauma resuscitation. The National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, the National Institute of Child Health and Human Development, the National Institute of General Medical Sciences, the Department of Defense, and the Food and Drug Administration sponsored a forum to set a broad research agenda on promising and novel life-saving therapies and to identify promising new directions in CPR and trauma resuscitation research.

STROKE RESEARCH CHALLENGES AND OPPORTUNITIES FOR NINDS

A major cause of permanent disability and a key contributor to late-life dementia, stroke is America's No. 3 killer. Many of our 4.5 million stroke survivors face debilitating physical and mental impairment, emotional distress and huge medical costs. About 600,000 Americans will suffer a stroke this year. Considered a disease of the elderly, stroke also strikes newborns, children and young adults.

We urge a doubling of the NINDS stroke budget by fiscal year 2003. An fiscal year 2002 appropriation of $1.371 billion for NINDS, with $151 million for stroke initiatives, would be the next step toward the goal. This will allow the NINDS to expand studies and start new initiatives to prevent stroke, protect the brain during stroke and enhance rehabilitation. Some challenges and opportunities follow.

—*Strategic Stroke Research Plan*.—As a result of report language provided by this Committee during the fiscal year 2001 appropriations process, NINDS is developing a 5-year strategic stroke research plan. Researchers, clinicians, pertinent organizations and advocacy groups will identify existing gaps in knowledge and areas ripe for advances. Expected to be released in fall 2001, the plan will strongly stimulate stroke research.

—*Emerging Stroke Risk Factors*.—More Americans are controlling major stroke risk factors, such as high blood pressure and smoking, yet the number of people falling victim to stroke continues to rise. Scientists are defining new stroke risk factors, re-examining existing ones and reconsidering the long-held belief that no difference exists in risk between young and older patients with similar risk factors. Researchers are studying heart valve disease, irregular heartbeats, the role of inflammation in clogging of arteries, and the long-term effects of previous high blood pressure. Increased funding to study these areas may lead to new ways to prevent stroke.

—*Therapeutic Strategies for Stroke*.—Several major clinical trials have identified new methods for preventing and treating stroke in high-risk populations. However, with the increased number of strokes, and with the disparities evident in the treatment of stroke, new ways to prevent strokes, to raise awareness, and to better treat strokes need to be developed and evaluated. Funding for new clinical studies is crucial for developing cutting-edge stroke treatment and prevention.

—*Stroke Education.*—Less than 5 percent of those eligible for tPa—the only approved emergency treatment for clot-based stroke—receive it. As a member of the Brain Attack Coalition, comprised of organizations committed to fighting stroke, we work with the NINDS to increase public awareness of stroke symptoms and to call 9–1–1. Together, we sponsor and distribute a televised public service announcement and are striving to develop systems to make tPA readily available to appropriate patients. When these measures are fully implemented, stroke treatment will change from supportive care to early brain-saving intervention. More funding is needed to educate the public and health professionals about stroke.

RESEARCH IN OTHER NIH INSTITUTES BENEFIT HEART & STROKE

The National Institute on Aging defines how the aging process contributes to cardiovascular diseases, a main disabler and No. 1 killer of older Americans. An fiscal year 2002 appropriation of $80.675 million for cardiovascular research will allow continuation of studies and expansion into promising areas of investigation.

The National Institute of Diabetes and Digestive and Kidney Diseases studies help in reducing cardiovascular disease death and disability. We advocate an fiscal year 2002 appropriation of $1.548 billion for the NIDDK to advance research to help diabetics, 2/3 of whom die from heart disease or stroke.

The National Institute of Nursing Research studies play a key role in promoting self-care and patient education. NINR research is key to primary and secondary prevention of heart attack, stroke and other cardiovascular diseases. We advocate an fiscal year 2002 appropriation of $121.591 million for NINR.

Animal research and nationally-supported clinical research at the local level are critical for heart and stroke research. We support an appropriation of $952.358 million for the National Center for Research Resources. Increased resources will fortify animal research, help correct deficiencies in animal research resources and strengthen nationwide General Clinical Research Centers and Biomedical Technology and Infrastructure Areas.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The lead health care quality agency, AHRQ acts as a "science partner" with public and private health care sectors in improving health care quality, reducing health care costs and broadening access to essential services. AHRQ is an active participant in developing evidence-based information needed by consumers, providers, health plans and policymakers to improve health care decision making. We advocate an appropriation of $400 million for the AHRQ to improve health care quality, reduce medical errors and expand the availability of health outcomes information.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Prevention is the best way to protect Americans' heath and ease the huge financial burden of disease. Commitment cannot stop at the laboratory door. Resources must be made available to bring research to places where heart disease and stroke live—the towns and neighborhoods of America.

CDC sets the pace on prevention. It builds a bridge between what we learn in the lab and how we live in communities. We advocate an fiscal year 2002 appropriation of $5 billion for CDC, with a $350 million increase for chronic disease prevention.

As a result of this Committee's support since fiscal year 1998, CDC's Cardiovascular Health Program now covers 25 states. It allows states to design and/or implement programs to meet local needs to prevent and control heart disease and stroke. CDC's 1997 report Unrealized Prevention Opportunities: Reducing the Health and Economic Burden of Chronic Disease states "strong chronic disease prevention programs should be in place in every state to target the leading causes of death and disability—and their risk factors." Until this Committee started the Cardiovascular Health Program, CDC's Preventive Health and Health Services Block Grant was the only source of federal funding to states for targeting cardiovascular diseases, the No. 1 killer in each state. An fiscal year 2002 appropriation of $50 million for the Cardiovascular Health Program will allow CDC to expand it to 10 more states, to total 35 states.

The Paul Coverdell National Acute Stroke Registry is designed to track and improve delivery of care to stroke patients. CDC is working with an expert panel to define data points for the registry prototypes. An appropriation of $5 million for the registry will allow CDC to continue this initiative.

WISEWOMAN builds on CDC's National Breast and Cervical Cancer Early Detection Program to also screen uninsured and low-income women ages 40–64 for heart

disease and stroke risk factors. We laud this Committee for providing funding to expand this program up to 15 states. An appropriation of $20 million will allow CDC to support up to a total of 20 states in WISEWOMAN.

Also, we recommend the following fiscal year 2002 funding levels for the following CDC programs:

—$210 million for the Preventive Health and Health Services Block Grant;
—$50 million for an extensive nutrition, physical activity and obesity program;
—$35 million for a comprehensive school health education program; and
—$130 million for CDC's Office of Smoking and Health to build a national program to prevent tobacco use, including a public education campaign to reduce youth access to tobacco products.

Coupled with a nationwide comprehensive Cardiovascular Health Program, these initiatives will help the fight against heart disease and stroke. We urge you to make cardiovascular health a priority.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

About 220,000 Americans die each year from sudden cardiac death—when a heart's electrical rhythms malfunction, causing the heart to suddenly stop beating. Only about 5 percent of the victims live. Small, easy-to-use devices, AEDs can shock a heart back into normal rhythm and restore life. For each minute the heart beat is not restored to its normal rhythm, the victim's chance of survival drops as much as 10 percent. The first responder to a cardiac arrest may not be a medical responder, so the Rural Access to Emergency Devices Act, part of Public Law 106–505, Public Health Improvement Act, authorizes up to $25 million over 3 years to help rural communities buy AEDs and to train emergency responders to use them. An appropriation of $12.5 million is needed to further implement the rural AED component.

DEPARTMENT OF EDUCATION

Physical inactivity is a major risk factor for heart disease and stroke. So the grim decline in daily enrollment in physical education (PE) classes is a key concern. To address this matter, in fiscal year 2001 Congress appropriated $5 million for the Physical Education for Progress Act. Under PEP, the Education Secretary can award grants to start, expand and improve PE for kindergarten through grade 12. Funds can be used to buy equipment, develop curriculum, hire and/or train staff and support other efforts so students can participate in PE. We advocate an appropriation of $70 million for PEP in fiscal year 2002.

ACTION NEEDED

Significantly increasing funding for research and community programs will allow us to continue making strides in the battle against heart disease and stroke. Our government's response to this challenge will help define the health and well being of Americans in this new millennium.

PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL SOCIETY

SUMMARY OF RECOMMENDATIONS

As a member of the Ad Hoc Group for Medical Research Funding, APS recommends $23.7 billion for NIH in fiscal year 2002 as the 4th installment of the 5-year doubling plan.

APS requests Committee support for increased behavioral and social science research and training at NIH in order: to better meet the Nation's health needs—many of which are behavioral in nature; to realize the exciting scientific opportunities in the fields of behavioral and social science research; and to accommodate the changing nature of science, in which new fields and new frontiers of inquiry are rapidly emerging. Specifically, we ask that you help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, and by encouraging NIH to advance a model of health that includes behavior in deciding its scientific priorities.

Specific Committee support is requested for behavioral science activities at a number of individual institutes and examples are provided to illustrate the exciting and important behavioral and social science work being supported at NIH.

Mr. Chairman, Members of the Committee: On behalf of our members, I want to thank this committee for your leadership in the bipartisan effort to double the NIH budget. As a member of the Ad Hoc Group for Medical Research Funding, the Amer-

ican Psychological Society recommends $23.7 billion for NIH in fiscal year 2002 as the 4th installment of the 5-year doubling plan. The rationale for these aggressive increases remains as compelling today as it was in fiscal year 1999, the first year that you and your colleagues in the House embarked on this path. Our Nation's health needs, scientific opportunities, and the changing nature of health research all warrant this expansion. I will talk about these three areas in terms of the field that I represent, which is behavioral and social science research—specifically, psychological science research.

Health Needs.—The effects of behavior on health have been widely documented. Behavior is as threatening as any genetic or biological condition. When you look at what determines health, you can't help but notice behavior. Smoking, drinking, taking drugs—all begin as behaviors. And many other leading health concerns are behavioral in origin or in their manifestation: Heart disease, lung disease, diabetes, mental illness, developmental disabilities, brain injury, AIDS, and so many more cannot be fully understood without studying the behavioral and psychological factors involved in causing, treating and preventing them.

Scientific Opportunities.—Many of the 15,000 people who belong to APS are scientists at our Nation's leading universities and colleges, conducting research and training supported by NIH. The behavioral research enterprise at NIH spans from theoretical to applied, from basic to clinical. Virtually every institute at NIH supports some amount of psychological science. Examples include investigations into: The connections between the brain and behavior; the basic processes of cognition and memory; social interaction in people of all ages; the interactions of such things as emotion, stress, and psychophysiology and their impact on health; research into how children grow and develop; management of debilitating chronic conditions such as diabetes and arthritis as well as depression and other mental disorders; and the behavioral aspects of smoking and drug and alcohol abuse, to find ways people can escape addiction. These topics represent some of the most exciting research frontiers today, and our field is poised to make significant strides in a number of scientific areas that a few years ago didn't even exist.

Changes in the Nature of Research.—If we didn't know it before, the recent publicity surrounding the sequencing of the human genome has hit home the notion that we are in a new era of science. In the flurry of interviews and opinion pieces that followed the recent publication of human genome research articles, leaders of the human genome projects and other scientists have repeatedly stressed that genes alone cannot explain complex behavior or account for all risks for developing a particular physical or mental illness or for behavioral problems. They consistently caution against the notion that genes determine behavior. As noted by Robert Plomin, a distinguished APS Fellow and pioneer in the field of behavioral genetics, the influence of genes on behavior is "probabilistic, not deterministic."

The implications of mapping the human genome are enormous for psychological research. Psychologists and other behavioral scientists already are asking such questions as: How do the effects of specific genes unfold in behavioral development? How do they interact with experience and other environmental factors? In other words, now that we have genes, how do they work?

As just one example of what I mean, psychologists soon may be able to use genes to better target behavioral interventions to the people who need them most—to tailor our interventions to those at highest genetic risk. For example, if we learn that certain genes put children at risk for behavioral disorders, say anorexia, depression, or even for diabetes, then those are the children for whom we need to develop specific prevention strategies. For diabetes, this may mean a much more aggressive approach to diet, weight control, and a program to maintain compliance with taking medication, an often-ignored but critically important and totally behavioral part of managing a disease. What this requires, however, is that at the same time we are trying to understand how genes influence behavior, we need to more systematically study the behavior itself and use that information to develop more targeted interventions.

The emergence of fields such as behavioral genetics draws from the progress made both in genetics and behavioral research, and illustrates the seamless connection between behavior and biology—a continuum we would like to see NIH promote more than it does now. Cognitive neuroscience, the combined approach of mapping the brain's psychological functioning onto its physical and biological functioning, is another such area. Unfortunately, NIH's research and training policies sometimes make it appear as if there is an artificial distinction between the behavior and biology. There is excellent behavioral science work being done at NIH, producing quality knowledge and breakthroughs that should be a source of enormous pride for NIH. But too often in the NIH model, behavior is ignored, particularly basic behavioral research. It isn't until a person gets lung cancer, emphysema, heart disease,

liver damage, brain damage, that behavior is thought of. As important as the molecular and cellular origins of these problems are, the behavioral origins are equally important. For example, how do the basics of learning, memory, perception, emotion, or even social development interact with the biology of various diseases? The answer is, there is a great deal of interaction among these factors. Almost none of the disorders NIH addresses can be fully understood without also understanding their behavioral dimensions.

Mr. Chairman, I ask you and the Committee to give your fullest consideration to these concerns as part of your deliberations on the fiscal year 2002 budget for NIH. Specifically, we ask that you help make behavioral research more of a priority at NIH, both by providing maximum funding for those institutes where behavioral science is a core activity, and by encouraging NIH to advance a model of health that includes behavior in deciding its scientific priorities.

Training: A Return on the Investment.—When discussing the budget for NIH and other federally-funded science agencies, we often talk in terms of investment—putting money into activities where the return will be realized somewhere down the road. In providing research grants, sometimes we don't know when or even whether there will be a significant payoff—we have an extensive review system that helps minimize the likelihood of a washout, but still, the outcomes of science are unpredictable.

One part of science where the investment is almost guaranteed to payoff is in the area of training. We know that if we provide support now for a young investigator, we will have a well-trained, highly-qualified scientist as a result. We also know that without training, we will not have an adequate pool of researchers to pick up where preceding generations leave off. Supply is a critical issue in behavioral science at NIH. Right now, NIH institutes are competing for a comparatively small pool of behavioral science researchers. In fact, we are seeing some institutes with new or expanding behavioral science programs enticing senior behavioral grantees from sister institutes, leaving the "old" institutes with critical gaps in their portfolios.

To address this problem, institutes need to "grow their own"—the responsibility for training behavioral scientists should be shared across all of the institutes because of the role of behavior in virtually all of the major health issues being addressed by NIH. Toward this end, several institutes have established B/START (Behavioral Science Track Awards for Rapid Transition) programs of small grants to encourage newer behavioral science investigators. This has proved to be an effective mechanism and should be used across NIH.

But training shouldn't be just an issue of supply and demand. As I noted earlier, health needs should be the most important factor in determining our research and training priorities. In behavioral and social science research, training is essential not only to ensure future supply of scientists, but also to ensure that our Nation's best minds are working on the issues that are most directly linked to health.

Dozens of reports from the National Research Council and the Institute of Medicine have recommended increased training for health and behavior research. One such report, Bridging Disciplines in the Brain, Behavioral and Clinical Sciences, notes that "newly emerging health problems, as well as those that have plagued us over time, are proving to be surprisingly complex as scientists and health care providers begin to recognize the intricate interplay among environment, behavior and disease." The report adds that this is "driving disciplines toward each other" and that "the next generation of scientists must be prepared to integrate the advances of rapidly progressing disciplines." The report nicely complements the changes in the nature of research that I highlighted above.

Meeting the future needs of research in health and behavior means NIH must have a comprehensive training strategy today, a strategy that focuses on training young investigators in the core disciplines of behavioral and social science research as well as in the multidisciplinary perspectives alluded to in the NRC report and elsewhere. In addition to encouraging behavioral science training at individual institutes, NIH needs an overall plan that will minimize unnecessary duplication and will establish an appropriate behavioral science training enterprise that can serve the needs that exist throughout NIH's institutes and offices.

We ask the Committee to support the development, in consultation with the relevant scientific community, of a comprehensive training strategy for behavioral and social science research at NIH. This strategy should include all training mechanisms, and should be balanced between interdisciplinary research and traditional core disciplines in the behavioral sciences.

National Institute of Mental Health (NIMH).—Translational Research—In an effort to more closely link basic and clinical research in behavioral science, NIMH is implementing an institute-wide plan to expand its "translational research" activities that are intended to bring knowledge from the lab into practice, and for practice to

influence what occurs in the laboratory. Responding to recommendations from a report conducted under the auspices of its national advisory council, NIMH is stimulating new connections between basic and clinical research through such mechanisms as: Requests for Application (RFAs); providing greater access to clinical populations and collaborators; workshops connecting basic researchers with public health and clinical investigators; and new peer review procedures that draw on experts from both clinical and basic perspectives. NIMH is also considering support for translational research centers in behavioral science.

Basic Behavioral Research.—We applaud NIMH for its efforts to promote the transfer of knowledge into application. But basic behavioral research at NIMH must continue to receive the same strong support it traditionally receives there. This is important not only to ensure the foundation of basic knowledge in mental health, but also because NIMH is a de facto source of basic behavioral knowledge that is tapped by many other institutes. Until other institutes begin to support larger amounts of basic behavioral science research connected to their mission, it is essential that NIMH's programs of research into behavioral phenomena such as cognition, emotion, psychopathology, perception, development, and others continues to flourish.

We ask the Committee to encourage NIMH's continued efforts to strengthen the ties between basic and clinical behavioral research, and to encourage NIMH's basic behavioral science portfolio in order to ensure continued progress in our understanding of the causes, treatment, and prevention of mental illness and the promotion of mental health.

National Institute on Drug Abuse (NIDA).—NIDA's dramatic progress in addressing the Nation's drug problems (many of which are behavioral in nature) has been accompanied by a broadening of its behavioral science portfolio. Under the leadership of psychologist Alan I. Leshner, NIDA has launched a widescale Clinical Trials Network (CTN) to test drug treatment strategies that have proven effective under controlled research conditions. Most of the interventions currently being tested are based on behavioral treatments, since those have been found to be effective. The CTN was recommended by the 1998 Institute of Medicine report, Bridging the Gap Between Research and Practice, as the single mechanism most likely to improve drug abuse treatment in this country. Given the enormous promise of this initiative to improve the Nation's drug treatment programs and the urgency of the Nation's public health problems associated with drug abuse and addiction, we ask the Committee to increase funds for NIDA's Clinical Trials Network in fiscal year 2002.

In addition to the Clinical Trials Network, NIDA's basic behavioral research helps treatment providers better understand and address the dynamics of addiction. NIDA is placing special emphasis on cognitive research because processes such as learning, memory, decision-making, and other cognitive factors play a central role in virtually every aspect of drug abuse and addiction, including vulnerability, craving, relapse, self-regulation, and treatment. The knowledge from NIDA's basic behavioral science research has enormous potential for reducing demand for drugs at the individual, family and community levels. We ask this Committee to increase NIDA's budget as part of an overall policy of creating a more balanced and effective drug control strategy for the Nation.

National Institute on Alcohol Abuse and Alcoholism (NIAAA).—College-age drinking and underage drinking are two behavioral topics of enormous concern to the Nation's universities, parents, and communities. A subcommittee of the NIAAA national advisory council is completing a report addressing various aspects of campus drinking. The report, being developed jointly by alcohol researchers and college presidents, describes the scope of the problem, examines the effectiveness of current interventions, and will recommend priorities for developing effective, science-based interventions to reduce college drinking.

NIAAA has made substantial efforts to broaden its behavioral science portfolio to understand the underlying psychological and cognitive processes that lead people to drink, and the impact of chronic alcohol abuse on those processes. As one example, NIAAA convened a workshop of national experts on social identification and alcohol research to examine ways that peer pressure in groups and group norms concerning drinking may influence drinking behaviors. More recently, the institute convened a group of experts in cognitive research to explore the effects of alcohol abuse on memory, decision-making, cognitive development, in order to begin looking at issues of cognitive rehabilitation.

Understanding the behavioral origins and manifestations of problem drinking and addiction is the key to addressing the Nation's epidemic of alcohol-related behavioral health problems, which range from brain disease to drunk driving. We ask Congress to increase NIAAA's budget in fiscal year 2002 in order to reduce the Nation's alcohol-related health problems.

National Institute of General Medical Sciences (NIGMS).—NIGMS is the only national institute specifically mandated to support research not targeted to specific diseases or disorders. NIGMS does not now support basic behavioral science research, despite the wide range of fundamental behavioral topics with relevance to a variety of diseases and health conditions. The lack of behavioral science research at NIGMS represents is an enormous gap, given the basic behavioral research and training that NIGMS should be supporting. Congress addressed this issue for the past two years in appropriations reports on the fiscal year 2000 and fiscal year 2001 budgets for NIH. Specifically, you said: "There is a range of basic behavioral research and training that the Institute could support, such as the fundamental relationships between the brain and behavior, basic cognitive processes such as motivation, learning and information processing, and the connections between mental processes and health. The Committee encourages NIGMS to support basic behavioral research and training, and to consult with the behavioral science research community and other Institutes to identify priority research and training areas." NIGMS has not responded to your requests. We continue to believe strongly that NIGMS should develop a basic behavioral science research program. Accordingly, we ask the Committee to direct NIGMS to develop a plan for basic behavioral science research at NIGMS.

National Cancer Institute (NCI).—NCI has expanded its commitment to behavioral research in a comprehensive program that ranges from basic behavioral science to research on the development, testing and dissemination of disease prevention and health promotion interventions in areas such as tobacco use, diet, and even sun protection. Recognizing the central role of effective communication in addressing issues of health and behavior, NCI has also undertaken a major effort to develop science-based communications strategies for disseminating information and persuasive messages about cancer prevention and treatment to the public. These messages draw from a foundation of basic behavioral and social science research into such issues as how people learn and remember health information, how they perceive health risks, and how they are persuaded to adopt healthy behaviors.

One of NCI's scientific priorities in fiscal year 2002 is tobacco-related research. A significant portion of this initiative is devoted to behavioral and social science research into such topics as identifying populations at risk for tobacco use, formulating effective prevention and quitting strategies, and capitalizing on legal, social and public policy developments on tobacco use and addiction.

Other basic behavioral research programs include research to develop theoretical models, identify underlying mechanisms of behavior change, and to develop and test science-based interventions. For example, NCI supports research that examines how stress and psychosocial influences on behavior, the central nervous system, the immune system, and CNS-immune system interactions affect the progression and remission of cancer. Other examples include research into the psychophysiological and genetic processes involved in health behaviors, and the psychosocial and behavioral consequences of cancer risk assessment, including the impact of genetic testing on the individual and the family.

NCI's behavioral research program also supports health promotion research, including behavioral science relating to cancer prevention and program evaluation. We ask Congress to support NCI's expanded behavioral science research and training initiatives.

National Institute on Aging (NIA).—NIA is a major supporter of behavioral and social science research. NIA has reorganized its behavioral and social science programs in order to respond to—and create—new opportunities in the study of aging processes, how older people function in society, and how people change with aging. NIA also looks at the social institutions such as family and the health care system in terms of their impact on the health of older people. Areas of emphasis in NIA's behavioral and social science programs include health disparities, aging minds, health expectancy, health, work and retirement, behavior change, and the interplay among genetics, behavior, and social environment. NIA also supports a significant amount of research in cognitive functioning in its neuroscience and neuropsychology program, which looks at the effects of aging on memory and other brain-based behavioral functioning. We ask the Committee to support NIA's commitment to behavioral and social science research on aging.

National Institute on Child Health and Human Development.—Child development involves some of the most complex and important questions facing behavioral and social science researchers. Understanding the interplay among behavior, social and physical environment, and biology is central to discovering ways to prevent behavior-based health problems ranging from fetal alcohol syndrome to teen pregnancy to violence. NICHD's Child Development and Behavior Branch supports research on the cognitive, social, and emotional development of children from newborns to ado-

lescents. We are concerned that NICHD has received a below-average share of NIH's budget increases in the past few years; what this conveys, whether intended or not, is that children's issues have lower priority in health research. We hope you will send a strong counter-message this year, and allow NICHD to enhance its child development portfolio. We ask the Committee to allocate the necessary resources in fiscal year 2002 to allow NICHD to fulfill its mission in these areas.

On a related topic, NICHD has been supporting the Study of Early Child Care and Youth Development, the most comprehensive study to date of child care experiences and characteristics and developmental outcomes. NICHD is now sharing the rich body of data from the study with other qualified researchers in order to allow an even greater number of researchers to explore issues around child care, including those that may affect child development. We ask the Committee to support this study and NICHD's data-sharing initiative.

NIH Office of Behavioral and Social Sciences Research (OBSSR).—We ask the Committee to welcome Raynard Kington as the new director of OBSSR, and to encourage him, as he contributes his expertise to NIH's "Health Disparities" initiative, to ensure that the full spectrum of behavioral and social science research be brought to bear on this important topic as well as on the other initiatives that are within OBSSR's purview.

Communication Disorders, Visual Perception, Diabetes, Brain and Behavior.—Although space doesn't permit me to describe fully some of the other behavioral science activities across NIH, I want to note the impressive behavioral science work being done in such areas as communication disorders, visual perception, diabetes, and brain research, all of which merits the encouragement and support of this Committee. We ask that in fiscal year 2002, support be given to expanding the behavioral science research and training programs at institutes where this important work is being done.

This concludes my testimony—I would be pleased to answer your questions or provide additional information.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

The American Society of Clinical Oncology (ASCO) represents more than 16,000 physicians involved in cancer research and treatment. ASCO is the leading voice among medical professional societies concerning issues of cancer clinical research. The Society is pleased to have the opportunity to comment on fiscal year 2002 appropriations for the National Institutes of Health (NIH) and the National Cancer Institute (NCI), as well as other issues related to the missions of NIH and NCI. These matters are of great importance to clinical researchers, physicians, and their patients.

FISCAL YEAR 2002 APPROPRIATIONS FOR NIH AND NCI

ASCO applauds the commitment of this Subcommittee and the outstanding leadership of Chairman Arlen Specter and Ranking Member Tom Harkin to doubling the budget for NIH between 1999 and 2003. This panel's commitment has been essential to ensuring predictability and stability in NIH funding and allowing scientists to pursue exciting new research endeavors. We believe the biomedical research effort of this country is so strong largely because of the unwavering support of Congress.

As you know, sustaining progress toward the goal of doubling the NIH budget by 2003 requires a funding boost of 16.5 percent in 2002. We greatly appreciate the budget amendment sponsored by the Chairman and Ranking Member to achieve this effort. We strongly support a 16.5 percent increase for NIH and will work with you toward that goal.

In addition, we recommend that funding for NCI be enhanced in accordance with the Institute's plan and budget proposal for fiscal year 2002 (the "Bypass Budget"). As directed by Congress in the National Cancer Act of 1971, each year the NCI delivers a "bypass" budget directly to the President. This process was implemented to ensure that the President and Congress directly receive NCI's scientific recommendations on the best way to appropriate funds to build on research successes, support the cancer research workforce, and ensure that recent discoveries are translated into improved patient care. For fiscal year 2002, the NCI recommends funding of $5.03 billion, an increase of $1.27 billion. Funding NCI at this level will allow the Institute to fund promising and innovative investigator-initiated research proposals and facilitate research that capitalizes on important advances in molecular biology. ASCO believes the bypass budget includes a persuasive rationale for boost-

ing the NCI budget to $5.03 billion, and we urge the Subcommittee to begin the new millennium by implementing this carefully considered budget proposal.

FUNDING FOR CLINICAL TRIALS OPERATION

If promising basic research advances are to have meaning for Americans, they must be translated into medical practice. This translation process can only be accomplished through clinical research. NCI provides essential support for cancer clinical research. NCI-sponsored trials represent at least half of all cancer trials. Unfortunately, NCI does not provide adequate funding to support the grants they award. ASCO funded three surveys in September 1998 to examine (1) oncologists' experiences and perceptions associated with clinical trial participation; (2) pharmaceutical industry participation in clinical trials; and (3) the costs associated with conducting clinical trials. The surveys indicated that physicians prefer to participate in NCI trials, especially those conducted through the cooperative cancer groups. They report that these trials are exceptionally well designed, respond to the critical goals of oncology, and are intellectually challenging. Participating in these trials, however, amounts to an act of good will, since physicians lose money on every NCI trial they conduct.

Conducting a clinical trial requires tremendous resources for a physician practice. These resources include trained research nurses and data managers and the computer equipment needed to compile and analyze the data. In fact, it takes 15 separate activities to enroll patients and conduct a clinical trial. The most time-consuming of these activities include recruiting patients, seeing patients in the physician's office, and completing forms. Overall, 200 hours of work are required to see one patient through the clinical trial process. Our 1998 survey found that the average cost to enroll a patient in a clinical trial is $2,000 per patient. Current NCI reimbursement is $1,500 per patient.

Our ability to find better cancer treatments and improved understanding of this dreadful disease are inextricably linked to a thriving clinical research network. Without proper reimbursement, physicians will be pressed to devote less time to clinical research—especially with the pressure that managed care is placing on practices to seek higher reimbursements. If trials are adequately funded and supported, we could shorten the length of time it takes to complete patient accrual—thus quickening the time it takes to complete research and improve patient care. We will not reap the full rewards of our increased investment in NIH and NCI unless we provide adequate support to the physicians who are conducting clinical trials.

CLINICAL RESEARCH STUDY SECTION

Investigator-initiated clinical research proposals have not fared well historically at NIH because they have been reviewed by basic researchers who are not well versed in patient-oriented research. ASCO has maintained that allowing the proportion of reviewers for such patient-oriented research proposals to be dominated by basic researchers is inequitable, a position endorsed by several blue ribbon panels charged with oversight of the NIH peer review process. Furthermore, physician scientists' success in obtaining NIH funding for investigator-initiated research has a significant impact on their willingness to remain in the field, according to reports. Therefore, the research review process has a significant impact on today's clinical research and on the future of patient care.

ASCO has previously brought the issue of peer review of cancer clinical research to the attention of this Subcommittee, and the panel has supported efforts to improve the grants evaluation process. As a result of Subcommittee directives to the NIH, the Center for Scientific Review (CSR) appointed a special emphasis panel (SEP) to review clinical oncology research proposals. The Clinical Oncology (CONC) SEP is composed of clinical researchers who have the expertise and experience to evaluate cancer clinical research proposals. We are pleased that a number of clinical oncologists sit on the CONC SEP, and reports on its work have been positive. We are also pleased that CSR is currently in the process of making the CONC SEP into a permanent study section. We believe this will result in a system of fair and informed review of clinical oncology research.

Through this transition and the larger CSR transformation of the Integrative Review Group (IRG) system, we remain chiefly concerned that clinical oncology research proposals are reviewed by committee members with expertise in patient-oriented research. External NIH advisors have consistently recommended that NIH avoid a review process where basic researchers dominate the review of patient-oriented research proposals. A majority of the membership of panels reviewing clinical research should have experience in reviewing and/or conducting patient-oriented research. ASCO urges the Subcommittee to renew its directive to NIH officials to

maintain a peer review system that has researchers with patient-oriented research expertise making up the majority of researchers reviewing cancer clinical research proposals. The Subcommittee's involvement will be particularly timely, as CSR is currently in the process of appointing steering committees and study teams to begin work on organizing the Oncological Sciences IRG in the coming months. ASCO believes that a rigorous peer review system is fundamental to a strong clinical research effort.

CLINICAL TRIALS COVERAGE

ASCO has worked for several years for enactment of the Medicare Cancer Clinical Trials Coverage Act, which would require Medicare to reimburse the routine patient care costs for those enrolled in cancer clinical trials. We are pleased that President Clinton responded to our decade-long legislative effort by issuing an Executive Memorandum last year that provides Medicare coverage of the routine patient care costs of those enrolled in trials. The new Medicare policy lays the groundwork for increasing seniors' participation in clinical trials—thereby improving their access to state-of-the-art care and speeding the translation of research discoveries into effective patient treatments.

We are continuing our work to ensure that enrollees of private-sector health plans have access to this same quality cancer care. We have been actively involved in efforts to ensure clinical trials coverage provisions in the Patients' Bill of Rights. Although coverage for routine patient care costs is not technically a matter for this Subcommittee, assurance of such coverage is critical to the efficiency of the research enterprise and is therefore surely a concern for this panel. Only if treatments can be tested in clinical trials can clinical researchers determine their effectiveness. If reimbursement denials or the fear of such denials slow accrual to clinical trials, this will adversely affect the ability of researchers to answer questions about new treatments. ASCO believes it is absolutely necessary that barriers to enrollment in clinical trials, including possible reimbursement uncertainties or denials, be eliminated.

ASCO appreciates the opportunity to submit its views on NIH funding and clinical research. On behalf of oncologists and their patients, we urge Congress to continue its strong support of NIH. We also recommend that special attention be paid to the clinical research enterprise to ensure that basic research findings are promptly brought to the patient bedside.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

The United States is approaching a serious shortage of medical laboratory personnel. The vacancy rates for seven of ten key laboratory medicine positions is at an all time high.

Vacancy rates for cytotechnologists, the professionals who interpret cellular material such as Pap smears, and histotechnologists, the individuals who prepare tissue specimens, are at a disturbing high of over 20 percent. This is a cause for immediate concern as some laboratories will not have the appropriate personnel available to evaluate Pap smears or prepare biopsies.

The American Society of Clinical Pathologists' Board of Registry, in conjunction with MORPACE International, Inc., Detroit, conducts a biennial wage and vacancy survey of 2,500 medical laboratory managers. The survey measures the vacancy rates for 10 medical laboratory positions, and compares and contrasts these data with that from 1988, 1990, 1992, 1994, 1996, and 1998 studies. The data for 2000 was published in March 2001, and this statement gives a glimpse of what was found.

Vacancy rates for cytotechnologists in the northeast average 45 percent, 16.7 percent for the east north central, and 33.3 percent for the far west. Rural areas average a 20 percent vacancy rate for cytotechnologists, and large cities a rather surprising 28.3 percent rate.

Private reference laboratories have an average vacancy rate of 20 percent for histotechnologists, and hospitals have a 37.7 percent shortage of the same profession. The west south central region of the country has a 73.7 percent vacancy rate for histotechnologists, and the south central Atlantic states have an average vacancy rate of 16.7 percent.

By comparison, the vacancy rate for medical technologists will not appear to be of concern, but it too is reason for concern. Medical technologist vacancy rate averages 11.1 percent, but rural areas show 21.1 percent vacancy and hospitals with 100–299 beds have a rate of 17.6 percent.

MEDICAL LABORATORY PROGRAMS

One of the logical solutions to this vacancy rate problem is to train more students; however, the number of programs are decreasing.

According to the "Health Professions Education Directory" published by the American Medical Association, the number of medical technology programs decreased from 383 in 1994 to 273 in 1999. The number of graduates in medical technology has similarly decreased from 3563 in 1994 to 2491 in 1999, a 30 percent decline in five years.

ASSESSMENT

There are several reasons why the vacancy rate is increasing and the number of program enrollees is decreasing. A number of available positions are outside the traditional clinical laboratory. Some program directors have reported that graduates are gaining employment in laboratory information systems companies, "dot.coms," and corporations that manufacture or distribute diagnostic reagents, supplies or equipment. With limited resources, hospitals have merged, thus decreasing the availability of training sites for medical laboratory programs. Some programs have responded by increasing access to other laboratory training sites, such as forensics laboratories, blood centers, physician offices, and outpatient clinics. Yet, with these shifts, the continued demand for laboratory services is real and is expected to grow.

In Pennsylvania, according to the Bureau of the Census, the population is projected to grow by 3 percent by 2020, and the population over age 65 is projected to grow by 24 percent in the same time period. In Iowa, the population is projected to grow by 4 percent by 2020, and the population over age 65 is projected to grow by 37 percent in the same time period.

Given the country's aging population, the number and complexity of biopsy specimens and the use of molecular techniques will likely increase during the next decade. Laboratory professionals who entered the workforce in the 1960s and 1970s will be retiring soon. Also, the threat of bioterrorism calls for trained laboratory professionals to respond. The laboratory-allied health workforce will need to be able to react accordingly with appropriate numbers of trained and educated personnel.

SOLUTIONS

There are solutions to these problems. There are grants available to help attract laboratory professionals to the field, especially minorities and individuals in rural and underserved communities. The Allied Health Project Grants program, administered by the Health Resources and Services Administration, has been successful in effectively attracting new allied health professionals into the laboratory field.

For example, the University of Nebraska Medical Center established medical technology education sites in four communities in rural Nebraska, including a student laboratory in central Nebraska, under an Allied Health Project Grant. As of 1999, of 69 graduates, 99 percent took their first job in a rural community, and 74 percent took their first job in rural Nebraska.

The grants are also designed to create successful minority recruiting and retention programs for medical technologists. This was the focus of a University of Maryland, Baltimore project initiated by allied health grant funding in 1991. Through utilizing a four phase design, which begins with career awareness activities for elementary and middle school students, this model provides a continuum of activities that progressively focuses on identifying, retaining, and advancing interested students to the completion of a baccalaureate degree. Because of this program, the University of Maryland, Baltimore has attained a current 70 percent minority medical technology student enrollment at a majority institution, and an average 89 percent student retention rate, placing it among the highest in the country. 95 percent of the graduates of this program receive immediate placement.

Most allied health grant projects continue after federal funding ends, making them a long-lasting, worthwhile investment in the future of allied health.

While allied health professionals comprise more than 60 percent of the entire health care work force, and number more than 3 million individuals, the attention paid to these health professionals is rather small. Allied health professionals are involved in the prevention, identification, monitoring, and evaluation of diseases, disabilities and disorders. The Allied Health Project Grants program is a relatively small step in assuring that funding is available to attract allied health professionals to the professions and to underserved communities, but, given the critical shortages mentioned, it needs to be taken quite seriously.

We respectfully request funding for the Allied Health Project Grants in the amount of $21 million.

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

Thank you for this opportunity to submit written testimony for inclusion in the hearing record.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) gratefully acknowledges Congress' increased support for the Centers for Disease Control and Prevention (CDC), particularly for the CDC's National Center for Infectious Diseases (NCID), which supports programs to address emerging and drug resistant infectious diseases, public health infrastructure, bioterrorism preparedness and food safety. The CDC is the primary agency responsible for guarding the public's health, including protecting the nation against potentially life threatening infectious diseases. The ASM appreciates Congressional recognition for CDC's role in responding to the threats of emerging infectious diseases and encourages Congress to maintain and renew that support.

The ASM endorses the recommendation of the CDC Coalition to increase the overall CDC budget to $5 billion in fiscal year 2002 to provide additional new resources for CDC programs focused on national and global health and security. The CDC is called upon constantly to identify, control, and prevent outbreaks of disease here and abroad. For the past fifty years, members of the CDC's Epidemic Intelligence Service have helped solve microbial mysteries, such as the recent outbreaks of Legionnaire's disease at a Cleveland automotive plant and the unexpected arrival in New York of West Nile encephalitis. Despite this nation's successes against certain diseases, our public health system continues to be at risk from both new and re-emerging infectious diseases, from threats of bioterrorism and antibiotic resistant pathogens, and from an aging public health infrastructure. These areas are of particular concern to the ASM, which represents more than 42,000 members from a broad spectrum of microbiology-related professions, including microbiologists who work in biomedical, clinical, public health, and industrial laboratories.

Prevention strategies promoted by the CDC promise significant rewards in the form of improved public health. Likewise, strong financial support for the CDC will give Americans both a healthier society and cost-saving benefits. The multi-billion-dollar cost of microbial diseases in this country alarms all of us. Foodborne diseases alone cost the national health care system more than $3 billion per year, added to annual lost productivity estimated at $8 billion. On a global scale, the CDC's participation in eradication campaigns like that against polio also promises high returns: the United States would save more than $230 million annually in vaccine costs, and worldwide the estimated savings would exceed $1.5 billion. Investment in a stronger CDC undoubtedly will yield measurable positive results in the form of disease identification and control, helping to fulfill the CDC's vision of a healthier 21st Century. Investment in CDC will also enhance national and global security, both economic and political. For these reasons, the ASM asks Congress to respond aggressively to threats from infectious diseases with generous support of the Centers for Disease Control and Prevention.

INFECTIOUS DISEASES—THREATS TO NATIONAL AND GLOBAL HEALTH AND SECURITY

Microbial pathogens and the diseases they cause persist as a leading cause of death worldwide and in the United States. In today's global society, it is possible for a new disease to spread internationally within days, perhaps hours. It is alarming to realize that infectious diseases would cause even more deaths in this country if it were not for a persistent federal assault against these pathogens.

The CDC's vision for the 21st Century is "healthy people in a healthy world—through prevention." Toward this goal, the CDC launched a nationwide effort to protect the public from infectious diseases that includes surveillance and response, applied research, infrastructure and training, and prevention and control. In 1998 the CDC developed a comprehensive plan, "Preventing Infectious Diseases: A Strategy for the 21st Century," listing a sobering array of new and re-emerging infectious diseases and the obstacles that make stopping these diseases so difficult. Last year, Congress passed the Public Health Threats and Emergencies Act to strengthen the public health infrastructure in the areas of antimicrobial resistance, bioterrorism and major infectious disease outbreaks.

New and re-emerging infectious diseases pose unique challenges to the CDC in its role as the nation's prevention agency. More than 35 new infectious diseases have been identified since 1973, among them those caused by HIV, *E. coli* O157:H7, and airborne Ebola virus. The ever-changing threats posed by infectious diseases demonstrate the importance of a public health infrastructure capable of rapid and accurate disease identification and prevention anywhere in the United States or abroad. On-call CDC personnel consistently assist local and state health departments across the United States in identifying outbreaks due to such emergent microorganisms as the West Nile virus.

First described in New York State in 1999, West Nile encephalitis spread to a wider area during the summer of 2000, carried by mosquitoes and underscoring the need to rebuild our capability to deal with vector-borne diseases. The CDC's response illustrates its four-pronged approach—surveillance and response; applied research; infrastructure and training; and prevention and control—to protect the public against infectious diseases. The agency developed a national electronic surveillance system (ArboNet) to track the virus in humans, birds, mosquitoes and horses. It also helped develop rapid laboratory tests to detect the presence of the virus, as well as a DNA vaccine that thus far looks promising in animal studies. Funding to 49 state and local health departments and related training sessions and educational materials enhanced the public health system's chance of stopping the virus. To prevent spread of the virus, the CDC formulated a large-scale emergency plan for mosquito control in affected areas.

A similar multifaceted CDC program is in place against hepatitis C viral infection (HCV), a relatively recent problem in the United States. HCV is the most common chronic bloodborne viral infection in the United States, where it has infected more than 4 million people, nearly 75 percent of whom remain chronically infected. Persistent infection often leads to serious medical conditions, possibly cirrhosis or liver cancer; in fact, an estimated 40 to 60 percent of chronic liver disease is due to this virus. The CDC supports a national survey of blood collection centers and hospital transfusion services to determine the progress of notifying transfusion recipients who received blood from donors who later tested positive for HCV, works with state and local health departments to coordinate activities including viral hepatitis education and counseling, testing, referral, surveillance and vaccination efforts, and coordinates the Hepatitis C Public Information Campaign. CDC will continue to fund new studies to monitor the transmission of HCV among various populations, enhance support for state and local health department programs, and develop and provide training to healthcare professionals.

New infectious diseases are not the only menace to public health. Historic killers such as malaria and influenza continue to challenge national and global health systems. Of all the emerging and re-emerging infections, influenza has the greatest potential to cause catastrophic morbidity, mortality, and social disruption both locally and globally. Three pandemics in the past century were grim reminders of how dangerous influenza can be. The CDC actively supports influenza surveillance in other countries, to monitor for variant viruses that may cause new pandemics. Agency mathematical models suggest that an influenza pandemic could result in a five-fold increase in U.S. deaths, compared with non-pandemic years. In a typical year, the disease causes an average of 20,000 deaths in the United States, along with more than 110,000 hospitalizations. Each year brings new influenza viruses and fears of even more serious U.S. epidemics, during which up to 40,000 deaths and 200,000 hospitalizations can occur. The CDC counters such persistent problems with long-term, year-round surveillance both in the United States and in countries known to be sources of new viruses. As with other diseases, the agency also works to improve individual states' ability to respond to epidemics and to strengthen the international network of laboratories and personnel able to identify outbreaks. Recognized as a global leader in responding to any disease outbreak, the CDC must be provided with sufficient resources to improve its readiness for any future pandemic.

Antibiotic resistance in pathogens and the threat of bioterrorism have further complicated the current global infectious disease crisis, forcing health officials to rethink our approach to both old and new infectious disease. Overuse of antibiotics contributes to a rising incidence of microbial mutants resistant to the traditional therapeutic-of-choice. In some areas of the United States, more than 30 percent of pneumococci resist penicillin, a drug once effective against virtually all pneumococcal pneumonia and meningitis. More than 90 percent of strains of *Staphylococcus aureus* in U.S. hospitals are resistant to penicillin; these strains now are spreading into the general community. Other common infections, such as gonorrhea and salmonella, also are becoming more difficult to treat. The cost of resistant diseases is significant: the U.S. health care system spends an estimated $1.3 billion, annually, on the treatment of nosocomial infections caused by resistant organisms. It normally

costs $2,000 to treat a patient for tuberculosis in this country, but if the tubercle strain is resistant, that cost may be inflated 100 times.

On January 18, the Department of Health and Human Services released its plan to combat antimicrobial resistance, to be led by the CDC, the Food and Drug Administration (FDA) and the National Institutes of Health. The plan, which provides a blueprint for coordinated federal action, has four components—surveillance, prevention and control, research, and product development. CDC personnel and collaborators will work with state health departments and others to coordinate and improve surveillance methodologies. The CDC already has begun preparation of clinical guidelines for health professionals on the best use of antimicrobials and on infection control practices, to prevent the spread of drug resistance. With the FDA and the U.S. Department of Agriculture, the CDC is monitoring resistant nosocomial infections in 300 hospitals in 15 states. This program complements the CDC's National Nosocomial Infection Surveillance System (NNISS) already in place, a prototype system for preventing adverse health care events. An estimated 44,000 to 98,000 Americans die each year from preventable medical errors, which include nosocomial infection. In the past decade, hospitals participating in the NNISS have had a 30 percent decline in targeted infections.

Substantial funding and flexibility is needed to enable CDC to fully implement the goals set forth in its strategic and comprehensive plan against emerging and reemerging infectious diseases. The ASM recommends an additional $120 million in fiscal year 2002 to achieve such goals as improving the detection and prevention of emerging pathogens, communicating among all levels of government health agencies, and integrating laboratory science with on-site epidemiology.

BIOTERRORISM PREPAREDNESS AND RESPONSE

Unfortunately, emerging infectious diseases and drug-resistant pathogens could also be used in terrorist attacks. The CDC considers bioterrorism as part of its mission against emerging infectious diseases here and abroad. It is worrisome that there is no guarantee that the nation's current public health infrastructure could adequately respond to a bioterrorist event. CDC has joined other federal agencies in implementing new programs and expanding others to include counterterrorism capabilities.

To diminish our vulnerability to such attacks, the CDC will continue to focus its attention on laboratory capabilities at CDC and at State and local health department levels; on the development and implementation of rapid diagnostic tests for biological agents; on surveillance activities with hospitals, health clinics, private and commercial laboratories, as well as with veterinary and agriculture partners; on electronic communication capacity at the local level with the Health Alert Network (HAN) and the National Electronic Data Surveillance System (NEDSS), designed to collect, analyze and interpret health-related data in a timely and efficient manner; and on public health preparedness and readiness activities such as the education and training of both public and private health care personnel, firefighters, police officers and emergency medical technicians.

In fiscal year 2002, ASM recommends that Congress provide an additional $100 million for CDC to continue and expand these activities to respond to the threat of bioterrorism.

BUILDINGS AND FACILITIES

In protecting American health and safety, the CDC puts science into action, shares vital information, and creates partnerships with public and private groups concerned with public health. But unless the CDC's buildings and physical infrastructure receive more funding from Congress, its ability to respond to disease anywhere, anytime, could be seriously undermined. The expansion of CDC's responsibilities around the world and in the United States has stretched thin the agency's infrastructure. CDC buildings in Atlanta cannot house the current staff and about half of that workforce labors in nearly two dozen leased offices around Atlanta. Much of CDC's laboratory equipment is outdated. According to the agency, at present 70 percent of its infectious disease scientists and all of its parasitology and environmental health specialists work in highly inadequate and potentially hazardous laboratories. Last year the CDC began a phased 10-year improvement of its Atlanta facilities. As a result, phase I of the infectious disease laboratory was completed and opened, and phase II will be completed this fall. In addition, the emerging infectious disease laboratory is currently being designed and construction has begun on parasitology and environmental health laboratories. The ASM appreciates Congress' attention to CDC's physical infrastructure needs and urges an additional $175 million in fiscal year 2002, for the construction of the emerging infectious dis-

ease laboratory, the design for the environmental toxicology laboratory and routine maintenance projects nationwide.

Thank you for the opportunity to submit ASM's recommendations for the hearing record of the House Appropriations Subcommittee on Labor, Health and Human Services, and Education, for the CDC's fiscal year 2002 appropriation.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) appreciates the continued bipartisan support of Congress for the National Institutes of Health (NIH). Through generous appropriations over the past years, Congress has brought biomedical research to the forefront of the national agenda and recognized the NIH's pivotal position in serving the American public through the support of biomedical research. Increased support for NIH not only helps to ensure the continued leadership of the United States in biomedical research, but it will also allow the United States to address the global health issues in infectious diseases that currently threaten national security.

The ASM commends President Bush's proposal for a record $2.8 billion increase for the NIH in fiscal year 2002. This proposed increase is a major step toward meeting the bipartisan goal set by Congress of doubling the NIH budget by fiscal year 2003, enabling the Institutes to take greater advantage of the many recent significant discoveries affecting human health.

Within the past few years we have seen exponential advances in knowledge in the biomedical sciences. The landmark advances of decoding the human genome and sequencing over 30 bacterial genomes, discovering new treatments for AIDS, and developing vaccines that can prevent meningitis and ear infections in children are only a few of the many accomplishments that have set the stage for an even more explosive growth in the benefits derived from NIH research.

The opportunities for substantial return on investment in biomedical research have never been greater, and it is essential that the NIH be supported at a level to take full advantage of promising existing and new areas of basic and clinical research. According to a report of the Joint Economic Committee, public investment in NIH yields returns to the economy of 25 percent to 40 percent per year. The development of the Hemophilus influenzae vaccine to prevent meningitis in children, for example, has saved an estimated $400 million yearly in treatment and long-term care costs.

At the same time, we are being challenged by emerging and existing infectious diseases, increasing resistance to antibiotics, and accumulating evidence pointing to an infectious cause for many chronic diseases, such as arthritis, heart disease, and some forms of cancer. In addition, each year the cost of illness in the United States totals an estimated $3 trillion in health care and lost productivity, representing 31 percent of the gross domestic product. The entire NIH budget equals less than 1 percent of this annual health-related burden on the national economy.

The ASM, therefore, joins with the Ad Hoc Group for Medical Research in endorsing an fiscal year 2002 budget increase of $3.4 billion (16.5 percent) for NIH to ensure we reach the goal of doubling the NIH budget by fiscal year 2003. Such an increase will also enable the NIH to increase the total number of research project grants it supports, thereby pursuing a greater number of scientific opportunities, and to expand training programs, ensuring an adequate scientific workforce that can translate research discoveries into significant patient care advances.

PUBLIC HEALTH NEEDS AND INFECTIOUS DISEASES

Past investments in medical research clearly have benefited both the United States and the world in terms of improved health care and increased understanding of disease. However, the ASM is concerned about the continuing onslaught of infectious diseases, a threat directly confronted by NIH-sponsored research. In the United States, infectious diseases remain a leading cause of death, with five of the top ten killers related to infection (pneumonia, AIDS, chronic liver disease, chronic obstructive lung disease and cancer). The estimated annual cost of infectious disease in this country exceeds $120 billion. Worldwide, infections account for more than 13 million deaths each year, potentially undermining both the political and the economic security of nations. Seven of the 20 leading causes of global death and disability are infectious diseases.

We can expect previously unknown infectious diseases—as well as old diseases with renewed virulence—to continue to imperil public health. Microbial diseases that appeared just in the last 25 years include legionnaires' disease, HIV/AIDS, Lyme disease, human cases linked to mad cow disease, airborne Ebola virus infec-

tion, and toxic shock syndrome. Medical researchers have identified nearly 40 new disease agents since 1973, some capable of massive destruction. In 1998, HIV/AIDS was the fourth leading cause of death worldwide, responsible for an estimated 2.3 million deaths that year. In the United States, pathogens such as hantavirus from rodents, the West Nile virus, and last year's new hemorrhagic fever virus (the Whitewater Arroyo virus) appeared during the past decade without warning, claiming human lives and placing new demands on our health care system. A recently described hepatitis virus, type C, infects almost 4 million Americans. Although numbers of new infections have decreased due to better public health efforts, about 9,000 die from HCV each year and many more may develop chronic liver disease. HCV is the leading cause of liver cancer and one of the major reasons for liver transplants.

In recent years there has been a resurgence of several long-time enemies of public health, historic diseases revitalized by acquired antibiotic resistance and expedited by global travel and commerce. Increasingly resistant to traditional therapeutics, malaria continues to ravage the world's populations, killing an estimated 1.1 million each year and infecting 275 million new victims. In response to such alarming statistics, the NIH is leading a multilateral initiative against malaria, hoping to maximize research against the disease in Africa. Another long-time threat, tuberculosis kills about 2 million people each year and persists as the eighth leading cause of death worldwide, with fully one-third of the global population infected with the tubercle bacterium. Once treated effectively with drug regimens, bacteria causing tuberculosis are developing multiple drug resistance. Not just a problem in developing countries, this more-virulent form of tuberculosis has now spread to several larger American cities, a disturbing trend in a health care system where antibiotics have become the second most commonly prescribed category of drugs.

Other pathogens, such as salmonella, Staphylococcus aureus, enterococci, and the gonorrhea bacterium, are similarly acquiring drug resistance, becoming more serious problems in our nation's hospitals. More than 90 percent of S. aureus found in U.S. hospitals are now resistant to penicillin and beta-lactam antibiotics, for example. In intensive care units, nearly one-third of hospital-acquired nosocomial infections are resistant to the preferred antibiotic treatment. Nosocomial infections caused by just six of the most common kinds of resistant bacteria cost the United States at least $1.3 billion annually. In response, the NIH, CDC and FDA just released the Antimicrobial Resistance Action Plan, a comprehensive, multidisciplinary collaboration with private and public groups to include surveillance, prevention and control, research, and product development. NIH will lead the research component, towards new information and technologies and support of clinical studies.

Among newly recognized infectious agents are those now believed linked to chronic disorders heretofore attributed solely to environmental or lifestyle factors, thus further complicating our efforts to improve the public's health. This new concept of infectious diseases will force a reassessment of chronic disease—one example of how NIH's focus will change in a new era of medical research. Medical experts estimate that infectious agents cause 16 to 20 percent of all cancers, and may be the underlying causes of common chronic diseases such as diabetes, multiple sclerosis, chronic lung conditions, and coronary artery disease. Specific infectious agents already have been indicted in certain conditions: for instance, Helicobacter pylori in peptic ulcers and *Borrelia burgdorferi* in some forms of arthritis and brain disorders. With advances in genomics, it now is possible to identify non-human genetic material in human diseased tissues, making this new field of medical research feasible. Investment of research dollars promises high returns, as suggested by estimates that more than 50 percent of stomach and cervical cancers could be avoided by preventing their suspected infectious disease etiologies.

Not only must the NIH focus on infectious diseases in this country, it also must address the cumulative burden of disease worldwide. Infectious disease agents easily cross national boundaries, creating a global health interdependence that impacts the health, economics and foreign policy of the United States. Infectious disease has become a national security issue, as we become tightly connected to the rest of the world physically, commercially and culturally. High incidence of mortality and disability can intensify social and political instability in countries where the U.S. has significant economic and political investments. Infectious diseases also raise the possibility of bioterrorism through deliberate spread of dangerous microorganisms. The NIH, through its research on diseases that primarily affect other countries—such as malaria and cholera—accepts a responsibility towards fighting global infectious disease. The ASM urges Congress to recognize the NIH's role in national security when determining the fiscal year 2002 budget.

THE NEED FOR BASIC MICROBIOLOGY RESEARCH AND NIH FUNDING

Scientific knowledge of microbes and their link with larger life has expanded exponentially in the last half of the 20th century. Scientists studying microbes discovered that DNA was the genetic material of life. Many believe that the future of humankind depends on our ability to understand microbes and how they work and to take advantage of their abilities to solve some of humanity's most difficult problems, including the prevention and treatment of infectious diseases.

The path of scientific investigation will shift in the coming decades, with new funding needed for a broader scientific base that will require much more multidisciplinary research. Genomics is just one aspect of the increasingly complex research enterprise needed to combat the diseases that afflict humankind. Conquering disease requires additional emphasis on environment and infectious disease. In particular the physiologies of organisms, that is the actual functioning of organisms from microbes to humans, requires multidisciplinary inputs. Institutes like the National Institute of Environmental Health Sciences need to do more in areas such as the environmental reservoirs and transport of pathogens so that we can understand the epidemiology of many environmentally borne infectious diseases and act judiciously to prevent them. Studies on the interactions of genetics, environment, and infectious diseases is critical for preventing and treating many human diseases.

Immediate attention is needed to reverse the decline in the field of microbial physiology or we risk losing ground in medical and environmental research and discovery. The once flourishing field of basic (prokaryotic) microbiology is no longer receiving sufficient attention. The decline in funding devoted by the NIH to bacterial physiology is compounded by the limited budgetary growth of other agencies, such as the National Science Foundation, to support the basic cellular biological studies of prokaryotes. Given that an understanding of bacterial physiology is a critical underpinning to overall cellular studies that are key to the advancement of the broader life and biomedical sciences, the NIH would be well served by coordinating with other agencies to ensure the adequacy of funding for bacterial physiology. This would be an important step for overcoming the shortage of qualified scientists with training in bacterial physiology to fill the employment opportunities available in biotechnology and biomedical research laboratories The ASM recommends that NIH recommit itself to rebuilding support for this critical area and to take steps such as training grants and requests for proposals to increase the number of laboratories, institutions, and scientists working in this area.

The ASM emphasizes the importance of providing increased support for the basic, untargeted research in the biomedical sciences supported by the National Institutes of General Medical Sciences (NIGMS), which provides the fundamental underpinning for all the disease-oriented research done by other NIH Institutes. If we are to sustain the momentum of NIH research in the future—and to build upon the notable advances made in recent years—it is important to recognize that basic and clinical research both are indivisible segments of successful medical science. Basic science is at the heart of what the NIH and research institutions do best. Basic research is the engine that drives scientific creativity and productivity making sustained funding for new research projects a particularly critical issue when deciding the fiscal year 2002 budget. There must be a high-quality continuum of not only new projects, but new scientist training programs, to keep American medical science of the future as vigorous as it is today. We also need more physician-investigators trained to translate discoveries into patient care and lives saved.

REQUIREMENTS FOR TODAY'S RESEARCH

Technological innovation may become the most visible hallmark of research in the 21st century, but it is just one aspect of an increasingly complex and expensive system needed to combat infectious diseases and other threats to national and global health. It is essential that financial support of the NIH includes sufficient funds for all facets of the research process, whether state-of-the-art DNA sequencing equipment or increased stipends for scientists-in-training.

New pathways to medical discoveries rely upon a complicated, interlocking framework of scientific infrastructure, which needs to be updated with an infusion of federal funding. Skilled personnel and premier research facilities are the foundation of U.S. research and make medical advances happen. The more the research landscape changes, the more researchers must have expertise outside the traditional boundaries of their disciplines, and research facilities must make this cross-pollination possible. The fields of bioinformatics, imaging, and computer science will repeatedly meld with biology and chemistry. These scientific cross-currents will require new and creative training programs to produce interdisciplinary scientists, as well as greater financial incentives to retain the best of these at federal research centers.

RESEARCH STEWARDSHIP FUNDING

The management and support budget of the NIH is decreasing as a percentage of the agency's entire budget, a trend that negatively affects the best administration of federal research dollars. This deficiency undermines the strength of the NIH and its promise to the American public to improve health and well-being.

ECONOMIC BENEFITS

Medical advances in the past have directly minimized the cost of specific diseases. The United States spent a total of $32 million over 10 years to support the global smallpox campaign. Economists estimate that, every 2½ months since the world was declared smallpox-free in 1977, the entire $32 million has been recouped in health cost savings. The ongoing anti-polio campaign promises similar results: The United States will save more than $230 million annually in vaccine costs, while globally, the annual savings is expected to exceed $1.5 billion. At the NIH's National Institute of Allergy and Infectious Diseases, research costing $31.8 million produced the hepatitis B vaccine, saving our health care system an estimated $73.7 million to $146.6 million each year. But the price of illness in this country will grow if we are not prepared to confront all new and costly diseases, such as antibiotic-resistant infections and the inevitable yet-unknown pathogens. The NIH, and specifically, the National Institute of Allergy and Infectious Diseases (NIAID), is at the center of a national mission to stop these diseases, a mission that must be adequately funded in the fiscal year 2002 budget.

The American Society for Microbiology, the largest single life science society with over 42,000 scientists, appreciates the opportunity to provide these recommendations to the Senate Subcommittee on Labor, Health and Human Services and Education Appropriations and stands ready to assist the Subcommittee in any way possible.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE

The American Society of Tropical Medicine and Hygiene (ASTMH) appreciates the opportunity to submit testimony to present our views on fiscal year 2002 funding priorities to the Subcommittee.

The ASTMH is a professional society of 3,500 researchers and practitioners dedicated to the prevention and treatment of infectious and tropical diseases. The collective expertise of our members is in the areas of basic science, medicine, vector control, epidemiology, and public health.

The staggering burden of tropical and infectious diseases confronts us on a daily basis. Poor health and the spread of infectious disease across borders have profound effects on the social and economic development and stability of nations around the globe. With the enormous volume of travel and trade today, and with the expanded deployment of American troops, infectious diseases can affect populations around the globe within 24 hours. The globalization of infectious disease has brought an increased realization that infectious diseases represent not only a humanitarian concern but also a bona fide threat to the health and national security of the United States.

Now more than ever, we must be vigilant in our efforts to control and eradicate infectious diseases. In this new millennium, we must marshal the efforts of government, industry, international organizations and private foundations if we are to protect our national security against biological and chemical attacks and protect Americans against infectious diseases and antimicrobial resistance. Tuberculosis (TB) and malaria are renewed threats because they are becoming increasingly drug resistant. Monitoring, preventing, and controlling antimicrobial resistance requires sustained effort, commitment, and collaboration among public and private sectors, with support and leadership from the Federal Government.

NATIONAL INSTITUTES OF HEALTH (NIH)

The Society thanks the Subcommittee for your strong leadership in the area of biomedical research and for pursuing budget increases that will effectively double the NIH budget by fiscal year 2003. Investments in NIH have led to an explosion of knowledge that promises to advance our understanding of the biological basis of disease and unlock new strategies for disease prevention, diagnosis, treatment, and cures. Congress responded to these opportunities by pursuing, in a bipartisan fashion, an effort to double the NIH budget over the five-year period of fiscal year 1999 to fiscal year 2003—and we are now over halfway to that goal. The ASTMH joins

the Ad Hoc Group for Biomedical Research Funding in urging you to maintain support for the Congressional campaign to double the NIH budget. We seek your support for an appropriation of $23.7 billion for NIH in fiscal year 2002. This $3.4 billion (16.5 percent) increase represents the fourth step toward the bipartisan goal of doubling the NIH by fiscal year 2003, and will allow promising research avenues to be pursued, including the development of new vaccines and drug therapies for diseases such as malaria, TB, dengue fever, cholera and other diarrheal diseases, HIV/AIDS, and a myriad of other viral bacterial, fungal, and parasitic disease agents.

As a result of the increased funding of the NIH, new scientific and research opportunities are being pursued that hold the potential to prevent and control tropical and infectious diseases around the world. Infectious diseases are the second leading cause of death worldwide, accounting for over 13 million deaths (25 percent of all deaths worldwide in 1999). Twenty well-known diseases—including TB, malaria, and cholera—have reemerged or spread geographically since 1973, often in more virulent and drug-resistant forms. At least 30 previously unknown disease agents have been identified in this period—including HIV, Ebola, and hepatitis C—for which no cures are available.

Additional support for clinical research is needed to take advantage of existing opportunities and develop new approaches to accelerate efforts to develop vaccines and drug therapies for HIV/AIDS, malaria, TB, and hepatitis C. Emerging scientific opportunities and recent developments in infectious disease research include sequencing the human genome and recombinant DNA technologies for developing new vaccines, such as the very successful vaccines against hepatitis B that are now given to all children in the United States. Although it will be a great challenge, we are optimistic that similar such vaccines can be developed against the big three global killers: AIDS, TB, and malaria.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The National Institute of Allergy and Infectious Diseases (NIAID) is the third largest institute at the NIH, with a fiscal year 2001 budget of more than $2 billion, a 15 percent increase from fiscal year 2000. During the past 15 years three factors have prompted NIAID to grow significantly: the emergence of HIV/AIDS in the early 1980s; results from basic research that are now driving new approaches to solving clinical and public health problems; and the realization that infectious diseases will continue to emerge unpredictably and at times explosively. There are several important on-going issues relating to NIAID's research efforts in tropical and infectious diseases that we would like to highlight.

Acquired Immunodeficiency Syndrome (AIDS).—In the United States, an estimated 271,000 people are living with HIV, and the rate of the new HIV infections, approximately 40,000 per year, continues at an unacceptably high level. NIAID-supported basic research identified the HIV protease enzyme as a target for antiviral drugs, which led to the development of very potent protease inhibitors, that have prolonged and improved the quality of life for many HIV-infected people. However, effective, low-cost tools for HIV prevention, such as a vaccine and affordable drug therapies, are needed urgently to bring the HIV epidemic under control.

Tuberculosis (TB).—TB is the eighth leading cause of death worldwide. One-third of the world's population has latent TB, constituting a huge reservoir from which active TB can surface. Moreover, multidrug-resistant TB is an increasing problem.

Malaria.—Malaria has been undergoing a global resurgence in recent years, partially related to drug resistance, with 275 million cases occurring annually, and a death toll estimated at 1 to 2 million, primarily children.

Hepatitis.—Hepatitis (liver inflammation) can be caused by several viruses. The most common are hepatitis A, a food- and water-borne infection that is a particular risk for travelers, and hepatitis B and hepatitis C, both of which are blood-borne. We now have excellent vaccines for hepatitis A and B, but none for hepatitis C, which kills about 9,000 Americans annually.

Emerging Infections.—There are numerous emerging infectious agents among the viruses, bacteria, protozoa, and fungi that make up the microbial world. Because the frequency of world travel makes the United States part of a global community, diseases that emerge in foreign countries are also health threats in the United States.

The Society commends the NIH and NIAID for their continued leadership and focus on tropical and infectious diseases. We urge the Subcommittee to strongly support efforts of the NIAID to develop new and improved methods for treating illness, controlling outbreaks, and preventing epidemics that continue to challenge global health.

Tropical Medicine Research Centers.—The NIH's tropical disease research program is funded primarily by the NIAID. This year marks the tenth anniversary of the International Centers for Tropical Disease Research network, established by NIAID to build new and strengthen established partnerships between U.S. scientists and investigators from tropical disease endemic areas; NIAID and other government agencies with interests in tropical disease research; and academic scientists and private industry, to encourage translational and collaborative research. The Society strongly urges that the Committee express its continued support for these unique research opportunities.

FOGARTY INTERNATIONAL CENTER (FIC)

The Fogarty International Center (FIC) is a unique component of NIH with a mandate to support training in biomedical research on behalf of the developing nations of the world. The ASTMH wishes to acknowledge the significant contributions of the FIC in overall support of tropical disease research, and their efforts to train scientists in molecular biology and molecular epidemiology techniques of relevance to developing countries in which research collaborations will be conducted. The new training program in clinical investigation is a necessary component of new NIH initiatives such as the HIV Prevention and Vaccine Trials Networks and other expanding human research programs in the developing world. The Society supports training local investigators as an investment in the research itself.

TRAINING/CAREER DEVELOPMENTS

It is clear to those of us who have devoted our careers to fighting tropical and infectious diseases that we need to attract the best and brightest young students and trainees to our field if we are to take full advantage of advances in science and technology and to make progress in the global war against infectious diseases. NIAID and the Fogarty International Center have taken the lead with initiatives for training students and young scientists and clinicians in tropical medicine and international health. However, compared to the need, there remains a shortage of training opportunities and especially support for junior researchers at the point in their training when they must choose between more mainstream careers in clinical medicine or other areas or research, or the sometimes more challenging path of tropical medicine and infectious disease research. We urge you to consider additional support for training and career development programs, which we feel are most successful when they are integrated with research funding.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The ASTMH appreciates the Subcommittee's past support for the CDC's infectious diseases program and requests your continued support for these critically important public health initiatives. Increased funding will help support the development of a national electronic disease surveillance network that will enable State and local health departments to respond to infectious disease outbreaks and share information about infectious disease emergencies and trends. We also urge you to continue to fund the CDC's efforts to control global malaria.

CONCLUSION

In the 21st Century we must aggressively pursue the battle against tropical and infectious diseases, which undoubtedly will intensify in the years ahead. We must have adequate surveillance systems and modern infrastructure, coupled with scientific expertise in both basic and clinical research, if we are to develop the tools necessary to rapidly respond to, and control, the threats posed by tropical infectious diseases. We stand at the threshold of an exciting new era of medical progress, exemplified by the recent completion of the sequencing of the human genome. Opportunities for new treatments, diagnostics, cures, and preventive measures have never been greater. We must also be prepared to confront the new challenges that will lie ahead. The path of progress will be different in the coming era, as the demand increases for a broader science base, more interdisciplinary research, and improved technology.

REQUEST

The Society greatly appreciates your support for our nation's investment in infectious disease research, control, and prevention activities. We urge you to continue your efforts to double the NIH budget over the next five years and towards this end we support an appropriation of $23.7 billion for the NIH in fiscal year 2002, with

a corresponding increase for NIAID. We also request that the Committee support increased funding for the CDC's infectious disease activities.

The Society of Tropical Medicine and Hygiene appreciates the opportunity to express our views and for your consideration of these requests.

PREPARED STATEMENT OF THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY, INC.

Good morning. My name is Julie Rish McCord. I am an infection control nurse for North Mississippi Medical Center, in Tupelo, Mississippi. I am here today representing the Association for Professionals in Infection Control and Epidemiology (APIC). APIC is a non-profit organization representing nearly 12,000 infection control professionals who work across the continuum of health care.

APIC has long been a strong proponent of science-based programs designed to protect patients and health care workers, such as those of the Centers for Disease Control and Prevention (CDC). We are extremely concerned, however, about regulations that are not based upon sound science and are unnecessary and costly to implement. Specifically, I am referring to the proposed OSHA rule to prevent occupational exposure to tuberculosis (TB).

OSHA's proposed requirements would place additional burdens on health care providers while failing to add protection for health care workers. We are in dire need of Congressional assistance in opposing this proposed rule. We greatly appreciate the efforts of Congressman Roger Wicker, who, at our request, sponsored language in the fiscal year 2000 appropriations bill calling for an independent study of the proposed rule by the Institute of Medicine (IOM). This study culminated in the publication of the report, "Tuberculosis in the Workplace," issued by the IOM on January 16, 2001. We would like to highlight seven of the report's major findings.

One: health care workers as a group are not at increased risk;

Two: the primary risk to health care, correctional, and other workers now comes from patients, inmates or clients with unsuspected, undiagnosed infectious TB. There is no regulatory standard that could ever address this risk, since TB is not even suspected in these patients;

Three: CDC guidelines for the prevention of occupational exposure to TB have been implemented, as appropriate, and are working;

Four: OSHA overstated the risks to health care workers by using out-dated information and data from outbreaks to craft a proposed rule that is unnecessary and would be ineffective and costly;

Five: OSHA vastly overestimated the benefit that could be derived from implementation of its proposed rule;

Six: A respiratory protection program should be tailored to the level of risk within a facility; and

Seven: the proposed rule will not allow the necessary flexibility for organizations to adopt the TB control measures that are most appropriate to the level of risk facing their individual workers.

The report states, ". . . if an OSHA standard follows the 1997 proposed rule it may not offer sufficient flexibility for organizations to adopt control measures appropriate for the level of risk facing workers. To the extent that an OSHA standard inflexibly extends requirements to institutions that are at negligible risk of occupational transmission of M. tuberculosis, the standard is unlikely to benefit workers at the same time that it would impose significant costs and administrative burdens on covered organizations and absorb institutional resources that could be applied to other, potentially more beneficial uses."

With this information, Congress should take further and stronger action to ensure that this rule, which will be virtually ineffective and overly burdensome to facilities, is not issued.

I bring this message to you on behalf of my professional organization, but I am also speaking to you today as someone who has had direct experience with TB disease. My mother was diagnosed with TB in the 1950s. In the years that followed, my family and I stood by her side as she experienced many complications as a direct result of TB, which contributed to her death in 1995. I can tell you from first-hand experience that TB is a truly devastating disease. APIC cares very much about protecting health care workers (including ourselves) from TB. While the intention behind this rule may be sincere, it does not address the area of true risk.

There is no doubt that in the late 1980s, the public health infrastructure and health care facilities were not prepared for the devastating combination of HIV/AIDS and TB, but the incidence of TB in the U.S. is now at its lowest level ever

recorded. TB is a public health issue, not a facility-specific issue. Health care workers are already protected from patients with known or suspected TB. In fact, the rate of TB in health care workers is lower than the rate among the general population.

TB is a public health issue because it is in our communities and largely undetected. People with active TB disease, who go undetected, pose a risk to others until they are identified, isolated and treated. Strengthening our public health programs will allow us to target prevention and treatment programs to high-risk populations—particularly immigrants—provide directly observed therapy, and thoroughly investigate all cases for spread to contacts.

With regard to this regulation, I would like to make one final point, as someone who has lost a family member to the complications of TB. If I believed for one moment that this rule would prevent people from contracting this terrible disease, I assure you, I would not be testifying before you today. The OSHA TB rule will offer no added protection for workers and will be logistically and financially burdensome for facilities nationwide. We would appreciate your assistance in halting the issuance of a final rule.

Infection control professionals nationwide wish to thank this subcommittee for its long-standing support of the Centers for Disease Control and Prevention (CDC), particularly with regard to funding for infectious disease programs. Through its efforts and expertise, the CDC has been instrumental in national as well as international efforts to control the incidence and spread of infectious disease. Since the CDC is the primary entity responsible for safeguarding the public's health, it is imperative that it be granted adequate resources to perform this monumental task. APIC recommends an fiscal year 2002 funding level of $5 billion and we hope that the subcommittee will take this into consideration during the appropriations process.

APIC believes that the CDC needs more resources in order to adequately address infection prevention and control at both the national and international levels. Infectious disease is the leading cause of death worldwide and a significant cause of death here in the United States. APIC members, many of whom work on the front lines in infection control and in public health capacities, recognize the urgent need for enhanced prevention measures as well as increased surveillance.

In recent decades, significant progress has been made in the prevention and control of many infectious diseases. Today, our efforts are confounded, despite our many accomplishments. Changes in human behavior, alterations to the environment, deterioration of our public health infrastructure, widespread antibiotic usage, and dramatic increases in international commerce and travel are factors contributing to the proliferation of drug resistance and new and resurgent microorganisms.

For this reason, APIC also strongly supports full funding of Public Law 106–505, the Public Health Improvement Act, which includes authorization language to address public health emergencies such as antimicrobial resistance and bioterrorism. We are requesting:

—$4 million through fiscal year 2006, to enhance surveillance networks throughout our public health system;

—$95 million through 2006 to establish competitive grants to address core public health capacity needs to best identify, monitor, and respond to public health threats;

—$180 million for fiscal year 2002, through 2010, for new facilities construction and renovating existing facilities at the CDC; and

—$40 million through fiscal year 2006, to establish an Antimicrobial Resistance Task Force, and to establish competitive grants and demonstration programs to conduct research and development for new antimicrobial drugs and diagnostics.

Federal funding would enhance surveillance sites, strengthen epidemiological and laboratory response capabilities and support efforts to address emerging infectious disease on a global level. We are hopeful that the committee will recognize the absolute necessity of this program and provide the highest possible level of funding.

Thank you for your attention to these concerns.

PREPARED STATEMENT OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

Mr. Chairman, thank you for the opportunity to present the views of the Association of Minority Health Professions Schools (AMHPS). I am Ronny B. Lancaster, Senior Vice President for Management and Policy at Morehouse School of Medicine, and President of AMHPS.

AMHPS is an organization which represents twelve (12) historically black health professions schools in the country. Combined, our institutions have graduated 50

percent of African-American physicians and dentists, 60 percent of all the nation's African-American pharmacists, and 75 percent of the African-American veterinarians.

Mr. Chairman, historically black health professions institutions are addressing a pressing national need in carrying out their mission of training minorities in the health professions. While African-Americans represent approximately 15 percent of the U.S. population, only 2–3 percent of the nation's health professions workforce is African-American. Studies have demonstrated that when African Americans and other minorities are trained in minority institutions, they are much more likely to: (1) serve in medically underserved areas, (2) care for minorities, and (3) accept patients who are Medicaid dependent or otherwise poor. This is important Mr. Chairman because the gap in health status between our nation's minority and majority populations continues to widen due in part to the lack of access to quality health care services in minority communities. As a result, we believe it is imperative that the federal commitment to training African Americans and other minorities in the health professions remains strong.

In spite of our proven success in training health professionals, and the important contribution these professionals make, our institutions continue to face a financial struggle inherent to our mission. The financial challenges facing the majority of our students affect our institutions in numerous ways. For example, we are unable to depend on tuition as a means by which to respond to any discontinuation of federal support. Moreover, the patient populations served by the AMHPS institutions are overwhelmingly poor. As a result, our institutions cannot rely on patient care income at a time when the average medical school gets 40–60 percent of its operating revenue from health care services.

Mr. Chairman, due to the many challenges facing our institutions, AMHPS was very pleased that the Department of Heath and Human Services made reducing the health status gap between our nation's minority and majority populations a top priority in fiscal year 2001. We look forward to continuing to work with all agencies of the Public Health Service in fiscal year 2002 to make additional progress toward the goal of eliminating all health status disparities by 2010.

Mr. Chairman, before I present AMHPS's appropriations recommendations for fiscal year 2002, I would like to state for the record that these programs represent, quite frankly, the difference between keeping the doors open or closed at many of our nation's minority health professions institutions.

FISCAL YEAR 2002 RECOMMENDATIONS FOR FEDERAL PROGRAMS OF INTEREST TO AMHPS

National Institutes of Health

Mr. Chairman, I would like to take this opportunity to thank you for your support of the establishment of the National Center for Minority Health and Health Disparities at NIH last year. As you know, ethnic minorities and medically underserved populations suffer disproportionately from virtually every major form of disease. Despite this longstanding public health problem, the former Office of Research on Minority Health at NIH had neither the authority nor the resources to adequately address the challenges in this country with respect to health status disparities.

The new National Center and its leadership now have the authority to:

—Directly support biomedical research, training, and information dissemination focused on eliminating health status disparities.

—Serve in a leadership capacity in developing a comprehensive plan for minority health research at NIH.

—Participate as an equal when NIH institute and center directors meet to determine research policy.

—Establish and support research programs at health professions institutions that are studying diseases which disproportionately impact ethnic minority and medically underserved populations.

On behalf of the minority health community, I would like to commend the subcommittee for appropriating $130 million for the National Center in fiscal year 2001. Given the immense public health challenge of eliminating health status disparities in this country by 2010, AMHPS is recommending that the National Center receive an appropriation of $200 million in fiscal year 2002. In addition, AMHPS strongly supports the goal of doubling the NIH budget by fiscal year 2003 and joins with the Ad Hoc Group for Medical Research Funding in recommending a 16.5 percent increase ($3.4 billion) for NIH in fiscal year 2002.

Research Centers at Minority Institutions

The Research Centers at Minority Institutions program (RCMI) at the National Center for Research Resources has a long and distinguished record of helping our

institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, AMHPS recommends that funding for this important program grow at the same rate as NIH overall in fiscal year 2002.

Animal Research Facilities Improvements

Minority health professions institutions have identified a pressing need to upgrade our animal research facilities in order to remain competitive in the field of biomedical research. We are grateful for the subcommittee's support last year of our "animal facilities improvement initiative" and are pleased to report that a majority of our institutions are working with NCRR to upgrade their animal care infrastructure.

To continue this important initiative we urge the subcommittee to provide an adequate level of funding within the Developing and Improving Institutional Animal Resources program at NCRR to assist the remaining schools in improving their animal facilities.

Extramural Facilities Construction

The minority health professions community thanks the subcommittee for its support of NCRR's Extramural Facility Construction program over the past two years. It is critical that our nation's research infrastructure remain strong if we are to take full advantage of the historic increases in biomedical research funding that the Congress has provided to NIH.

Under legislation passed last year, the authorization level for the Extramural Facility Construction program was increased from $150 million to $250 million. Moreover, the new law maintains the 25 percent set-aside for Institutions of Emerging Excellence (many of which are minority institutions) for funding up to $50 million and allows the NCRR director to waive the matching requirement.

Current funding for the Extramural Facility Construction program at NCRR is $75 million. AMHPS encourages the subcommittee to continue its strong support for this program in fiscal year 2002 by increasing its appropriation by the same percentage as NIH overall.

Research Infrastructure Development

Mr. Chairman, as we review the priorities of our member institutions with respect to NIH, clearly most of our needs relate to institutional infrastructure, and those programs which help our schools enhance their capabilities to compete for research funding on a level playing field. Now that these programs are in place, we believe there should be an effort to coordinate these infrastructure development programs so our schools can work with NIH to approach them on a comprehensive, rather than on a piece-meal basis. It would seem more efficient for NIH to work with our schools to collaborate on our infrastructure needs, and coordinate efforts to help us build our infrastructure.

Strengthening Historically Black Graduate Institutions—Department of Education

The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to AMHPS institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities.

Mr. Chairman, we applaud the subcommittee's leadership in securing a funding level of $45 million (an increase of $14 million) in fiscal year 2001 for this vital program. For fiscal year 2002, AMHPS recommends an appropriation of $60 million to continue the vital support that this program provides to historically black graduate institutions.

Health Professions Training for Diversity at the Health Resources and Services Administration

The health professions programs supported by this subcommittee are the only federal initiatives designed to address the longstanding under-representation of minority individuals in health careers. HRSA's Minority Centers of Excellence, Health Careers Opportunity Program, and Scholarships for Disadvantaged Students, support those institutions with a historic mission and commitment to increasing the number of minorities in the health professions.

Mr. Chairman, our schools and students greatly appreciate the consistent support of this subcommittee for these important programs and recommend the following funding levels for fiscal year 2002:

—$40 million for Centers of Excellence (an increase of $9.4 million over fiscal year 2001).
—$40 million for the Health Careers and Opportunities Program (an increase of $7.2 million over fiscal year 2001).
—$50 million for the Scholarships for Disadvantaged Students program (an increase of $5.5 million over fiscal year 2001).

Finally, we are working with HRSA and Bureau of Health Professions leaders to ensure that the COE and HCOP programs continue to focus on providing support to minority serving institutions. Recently proposed changes to the eligibility criteria for COE, and the process for awarding HCOP grants, have raised some concerns in the HBCU community. We look forward to working with the subcommittee to ensure that these programs continue to benefit those institutions with the greatest need.

HHS Office of Minority Health

The HHS Office of Minority Health (OMH) plays a critical role in ensuring that all Public Health Service agencies focus appropriate resources on improving the health of our nation's minority citizens. Although their task is daunting, progress has been made thanks to the leadership of OMH.

OMH has helped our institutions directly by supporting a comprehensive study on how our schools can better compete as health care providers and educational entities in the age of managed care. Moreover, we are working to develop a partnership with OMH in support of AMHPS's Annual Symposium on Careers in the Biomedical Sciences. This unique event brings together over 1,000 minority and other high school and college students each year to expose them to career and educational opportunities in the health sciences. Many believe that this is the best program of its type in the country.

To continue the important mission of the Office of Minority Health, we are recommending a funding level of $60 million in fiscal year 2002 (an increase of $11 million over fiscal year 2001).

Centers for Disease Control and Prevention

Minority populations of many ethnic backgrounds are at an increased risk of suffering from low birth weight, infectious disease, sexually transmitted diseases, tuberculosis, and other chronic disorders.

The Centers for Disease Control and Prevention has taken a leadership role in combating these problems through its various health status disparities initiatives. Because of the proximity of minority health professions institutions to disadvantaged, medically underserved communities, our institutions frequently partner with CDC in support of community based, prevention and control initiatives. We encourage the subcommittee to provide CDC with an overall appropriation of $5 billion in fiscal year 2002 (an increase of $1.1 billion over fiscal year 2001).

Mr. Chairman, once again, thank you and this subcommittee for your longstanding support of these very important programs. I appreciate the opportunity to present the views of the Association of Minority Health Professions Schools.

PREPARED STATEMENT OF BABYLAND FAMILY SERVICES, INC.

Mr. Chairman: On behalf of Babyland Family Services, Inc. I appreciate the opportunity to submit this written testimony to you on three important initiatives: (1) a Pediatric Health Center; (2) an Education Technology project; and (3) a Family Violence and Child Abuse Initiative.

Babyland provides child care and early childhood education services for 750 children (0 to five years old) at eight child care centers and provides emergency shelter and family support services to 750 other at-risk and low-income children and families. Babyland is currently Newark's Early Head Start grantee (serving children 0 to 3 years old, pregnant teenagers, young fathers and families living with HIV/AIDS) and has a partnership with the Newark Public Schools to provide Abbott preschool services to over 250 children. The agency has an extensive partnership with the New Jersey Department of Human Services for the provision of child welfare, family violence and child care services. Babyland is a leader in Newark for the promotion of accredited child care centers and has been recognized by The Annie E. Casey Foundation as a model child and family development organization through its 2001 Families Count Honors Program.

Babyland is a lead agency for the United Way's Success By 6 Initiative and the State's Family and Children Early Education Services (FACES) Initiative which, combined, provides early childhood support services to 2,000 children and over 20 other child care agencies and schools. Finally, Babyland and Passaic Beth Israel Hospital have partnered to implement the Pediatric Asthma Reduction Effort

(PARE), which is funded by the Robert Wood Johnson Foundation to develop a model pediatric asthma education and management program for children in Newark and Passaic.

THE BABYLAND PEDIATRIC HEALTH CENTER: WHERE HEALTHY BEGINNINGS LEAD TO BRIGHTER FUTURES

Babyland is seeking $1 million for the rehabilitation or construction of a Pediatric Health Center. Babyland is in a unique position, as the lead agency for several collaborative initiatives that promote the development of young children under six years old, to launch a pediatric health initiative that will prevent and manage childhood illnesses in Newark. As part of the agency's new multipurpose building, this federal funding will enable the agency to include a pediatric and family health center that will directly provide basic health services to over 1,000 families and provide health education, assessments, screening and follow-up services to 2,000 families with children under six years old. In addition to the pediatric and family health center, the new multipurpose building will include a child care center for 137 children (0 to 5 years old), a computer technology center, an employment training and placement center and family resource center. The new health center will particularly focus on increasing immunizations, screening for lead poisoning, asthma management, preventive dental care services, nutrition, prenatal care, home safety, parent education and child development, HIV/AIDS prevention and other preventive health education.

In partnership with over 20 child care agencies, elementary schools and local health care providers, Babyland will develop a coordinated community-based approach for residents to gain access to health care services. Increased access to health care services will be achieved through the following methods: training for over 50 Abbott Family Workers who provide case management services for 2,000 preschoolers; parent-to-parent workshops that will be part of a series of parent and health education workshops; and creative grass-roots efforts that will encourage families to utilize the health center's resources. Community outreach workers, parents, nurses and a team of other health professionals will provide health outreach, education and services. Services will be coordinated with the Newark Department of Health, the Newark Public Schools and other local health care service providers.

Matching Funds.—$1 million capital funding from the following: The Annie E. Casey Foundation ($500,000 unrestricted award) and $500,000 from a lender. Operating funds will come from the United Way and the State of New Jersey. Other potential funders could include previous health-related supporters such as the Robert Wood Johnson Foundation and the Healthcare Foundation of New Jersey.

THE NEWARK PROJECT: A SOLUTION TO THE DIGITAL DIVIDE AMONG URBAN FAMILIES

The purpose of this initiative is to serve as a model educational program that closes the digital divide among minority inner city children and families. This technological network links center and home-based child care centers and schools; community resources and service providers; educational, economic and resource information sources; training centers and administrative offices. The establishment of this network will be a model for educating urban children and serve as a conduit for comprehensive family support services.

The focus of this initiative is to establish the telecommunications linkages necessary for the educational development of 1,000 preschool and school-age children and to provide computer and technology training for 2,000 parents, teachers, family service workers and entry-level employees. As a result, this initiative will strengthen children's educational skills; promote the self-sufficiency of and enhance the educational skills of parents; enable the agency to better track child and family needs in order to enhance client services; and link the community to local and national resource centers.

Computer technology is transforming the economic and social landscape of this country by offering information and educational opportunities for individual growth and community development. Inner-city children and residents are inadequately prepared to take advantage of these growth opportunities. If the gap in information technology—the digital divide—is not bridged, a large segment of society will be further polarized and left without the tools needed for full participation in society.

This technology initiative will assist clients who have no other tangible means of becoming computer literate and of acquiring the requisite skills necessary to be informed and self-sufficient.

Specific Provisions

—Technology Center, as part of a new multi-purpose community resource and education center, that will provide distance learning, online and network linkages to educational institutions and community resources, professional development and training in basic and advanced computer and technology skills for low-income parents, neighborhood residents and entry-level employees.
—Technology hardware and software (technical assistance, network installation and expansion, wiring, modems, printers etc.) for children, parents and residents, and teaching/social service staff in classrooms, homes, family resource centers and safe havens.
—Technology Training, Curriculum Development and Professional Development for children, parents and residents, educational and social services staff, as well as local, State, national and international community-based family service providers.

The initiative will benefit the following

—Children at nine child care centers (850 preschoolers) and 400 school-age children (charter school and after school/summer enrichment programs) at six centers and schools.
—Parents and family members (2,000) at 14 Babyland sites with links to community resources;
—Agency Staff (300), including teachers and family service workers, for client tracking purposes; training and professional development; and access to community resources to be provided through workstations, wireless technology and/or palm pilots.
—Parents and children in the home for educational instruction and support, economic and resource information, links to other parents and teachers, parenting education (child and family health, child behavior and development, cultural sensitivity, etc.) and professional education (ex. Certifications, GED, etc.).
—Family day care homes with links to community resources, professional education, BFS child care centers and other child and family resource centers.
—Child and family service providers, throughout Newark, New Jersey, the nation and South Africa, who will receive training in child, family and community development.

Key Outcomes

—Enhanced early childhood development and education for children (three to 13 years old).
—Enhanced ability of inner city residents, especially low-income parents and teenagers, to learn computer and technology skills.
—Enhanced tracking of 1,500 children in center- and home-based child care facilities; teenage parents; victims of domestic violence; homeless families; and children in foster care.
—Enhanced delivery of professional development of teaching and family service staff.
—Enhance the provision and delivery of parent education programs.
—Enhanced delivery of clinical and therapeutic services to parents and children.
—Enhanced ability to fulfill State and Federal reporting requirements and to provide community development consultation to local, State, national and international family service providers.

This project received an allocation of $723,000 in the last fiscal year. But in order for the system to be fully operational and implemented for the entire target clientele population, an additional allocation of $2 million is being sought.

MEN FOR PEACE

Babyland is seeking $500,000 under the Administration on Children and Families Community Services Block Grant to integrate its family violence and child abuse prevention and crisis intervention services in order to develop a comprehensive program for 500 children and families. Key components of the initiative will include: Intensive family reunification and permanency planning for children in foster care; counseling for male batterers; parent education; mental health counseling; substance abuse counseling; and specialized services for at-risk men.

Babyland currently provides prevention and crisis intervention services for 500 abused and neglected children (under five years old) and 200 battered women. The agency provides foster care services for nearly 300 children (siblings and infants, or boarder babies). Babyland is also a lead agency for the Responsible Fatherhood Initiative, which utilizes a collaboration of several support service agencies to mentor young men who have substance abuse problems.

This project will enable the agency to integrate and build components of its prevention and intervention services that emphasize the utilization of men—fathers and male role models—toward the reduction of child abuse and domestic violence. This initiative will draw upon the strengths of specially trained male role models in providing mentorship and parent education for young fathers, counseling for batterers and men at risk of abuse or violence as well as outreach to fathers with children in foster care. The project will employ innovative methods to engage and educate young men and fathers as well as comprehensive support services that will promote self-sufficiency and family development.

Matching Funds—$500,000 from the United Way of Essex and West Hudson and the NJ State Department of Human Services

Thank you for your consideration.

PREPARED STATEMENT OF CANAVAN RESEARCH ILLINOIS

Dear Mr. Chairman: Thank you for hearing my testimony explaining why orphan diseases, and Canavan disease in particular, are in desperate need of Government funding for medical research.

Because neurodegenerative diseases are all related, there will be gains in medical science that reach far beyond these rare diseases. Research for Canavan disease will have a spill over effect, and ultimately help millions of Americans.

I can personally attest to the impact that Canavan disease has on the family it affects. Canavan disease develops in early childhood and is 100 percent fatal. Canavan disease (CD) is progressive; our children lose motor skills until eventually they can no longer even breath or swallow. As parents, we are forced to become full time caregivers and fundraisers, which puts a tremendous burden on the family, both emotionally and financially.

When I found out that my precious little baby, Max, would die I thought that was the end of the world. But, if anything could possibly be worse, it was when I realized that in addition to living with this disease my family and I would also have to financially support medical research in order to give Max a chance. Due to the lack of funding from our Government, we the parents of dying children, have worked tirelessly raising money to pay for research that may help our children enjoy a better quality of life, and possibly live longer.

While there are approximately ten families who actively raise money for research, it is simply not enough to sustain our effort. For example, my family has been aggressively fundraising for over three years and founded a charity, Canavan Research Illinois. We have raised just under a quarter of a million dollars. Though this may sound like a lot of money, even when combined with funds from other Canavan foundations, it does not compare to the astronomical costs of both research and clinical trials. Orchestrating a safety trial is both time consuming and costly. Together, families affected by Canavan disease have raised over two and a half million dollars in five years, but we will need seven million dollars over the next three years to continue the research that we have started.

I have dedicated my life to working towards finding a cure for Canavan disease. My husband, Michael, Max, and I live on one moderate income, so I can work full time as an unpaid volunteer for the public charity I co-founded. I have chosen this path because I believe a cure can be found; it is just a matter time, and money. However, as the mother of a very sick little boy there are many other demands on my time. Max goes to school and therapy everyday, so I spend a great deal of time in our van shuttling him from place to place. The time required to be a full time caregiver for a profoundly handicapped child with multiple disabilities is in itself a full time job. This is why I am asking for your help. Help us find a cure, but also help us fund a cure!

Medical research is too expensive to be funded solely by private donations. We can no longer do it. We have exhausted our resources. Our friends and family have generously donated money when they have been asked, but this has decreased over time. We are out of resources, and our children are losing precious time. Science cannot move ahead if it is only supported by dinner dances, raffles, auctions, and donations from friends. I get extremely discouraged when I work forty to fifty hours a week fundraising to save my baby and then hear from our privately funded researcher that we are out of money, again. This means we are out of hope. I have worked too hard to stop now. So I am pleading with you, Mr. Chairman that in addition to granting additional funds to the NIH, that you encourage them to make a concerted effort to look at granting more research funds towards medical interventions for the young children afflicted with Canavan disease. The children who are dying now deserve a chance.

While Canavan disease is rare, and may require millions of dollars for medical research, the beneficiaries of this research are not limited to the Canavan children. There are many related diseases that will benefit from this research including: Alzheimer's, ALS, Parkinson's, MS, Spinal Cord Injury, and Stroke.

Canavan disease is a very good model for neurodegenerative disease. It is caused by a single mutated gene, which has been identified. The defective gene in Canavan children is responsible for making one enzyme, which also has been identified. If the doctors and scientists had the funds necessary to expand our understanding of CD, we would be able to develop a treatment or cure for it and apply this knowledge to the other neurodegenerative diseases.

If you look at all the related diseases it is clear that research in one area, will spill over and help research in another. But the millions of dollars necessary for this to happen have simply never been granted to the Canavan researchers who are working on treatments that are ready to be used in human clinical trials. Testing mice and rats for ten years will not help the people who are dying today. Because there is no funding for the disease my son was born with, he does not have access to any treatment.

I believe that every American is entitled to have access to some course of medical treatment. The little children dying of Canavan disease deserve a chance. Without Government funding they will not have that chance. Many of these children are already medical pioneers and have undergone experimental therapies to try and improve their lives, and the lives of children in generations to come but, sadly this will come to an end. The financial burden of supporting medical research is too much for the friends and family of a dying child. Without Government grants that will be used towards medical interventions for the people who need help now, the science we have all so vigorously supported will come to a screeching halt, and our children will die.

We need research dollars now. Our children are running out of time, along with the other people who suffer from degenerative brain diseases. We cannot do this alone! The millions of dollars necessary to treat and cure Canavan disease will ultimately help millions of people.

Thank you for receiving my testimony.

PREPARED STATEMENT OF THE NATIONAL JEWISH MEDICAL AND RESEARCH CENTER

Mr. Chairman and Members of the Subcommittee, thank you for your support last year and the opportunity to present this testimony regarding the National Jewish Medical and Research Center's proposal to build an integrated Center for Environmental Health Research and Service (CEHRS). This Center will, under one roof, support research and provide clinical services for patients with respiratory and immune diseases with the mission of controlling or eradicating environmental and occupational illness in the Rocky Mountain Region. It will serve as a regional resource and national model for the delivery of environmental clinical health services, conduct both basic and field research on environmental illness, and "translate" new knowledge, to better inform the public and help guide rational environmental policy by government, at both regional and national levels.

National Jewish Medical and Research Center is known worldwide for the diagnosis and treatment of patients with environmental, respiratory, immune and allergic disorders, and for groundbreaking medical research. For the past 20 years, this century-old nonsectarian, nonprofit medical center has earned an international reputation for its treatment of environmental illness and for research leading to the detection and prevention of environmental disorders including asthma, berylliosis, tuberculosis, and building-related illnesses.

With funding from Federal agencies including the NIEHS, NHLBI, NIAID, EPA, DOE, and CDC/NIOSH, as well as foundations and private industry, National Jewish has become one of the leaders in the field of environmental health. National Jewish is deeply committed to providing accessible, affordable and high quality care for environmentally and occupationally exposed individuals, to consulting for government and industries in the region and nationally, and to educating medical professionals and the public on matters of environmental risk and health.

Our nation faces a significant challenge for the 21st century—how to safeguard the health of the American public from environmental hazards. We are faced with the reality that many Americans, particularly the working poor, blue collar middle class, minorities, children and the elderly, are exposed daily to environmental toxins that may cause major lung, heart, immune and allergic diseases, disability and untimely death. We must find ways to better diagnose, treat and, most importantly, prevent environmental disease. In addition, federal agencies and corporations face

the daunting task of cleaning up environmental "sins of the past"—without unduly endangering the health of today's hazardous waste workers and the members of communities that surround them.

The State of Colorado has historically been medically underserved, in environmental health services, with fewer than 40 medical practitioners in Colorado who are board certified to practice environmental and occupational health. While the Division of Environmental and Occupational Health Sciences at National Jewish provides consultation to industry, agriculture, community groups, and labor, its services are outstripped by the regional need for expertise. National Jewish is forced to turn away many patients and groups who have environmental concerns because of physical and staffing limitations at the Center. These needs range from community groups seeking advice on the hazards of radioactivity and of metal-contaminated soil, to industries needing help in the control of lead poisoning and biological hazard exposures, to regional agencies seeking aid in the investigation of disease outbreaks caused by airborne molds or tuberculosis-like organisms.

National Jewish is uniquely positioned in the Rocky Mountain region to serve as a model health care institution for implementing innovative environmental health programs that reduce the risk of respiratory and immune system disease. Regionally and nationally, the diseases that are treated at National Jewish Medical and Research Center are on the rise, including asthma, diseases due to environmental tobacco smoke, building-related respiratory and allergic illnesses. National Jewish Medical and Research Center specializes in helping both small and large regional employers address practical issues of toxic exposure assessment, exposure control, medical management of occupational illness, and remediation. Employees and their employers, while aiming to make the workplace safer and more productive, often lack enough information about the toxic effects of airborne chemicals, metals, and organic matter that produce disability. Recent studies show that 1 in 10 hospital admissions is related to a workplace injury or exposure. More than half of all patients seen in general medicine clinics in the central U.S. report past or ongoing exposure to one or more known toxin.

The solutions to these environmental health dilemmas are to prevent exposures from causing disease and, if environmental exposures have already occurred, to detect disease earlier and to develop more effective treatments for disease.

National Jewish can best increase our effectiveness by housing these major activities in a single, dedicated location. The CEHRS will be a showcase for the application of the most advanced environmental science and directly to the prevention of disease in groups of Americans at environmental risk. By showing how a multidisciplinary approach can help eradicate environmental respiratory and allergic diseases, our Center will be a model for other centers around the country who may address other forms of environmental illness, such as those linked to skin disease, neurologic disorders, liver disease, and cancer. National Jewish Medical and Research Center believes that by maintaining a tight focus of both clinical care and research in an area of great need—the respiratory and immune systems—its Center will be able to deliver long term solutions to the most important forms of environmental disease.

The CEHRS will meet this need by integrating the following existing and new program components in the new Center:

The Clinic for Environmental and Occupational Health Care.—A combined adult and pediatric outpatient clinical practice staffed by experienced environmental and occupational health physicians and nurses who diagnose and treat environmental disorders. Annually, this clinical group screens and evaluates more than 2,000 patients with suspected environmental or occupational lung and allergic disorders.

The Environmental Disease Prevention and Research Service.—A multidisciplinary team of physicians, researchers, epidemiologists, industrial hygienists, and health educators, who conduct practical research aimed at "real life" problems solving by measuring airborne exposures to toxins and implementing innovative programs that detect the effects of chemicals in individuals and in the air. The goal is to devise practical, cost-effective solutions to reducing risks of cancer, lung fibrosis, and allergic lung disease.

The Environmental Away-Team Consultation Service.—A mobile consultation service staffed by a team of environmental and occupational health experts who go anywhere in the country to measure environmental exposures, monitor for disease, and advise industrial and agricultural employers, labor, and private citizens on the management and control of environmental hazards. This service has gone on-site to more than 20 states.

The Respiratory Protection Program.—A mobile service that helps individuals and corporations to educate and provide appropriate types of masks for people being potentially exposed to airborne hazards. Firefighters, hazardous waste workers, mu-

nicipal employees, and others who encounter potentially lethal exposures to highly toxic materials call on this service.

The Environmental Education/Community Outreach Service.—A risk communication service that utilizes the internet as well as more traditional educational approaches to deliver up-to-date, balanced, practical environmental information to civic groups, labor, industry, and local and federal government agencies.

The Occupational and Environmental Medicine Training Program.—Based at National Jewish and the Department of Preventive Medicine and Biometrics at the University of Colorado School of Medicine, this is the only training program for environmental medicine in the state of Colorado.

The Environmental Toxicology Section.—A research unit dedicated to understanding oxidative stress which is a natural process that produces disease when undesirable oxidant gases or dusts are inhaled, causing inflammation.

The Environmental Immunology Laboratory.—A research unit dedicated to understanding how environmental toxins cause allergic diseases.

National Jewish is the only academic research facility in Colorado that provides clinical care for patients with suspected environmental or occupational illnesses. Patients from the region as well as from all 50 states come to National Jewish Medical and Research Center for medical diagnosis and care. Patients receive superior care without regard to their ability to pay. Each year $7 to $10 million of free or heavily subsidized care is provided.

National Jewish was recently ranked as the best hospital in the nation for excellence in treating respiratory diseases in U.S. New and World Report's "America's Best Hospitals." American Health magazine termed National Jewish one of the finest U.S. hospitals in allergy, immunology and pulmonology for both adult and pediatric patients. The Institute for Science and medicine rated National Jewish among the top 10 independent biomedical research institutions—of any kind—in the world, and the only one that also provides patient care. It was ranked as one of the three most influential research institutions for immunology and as the number one private immunology research institution in the world.

Partnerships with governmental agencies.—In addition to conducting research directly funded by several agencies, National Jewish faculty provide advice and consultation to local, regional and Federal Government offices, including: the Colorado Department of Health and the Environment, the Governor's Air Toxics Science Advisory Committee, the U.S. DOE Beryllium Standards Advisory Committee, oversight Boards for Hanford Reservation in Washington State, the Nevada Test Site, and Los Alamos National Laboratories, the EPA air pollution research advisory panel, and the OSHA Metalworking Fluids Standards Advisory Committee, and both CDC/NIOSH and NIH research advisory committees.

Partnership with community health organizations.—Faculty members conduct community outreach, speaking at local hospitals on environmental health. Three of our faculty have served as presidents of the Rocky Mountain Academy for Environmental and Occupational Medicine, the regional society for all physicians practicing in this field.

Partnership with regional industry and labor.—National Jewish has helped organize and conduct medical education and medical surveillance programs for many regional industries, helping them to protect employees from hazards in the workplace.

National Jewish proposes to continue the public/private partnership with the Federal Government by the establishment of the "Center for Environmental Health Research and Service." This partnership will cover the cost of the construction of a new, 113,000 square foot, state-of-the-art facility which will house research in the fields of asthma, inflammation, immunology, and environmental medicine. These basic and clinical/translational research programs address issues that are central to the mission of the Center for Environmental Health Research and Services. The new research facility will be closely integrated with the clinical care, outpatient services, and training programs that our Center for Environmental Health Research and Services uses to translate research to improve clinical services for patients with respiratory and immune diseases such as asthma, lung fibrosis, tuberculosis, and other lung and skin disorders which often stem from environmental and occupational hazards.

The total cost of the proposed facility and equipment is $39 million. Since fiscal year 1999, National Jewish has received a total of $3.75 million from the Labor, Health and Human Services, and Education Appropriations Bill under HRSA to carry out the initial phases for the construction of the CEHRS and has privately raised $29 million. National Jewish seeks $5.25 million in HRSA follow-on funding in fiscal year 2002 to complete the balance of the construction request.

PREPARED STATEMENT OF THE CHILDREN'S HEART FOUNDATION

Mr. Chairman and Distinguished Subcommittee Members: On behalf of The Children's Heart Foundation and all who are suffering with congenital heart defects we enter this testimony for consideration at the fiscal year 2002 budget hearing. The Children's Heart Foundation formally requests to be allowed to testify before the subcommittee during hearings on appropriations for fiscal year 2002 to the National Institutes of Health.

According to the NIH Guide: PEDIATRIC DISEASE CLINICAL RESEARCH NETWORK (release date May 24, 2000); about 32,000 babies are born each year in the U.S. with congenital cardiovascular malformations (CCVM). CCVM is considered the most common or number one birth defect and a leading cause of death in infants. CCVM occurs at least three times more often than childhood cancers and significantly more often than pediatric AIDS. The mortality rate for these children may be as high as fifty percent, depending on the condition.

The financial and social impacts on families are staggering. Many children who survive infancy are forced into a life of dependency on medications, medical procedures, and repeated open-heart surgeries. Parents of these children will struggle with high medical costs and low productivity when critical care is needed or when the child dies. This trauma can throw a family into emotional and financial devastation. In 1992 nearly $500 million was spent to pay for 44,000 hospitalized children who were under fifteen years old.

Because so few of these children live long enough to have children of their own, it has been difficult to carry out genetic studies of CCVM. However researchers have now come to the conclusion that most CCVM occurrences are caused by genetic deflects. According to information provided by the NHL&BI, the direct cause for at leapt eight different structural heart defects may be genetic.

While we at The Children's Heart Foundation applaud the genetic studies that have been ongoing at the NIH, we also realize that clinical studies on procedures and methods of treatment are vital to the future of patients suffering with congenital heart defects. For this reason we urge this distinguished committee to encourage the NHLBI to support more clinical research related to congenital heart defects.

In the next few pages we will present the stories of some of the families who have lived with these life-threatening conditions. One of these families has lost the battle while others still live with the daily difficulties that accompany their illness. Please accept these testimonies and the request to testify before this committee under the auspices of The Children's Heart Foundation.

ANDREA

My name is Andrea Piwowar. Twenty-three years ago, I was born with several congenital heart defects. I was diagnosed with tricuspid atresia with transposition of the great arteries and a large ventricular septal defect associated with pulmonary hypertension and an absent pulmonary valve.

When I was three months old, I had a banding of the pulmonary artery. In January of 1982, I had a modified Fontan, a surgical procedure that makes it possible for blood to enter the lungs without being pumped in by the right ventricle. This is achieved by connecting the pulmonary artery directly to the right atrium. In my situation, since I had transposition of the great arteries and a ventricular septal defect along with tricuspid atresia, the underlying need for the Fontan procedure, the surgeon corrected the transposition and closed the hole between the two atria.

Seven months following the modified Fontan, I had a stroke. In December of the same year, I had yet another stroke. It was thought that clots were forming in the pulmonary stump; therefore, after the second stroke, I was operated on again and the pulmonary stump was removed. The doctors could not find where the clots came from. As a result of the strokes, which occurred after my corrective heart operations, I have both orthopedic and speech impairments and require the use of an electric wheelchair for mobility purposes.

Throughout my childhood, my parents fought for the appropriate accommodations to be made in the school systems and for my right to be in classes with able-bodied children. I felt likes was necessary for me to work harder on class assignments just so I could keep up with the class. I also felt that I had to prove myself to my teachers. I am proud to say I am now an Indiana University/graduate.

Like other patients who have had the Fontan operation, I am beginning to see some of its side effects. Within two years, I have had atrial fibrillation three times, each time requiring a cardio version to get back into normal rhythm. I also have an enlarged atrium, which is causing my blood return to become sluggish. My first bout with atrial fibrillation occurred during the week of college midterms. I thought

it might have been something that I had brought on myself from stress, but I later found out in the hospital that it was a side effect from the Fontan procedure.

No one had informed me of any possible side effects of the Fontan. Only by speaking with my cardiologist and reading personal experiences of other Fontan patients I am beginning to understand more about the side effects; however, I have yet to understand why some people with congenital heart defects have strokes while others do not. No one can explain why I had two strokes after the Modified Fontan operation.

It is my hope that as more congenital heart research is performed, researchers may discover why some people are more prone to having a stroke than others and find a way to prevent them from occurring.

SAM

My name is Teresa Taylor from Skokie, Illinois and I would like to address this committee on behalf of all the children born with congenital heart defects, those surviving, and in honor of those that have lost their lives including my son, Sam.

My son Sam and countless others that have died prematurely are not forgotten but remembered. And to be a constant reminder for the need for additional federal funding for research on congenital heart defects.

Sam was born with hypo plastic left heart syndrome. In other words, his left side of his heart was underdeveloped. The left side of the heart is the main pumping chamber of the heart and pumps blood to the rest of the body.

The devastation over our son's condition has caused us great sorrow and pain. We knew very little in 1993 of his birth defect. There was little that we could do except listen to the doctors' prognosis and go along with the treatment they suggested. In 1993, the options for Sam were immediate open-heart surgery or wait for a heart transplant. We opted to place Sam on a heart transplant list. We were told that Sam would probably get a heart within the next 6–9 weeks. We did not receive a heart when we had thought. The heart for Sam came when he was 5 months old. He lived in the hospital his whole life on a ventilator. I would not call this life support but assistance so that his heart and lungs would not flood up with blood while he waited for a heart. Sam died two weeks after transplantation. He died due to lung and hospital related infections. Because Sam waited only two days short of the longest wait for an infant heart doctors did not know what to expect of his outcome. Today doctors know that an infant and most likely any patient waiting for a heart transplant cannot survive as long as Sam did on a ventilator. Because of Sam, doctors know that it is critical to find better ways to manage a patient waiting for a heart transplant and open-heart surgery. Today at Children's Memorial Hospital in Chicago, doctors have perfected open-heart surgery that would have been used on Sam instead of transplantation (the procedure is called Norwood). Research helped in this matter and patients like Sam helped them in their research. Sam and other children paid with their lives to help doctors understand congenital heart defects and find ways to better manage and treat their condition.

I have heard countless stories subsequent to our son's death. Stories of survivors with the same condition Sam was born with. These children are living today because of research in congenital heart defects.

JESSICA

My name is Jessica Cowin and I am 16 years old. I have had five heart surgeries since I was four days old because I was born with a hypo plastic left heart. A hypo plastic left heart is a heart that has no left side; in other words I had no pump. At four days and 18 months the doctors performed closed heart surgeries on me. At five years and 13 years, I had open-heart surgeries. All of these surgeries worked, for a while, but my heart began to fail in the last two years. The doctors and my parents agreed that I needed a heart transplant. It was very scary to think that the doctors were going to put someone else's heart inside of me, but if I wanted to live longer that's what I had to do.

On September 25, 1999, my mother got a phone call from the Children's Memorial Hospital in Chicago (where I have had all of my surgeries), saying that they had a heart for me. It has been two months since my transplant and even though I am on a lot of medication I already feel better. Before the transplant I had no energy and got sick more often than other children. I have missed a lot of school in the past three years and I missed my friends, too.

Without the research for congenital heart defects, I would not be here today. I was born in 1983 at Children's Memorial Hospital. At that time they were not even doing heart transplants there. They started doing transplants in 1988, when I was 5 years old. I have personally benefited from the research of all of my five surgeries.

PREPARED STATEMENT OF THE CITY OF MIAMI BEACH, FL

Mr. Chairman: On behalf of the City of Miami Beach, Florida, I appreciate the opportunity to submit written testimony on an extremely important program the City has undertaken to serve its elderly community both now and in the future. The City is seeking $500,000 in fiscal year 2002 appropriations through the Administration on Aging for the City's Elder Ready Community Pilot Initiative. We believe that this pilot project can serve as a national model for aging services programs as the nation's population continues to age.

ELDER READY COMMUNITY PILOT INITIATIVE

The Elder Affairs Office is part of the Housing Division of the City of Miami Beach, a public entity. The office assists the elder population in obtaining appropriate services through its information and referral service. Staff also identifies and coordinates services available in the community and serves as a liaison with other governmental and community based organizations. In addition, the Elder Services Initiative includes a needs and assessment that identifies programs that will enhance senior life on Miami Beach.

As you may know, the City of Miami Beach has traditionally been a destination for retirees. Over the last decade, the City has been revitalized as a tourist destination and as a business center attracting a younger resident population. At the same time, from 1990 to 2000, the population group ages 44 to 65 has increased from 19.4 percent to 23.2 percent of the City's total population. A key component of the Elder Services Initiative is the Elder Ready Communities Initiative that was developed by the Florida Department of Elder Affairs and was officially announced during Older Americans Month, May 2000. It seeks to enhance recognition of both the value of elders to Florida's communities and the need to plan for the accelerated demographic changes over the next ten years as the "baby boomer" generation reaches seniority. In order to seek the designation of the City as an Elder Ready Community, the Elder Affairs Office requests direct funding through the to undertake a comprehensive assessment of its elder community in regard to housing, transportation, city infrastructure, the business community and the availability of services.

The City of Miami Beach estimates that the cost of implementing an Elder Ready Pilot Program will be $500,000. The City has currently allocated an annual budget of $65,000 in general funds for its Elder Affairs Programs. In addition, the City has committed fiscal year 2000/2001 Community Development Block Grant funds in the amount of $90,000 and $65,000 in general funds to local providers of services to the elder community.

At this time, the City of Miami Beach is not receiving funding for this pilot program from any other Federal agency.

Florida is at the forefront of elder related issues that will greatly impact the rest of the country during the next decade. Florida has the largest proportion of elders of any state in the nation and all projections indicate that this will continue to be the case for the foreseeable future. The Florida Department of Elder Affairs leads the country in its creation of the Elder Ready Communities Initiative. The findings of this pilot project could be replicated in other municipalities across the country as the population continues to age. Through research, surveys and the ongoing commitment of the community, new and innovative systems can be implemented for the health and vitality of the entire City as well as for the rest of the country.

We hope you will find this critically important pilot project worthy of your support.

Thank you for your consideration.

PREPARED STATEMENT OF THE CITY OF NEWARK, NJ

Dear Mr. Chairman: The City of Newark, NJ hereby submits for the record, testimony regarding three innovative projects that are of great importance to the State of New Jersey's largest City. The projects described below each address an aspect of the needs of Newark's low income population. They are: (1) the Emergency Medical Services Demonstration Project, (2) the Children's Health Care Services and Outreach Center and (3) Babyland Family Services-A Solution to the Digital Divide among Urban Families.

NEWARK COORDINATED EMERGENCY MEDICAL SERVICES DEMONSTRATION PROJECT

The objective of Newark's Coordinated EMS Demonstration Project is to develop a coordinated model for a City-wide system for efficient patient transportation and emergency services utilization, tracking and billing. Funding is requested to assist

in the design and implementation of a system which will assure transportation of patients to the appropriate specialty hospital or other medical facility. The system will include a billing and service allocation component to reduce inefficiencies and deter fraud, waste and abuse. The system will be coordinated with the City's 911 integrated dispatch, to insure the timely transfer of calls and delivery of services. The City's dispatch center handles over 300,000 calls for service per year, and must efficiently channel calls for medical service to the EMS system in a manner that allows for tracking of services while transferring operational responsibility. Over 100,000 calls for service per year go to the Emergency Medical Services system in Newark.

Currently, the City of Newark contracts with the University of Medicine and Dentistry of New Jersey (UMDNJ), through University Hospital, to provide a complete system of dedicated 911 emergency medical services. These services include: basic life support units integrated with advanced life support services, emergency treatment and transportation to local area hospitals as defined in an Approved. Hospitals for Patient Transport policy, heavy rescue and vehicle extrication, and service as the lead agency in response to mass casualty incidents within the City. UMDNJ provides centralized medical dispatch communications per NJ State requirements, and the interface with City E911 services is crucial to both efficient and effective dispatching, as well as to securing appropriate and adequate reimbursement for services.

The combination of an increase in the number of calls for service, tremendous advances in available technology, and pressures on the billing system present both a challenge and an opportunity for a unique demonstration project. The City of Newark's Police Computer Aided Dispatch system is the central point for 911 emergency calls, and calls to it for medical assistance are transferred to UMDNJ. However, calls for assistance can also be placed directly to the emergency medical assistance provider. There is no integrated system which can track all calls, the disposition of them, and ultimately, the payment for them. The reimbursements paid by the City, Medicaid, Medicare, the State's Charity Care system, and managed care providers do not cover the cost of capital expenditure for system upgrades. Further, the integration of the City's E911 system with the UMDNJ system cannot currently be funded through municipal sources, due to other needs and demands. The City is now unable to track and verify EMS services and billing to residents and/or third parties for which it is responsible. Therefore, an allocation of $5 million is requested to establish a much needed demonstration project for an integrated system for coordinated delivery of emergency medical services.

NEWARK CHILDREN'S HEALTH CARE SERVICES AND OUTREACH CENTER

The objective of the Newark Children's Health Care Services and Outreach Center is to positively impact on the health of Newark's children through the development of a coordinated health care system that will allow the City to bring health care services to the community. The Children's Health Care Services and Outreach Center will provide a coordinated approach to offering health and social services to uninsured/underinsured pregnant women and children between the ages of 0 through 5. The City's Department of Health and Human Services will partner with other community organizations and hospitals to provide a full spectrum of health, social services and mental health services. At minimum, the Center will provide services that include, pre-conception counseling, early pregnancy testing, pre-natal care, substance abuse counseling and referral services, family counseling, pediatric practice with related services including WIC, immunization, nutritional counseling and case management services. Health education will be offered to develop parenting skills and managing households.

Through the use of focus groups, the DHHS will assess and re-evaluate Newark residents' use of existing services. Focus groups will be conducted to analyze barriers to services and residents utilization rates. Based upon the analysis, the DHHS will design the Children's Health Services and Outreach Center as a consumer friendly service center.

The City of Newark has been designated by the Centers for Disease Control and Prevention as a pocket of need for children. An analysis of trends in the City of Newark reveals that one-fifth of Newark resident births in 1996 were to teenage mothers (under age 20). Teenage mothers have accounted for 1 in 5 Newark resident births from 1989 through 1996. Over one-half of Newark resident women who delivered in 1996 began pre-natal care in the first trimester of pregnancy. In contrast three fourths of all New Jersey mothers giving birth in 1996 began pre-natal care in the first trimester. Since 1989 the percentage of Newark mothers receiving pre-natal care in the first trimester has generally declined for all age groups. In

fact, the rate of mothers giving birth in 1996 who received no pre-natal care was six times as high for Newark (8.3 percent) as for the State as a whole (1.3 percent). By race, nearly 12 percent of black mothers in Newark and 3 percent of white mothers received no pre-natal care.

In 1996 the number of Newark resident infant deaths 80, a 14.3 percent increase over the 70 infant deaths in 1995. Notwithstanding this one year increase, the number of resident infant deaths in Newark decreased from a high of 189 deaths in 1989 to the current level. Neo-natal deaths have been increasing over the past 8 years, from 52 percent of the total infant deaths in 1989 to 58 percent in 1996. The leading cause of death for infants in Newark in 1996 is low birth-weight. The second leading causes of death were congenital anomalies and sudden infant death syndrome.

Other ailments that affect the health of Newark children include pulmonary dysfunctions such as asthma and lead poisoning. As of December 31, 1998, Newark had a caseload of 1,613 children under age six with blood lead levels over 20 ug/dL. In 1998 an average of 25 percent of nearly 2,000 children tested had blood lead levels over 20 ug/dL.

In addition to services available at the Center, there will be an outreach team that will provide Newark residents with a mechanism that will link them to all services currently provided within the City of Newark, and that are identified through the focus groups. Teams will be assigned to identified neighborhoods, and will be comprised of a Public Health Nurse, Social Worker and Outreach worker. The teams will be responsible for visiting Newark children as well as older residents and assessing health and service needs. Working in coordination with neighborhood community based organizations, city-wide faith based agencies and area hospitals, citizens will be provided with referrals for care and services. There will be specific emphasis on reaching young mothers and their children who have not been previously involved with the health care system and available services.

Through the centralization of services, we believe that we can increase access to the array of health and social services needed by Newark residents to raise healthy children. The City seeks $2.5 million from the Centers for Disease Control (CDC) to support this initiative.

BABYLAND FAMILY SERVICES, INC.

THE NEWARK PROJECT: A SOLUTION TO THE DIGITAL DIVIDE AMONG URBAN FAMILIES

The purpose of this initiative is to serve as a model educational program that closes the "digital divide" among minority inner city children and families. This technological network links center and home-based child care centers and schools; community resources and service providers; educational, economic and resource information sources; training centers and administrative offices. The establishment of this network will be a model for educating urban children and serve as a conduit for comprehensive family support services.

The focus of this initiative is to establish the telecommunications linkages necessary for the educational development of 1,000 preschool and school-age children and to provide computer and technology training for 2,000 parents, teachers, family service workers and entry-level employees. As a result, this initiative will strengthen children's educational skills; promote the self-sufficiency of and enhance the educational skills of parents; enable the agency to better track child and family needs in order to enhance client services; and link the community to local and national resource centers.

Background: Computer technology is transforming the economic and social landscape of this country by offering information and educational opportunities for individual growth and community development. Inner-city children and residents are inadequately prepared to take advantage of these growth opportunities. If the gap in information technology—the digital divide—is not bridged, a large segment of society will be further polarized and left without the tools needed for full participation in society.

Babyland has been a major non-profit child and family service organization in Newark, New Jersey for over 33 years and currently provides comprehensive child and family development services to 1,500 at-risk children and their families each year. BFS programs provide a continuum of educational services to individual children from infancy to 18 years old (including teenage mothers and young fathers) as well as multiple support services for family members. The agency is able to build extensive relationships with families and to provide follow-up care. As a result, Babyland is in a unique position to launch and oversee a major computer and technology initiative that will provide extensive training and technology support for individual families. This technology initiative will assist clients who have no other

tangible means of becoming computer literate and of acquiring the requisite skills necessary to be informed and self-sufficient.

Specific Provisions

—Technology Center, as part of a new multi-purpose community resource and education center, that will provide distance learning, online and network linkages to educational institutions and community resources, professional development and training in basic and advanced computer and technology skills for low-income parents, neighborhood residents and entry-level employees.
—Technology hardware and software (technical assistance, network installation and expansion, wiring, modems, printers etc.) for children, parents and residents, and teaching/social service staff in classrooms, homes, family resource centers and safe havens.
—Technology Training, Curriculum Development and Professional Development for children, parents and residents, educational and social services staff, as well as local, State, national and international community-based family service providers.

The initiative will benefit the following

—Children at nine child care centers (850 preschoolers) and 400 school-age children (charter school and after school/summer enrichment programs) at six centers and schools.
—Parents and family members (2,000) at 14 Babyland sites with links to community resources;
—Agency Staff (300), including teachers and family service workers, for client tracking purposes; training and professional development; and access to community resources to be provided through workstations, wireless technology and/or palm pilots.
—Parents and children in the home for educational instruction and support, economic and resource information, links to other parents and teachers, parenting education (child and family health, child behavior and development, cultural sensitivity, etc) and professional education (ex. Certifications, GED, etc.).
—Family day care homes with links to community resources, professional education, BFS child care centers and other child and family resource centers.
—Child and family service providers, throughout Newark, New Jersey, the nation and South Africa, who will receive training in child, family and community development.

Key Outcomes

—Enhanced early childhood development and education for children (three to 13 years old).
—Enhanced ability of inner city residents, especially low-income parents and teenagers, to learn computer and technology skills.
—Enhanced tracking of 1,500 children in center- and home-based child care facilities; teenage parents; victims of domestic violence; homeless families; and children in foster care.
—Enhanced delivery of professional development of teaching and family service staff.
—Enhance the provision and delivery of parent education programs.
—Enhanced delivery of clinical and therapeutic services to parents and children.
—Enhanced ability to fulfill State and Federal reporting requirements and to provide community development consultation to local, State, national and international family service providers.

This project received an allocation of $723,000 in the last fiscal year. But in order for the system to be fully operational and implemented for the entire target clientele population, an additional allocation of $2 million is being sought.

The City of Newark wishes to express its deep appreciation to this Committee for permitting the presentation of these important projects. Your positive response for Newark's request for support will have a positive impact on the health and well-being of Newark's citizens.

PREPARED STATEMENT OF MISSISSIPPI STATE UNIVERSITY

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit this testimony regarding the National Institutes of Health Institutional Development Award (IDeA) program. I am Dr. Robert Altenkirch, and I am Vice-President for Research at Mississippi State University. I also serve as EPSCoR

State Project Director in Mississippi. I submit this testimony on behalf of the Coalition of EPSCoR States.[1]

I would like first to express my gratitude to Senator Cochran for his strong support of the IDeA program and the related Experimental Programs to Stimulate Competitive Research (EPSCoR) in other federal agencies. Senator Cochran has been a strong advocate of IDeA because he understands the importance of enhancing our nation's biomedical research infrastructure by building the research capacity of Mississippi and the other IDeA states. We Mississippians greatly appreciate his leadership on IDeA and a whole host of issues important to Mississippi. We are proud to have him represent us in the United States Senate.

IDeA was authorized by the 1993 NIH Revitalization Act (Public Law 103–43). IDeA works to improve our nation's biomedical research capacity by enhancing the capability of states that have not yet substantially participated in the NIH's research endeavors. The NIH has identified the following states as eligible for IDeA funding: Alaska, Arkansas, Delaware, Hawaii, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Rhode Island, South Dakota, South Carolina, Vermont, West Virginia, Wyoming and the Commonwealth of Puerto Rico. IDeA acknowledges that nearly one-half of the states do not have an adequate R&D infrastructure in the biomedical sciences. Clearly this is not in the long-term best interest of our nation.

IDeA is important, Mr. Chairman, because NIH research funds are extremely concentrated geographically. The 24 states that participate in IDeA received just 5.3 percent of NIH research funding over the fiscal year 1994-fiscal year 2000 period, while the top state alone received nearly three times that amount. The five most successful states combined received 48 percent of NIH funding over the same period.

For example, according to data compiled by the Social Science Research Center at Mississippi State University, Mississippi received $20 million in NIH research funding in fiscal year 1999, compared with a national average of nearly $250 million per state. Alaska received just $2 million, Idaho received $3 million, and New Hampshire received $50.3 million—all a fraction of the national average.

Our country has embarked on a great endeavor: to increase substantially the NIH research budget—possibly even doubling research funding over the next five to seven years. Many scientists and Members of Congress support this worthy goal, and I applaud this important effort.

While I strongly support efforts to increase biomedical research funding, I think it crucial that all regions of the country participate in this effort—not just existing centers of excellence in a small handful of states. If we are to double research funding we need to enhance our research capacity by including a greater portion of the country in our research endeavors. Every region of the country has talent to contribute to our nation's biomedical research efforts—and every region of the country should have the opportunity to nurture and develop their talent pool into individuals and centers that can compete successfully for NIH funding and develop the biomedical R&D base across our nation.

The 24 IDeA states have fine research institutions that are home to many talented researchers. The institutions and researchers in these 24 states should play a significant role in our nation's effort to expand research capacity; they are crucial to any serious effort to improve our nation's ability to treat, cure and prevent disease.

Mr. Chairman, the Congress provided the NIH with $20.3 billion in fiscal year 2001—an increase of $2.5 billion or 14 percent above the fiscal year 2000 level. It is the largest increase that NIH has ever received, and I understand the NIH could receive an increase this year as well. Mr. Chairman, the Subcommittee was helpful last year in providing IDeA with an increase, and we sincerely appreciate the Subcommittee's support. While last year's appropriation for IDeA is definitely a step in the right direction, we believe IDeA should be funded at $200 million or more.

We ask you to provide $200 million for IDeA in fiscal year 2002—a small fraction of the likely NIH increase. Building the research capability of the 24 IDeA states is crucial toward the goal of increasing and enhancing our nation's research capability. On behalf of the Coalition of EPSCoR States, I thank the Subcommittee for the opportunity to submit this testimony.

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[1] Alabama, Alaska, Arkansas, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, North Dakota, Oklahoma, Puerto Rico, South Carolina, South Dakota, Vermont, West Virginia, and Wyoming.

PREPARED STATEMENT OF THE COALITION FOR HEALTH FUNDING

Mr. Chairman, the Coalition for Health Funding is pleased to provide the Subcommittee with testimony recommending fiscal year 2002 funding levels for the agencies and programs of the Public Health Service. Since 1970, the Coalition's member organizations, representing 40 million health care professionals, researchers, lay volunteers, patients and families, have been advocating for adequate resources for the agencies and programs within the Public Health Service. The Coalition for Health Funding is the nation's oldest, most broadly based alliance focused on the breadth of discretionary health spending.

The Coalition sincerely appreciates the strong and continued support that the Subcommittee has given to health discretionary programs in the past. The Coalition recognizes the considerable funding limitations that the Subcommittee is likely to face in fiscal year 2002, but the Coalition urges you to seize every opportunity, as the process moves forward, to fund increases for critical public health programs.

On the cusp of the second year of the 21st Century, the nation, and the world, are at an unprecedented nexus of great promise and potential disaster. If we devote adequate resources to research opportunities at the National Institutes of Health we have the potential to advance our understanding of the biological basis of disease and unlock new strategies for disease prevention, diagnosis, treatment and cures. But we will not fully reap that potential for all Americans if we do not also invest in the other agencies and programs of the U.S. Public Health Service. We will not fully reap our investment in biomedical and behavioral research if we do not also invest in a strong public health infrastructure at the local, state, and federal level; translate biomedical and behavioral research into community-based prevention strategies; provide needed services for medically underserved populations; assure a well-distributed health and public health workforce in adequate numbers; and develop and translate the most cost-effective implementation of biomedical and behavioral research into medical practice. If we do not also do these things we risk disaster in the form of soaring medical care costs as the cohort of baby boomers ages with a host of preventable chronic diseases and there are not enough nurses, and other essential health care personnel, to care for them. We risk disaster if we do not continue to strengthen our seriously weakened public health infrastructure at the local, state and federal levels to prepare for a bioterrorist attack, a major outbreak of infectious disease such as the world experienced in the 1918 with pandemic flu, and to curb rapidly growing resistance to antibiotics used to treat serious bacterial infections. We risk disaster if we do not continue to try to meet growing demand for basic health and medical care services, particularly for mothers and children. A community is only as healthy as its weakest members. Failure to fully immunize children, adolescents, and vulnerable adults puts everyone at risk. Failure to respond to the health, mental health, and substance abuse needs of millions of uninsured Americans undermines the health of our workforce and undermines the health of our economy.

These are the major public health challenges ahead in the 21st Century. To address them and reap the potential of enormous positive returns requires adequate investment across the continuum of public health activity. The coalition's members recognize that no one component of the public health continuum can be effective in achieving the overall goal of improved health outcomes without the strong support of the components.

Each year, the Coalition for Health Funding works with other health alliances to determine an appropriate level of federal support for all health discretionary programs. For fiscal year 2002 the Coalition is recommending $44.2 billion be provided to address the nation's needs in the areas of biomedical, behavioral, and health services research; disease prevention and health promotion; health services for medically underserved populations; health professions education; and substance abuse and mental health services. The Coalition's recommendation also includes funding for the Indian Health Service and the Food and Drug Administration, which are not within the jurisdiction of this Subcommittee, but are important agencies within the U.S. Public Health Service. The Coalition appreciates that these funding levels, 20 percent over fiscal year 2001, may appear excessive, but they reflect both the professional judgment within the various agencies as well as our own members' assessment of community and national need. The Coalition presents these recommendations to the Subcommittee in the hope that it will view them as important targets for optimal health outcomes.

The following is a partial list of the Coalition's findings and recommendations; the attached table provides the Coalition's recommendations for all the public health agencies:

NATIONAL INSTITUTES OF HEALTH (NIH)

The Coalition supports an additional $3.4 billion in funding for NIH in fiscal year 2002, for a total of $23.7 billion, as the fourth installment toward doubling the NIH budget by 2003. But in recognition of the difficulty in achieving this goal, the Coalition cautions that this increase must not come at the expense of other public health programs.

The Coalition recognizes the critical importance of the research conducted at the NIH and that increases provided in fiscal year 1999, 2000, and 2001 must be continued in order to fully reap our investment. Three main reasons for continuing on the path to doubling the NIH budget include the many research challenges still confronting us, the burgeoning scientific opportunities that are now available in this post-genomic world, and the large economic benefits that accrue as we make progress against diseases. Examples of past investments in NIH research that have yielded important benefits include identifying a gene that contributes to susceptibility to type 2 diabetes, developing a vaccine to nearly eliminate infections caused by Haemophilus influenzae type b, using magnetic resonance imaging (MRI) measurements to predict who will get Alzheimer's disease, making landmark strides in the diagnosis and treatment of depression and schizophrenia, uncovering a hormone involved in the onset of osteoporosis, and growing replacement heart valves in the laboratory.

The Coalition appreciates that medical research is a vision not a precise blueprint. It must be flexible enough to respond to society's changing health care needs and dynamic enough to open the way to ever more promising frontiers of fundamental research. Scientific discoveries are the result of a series of incremental steps that pave the way for future breakthroughs. This process needs sustained support. With it, and support for other public health partners, we will be ready to meet the challenges of the future.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Coalition for Health Funding recommends an overall funding level of $5 billion for CDC in fiscal year 2002. The Coalition believes this is the amount needed to enable CDC to carry out its vital mission of disease prevention and health promotion.

The Coalition is very pleased that Congress provided $181 million in fiscal year 2001 to continue the process of re-building the nation's seriously eroded public health infrastructure in order to prepare for bioterrorism. The Coalition notes that landmark legislation passed last year, the Public Health Threats and Emergencies Act, builds on the three years of bioterrorism funding, to further strengthen public health infrastructure at all levels of government, but particularly the local and state levels. The Act authorizes $524 million in fiscal year 2002 to address three major threats: bioterrorism, antimicrobial resistance and major infectious disease outbreaks. The Coalition urges the Subcommittee to provide full funding for this critical effort; strengthening basic public health capacity also lays a foundation for addressing all disease and disabling conditions.

CDC administers many programs that utilize the research findings of the National Institutes of Health, and other public health agencies and programs, to develop community-based strategies to prevent disease and disabling conditions and promote improved health. Programs needing increases include those addressing chronic and environmental diseases such as cardiovascular diseases, diabetes, cancer, and asthma. This program line received a substantial, 40 percent increase in fiscal year 2001, but because there are over 40 separate programs included, some received significant increases, others small increases, and some no increases. Chronic diseases combined constitute the nation's most costly health problem, but we still do not reach all states with adequate funding to implement cost-saving and life-enhancing prevention efforts.

In the area of infectious diseases, the Coalition believes that significant increases are needed to enable CDC to fully implement its comprehensive plan, " Preventing Emerging Infectious Diseases: A Strategy for the 21st Century." In today's global society, it is possible for a new disease to spread internationally within days, perhaps hours. Since 1973, more than 35 new infectious diseases have been identified, including *E. coli* 0157:H7, airborne Ebola virus, and West Nile virus. Serious challenges lie ahead as these newly emerging and re-emerging diseases are identified, while at the same time, multi-drug resistant organisms, such as *Staphylococcus aureus,* proliferate. More than 90 percent of strains of *Staphylococcus aureus* in U.S. hospitals are resistant to penicillin. In some areas of the United States, more than 30 percent of the pneumococci resist penicillin, a drug once effective against almost all pneumococcal pneumonia and meningitis.

Increases are also needed for prevention of HIV transmission, which is receiving new focus within CDC. Prevention of HIV transmission is our best defense against the AIDS epidemic that has already killed over 400,000 U.S. citizens and is devastating the populations of nations around the globe. There are 40,000 new infections every year with one-half occurring in individuals under the age of 25.

Elimination of TB and STDs, especially syphilis, are now within our grasp. These welcome opportunities, if adequately funded now, will save millions in annual health care costs in the future.

Finally, also in the area of infectious diseases, significant increases are needed for immunization. An important IOM report on immunizations published last year entitled, Calling the Shots, stated that unstable funding for state immunization programs threatens coverage for specific populations and age groups. The report recommended an increase of $75 million for CDC's operations/infrastructure state grant program. Congress provided $42.5 million of this increase in fiscal year 2001; the full increase is needed in fiscal year 2002. In addition, significant increases are also needed for the domestic vaccine purchase program to meet the costs of the newly recommended pneumococcal conjugate vaccine, as well as the costs of expanding vaccines to the 1 million two-year-olds that are not fully vaccinated, and to adolescents and adults. Finally, increases are also needed for CDC's global immunization program.

In response to legislation enacted last year, CDC has created a new Center on Birth Defects and Developmental Disabilities. This exciting, strengthened focus on many preventable diseases and disabling conditions, as well as on improving the lives of those who live with disabilities, also needs new resources.

The Preventive Health and Health Services Block Grant is the only source of flexible funding to enable state public health officials to achieve Healthy People 2010 goals, address health gaps in discretionary funding, and respond to unexpected crises such as the emergence of West Nile Virus. The Block Grant was cut nearly $15 million (10 percent) in fiscal year 2000 to $135 million and level funded in fiscal year 2001. State health officials are requesting a 50 percent increase in the Prevention Block Grant for fiscal year 2002.

Prevention Centers and Prevention Research, important programs in the nation's foremost health prevention agency, should receive significant increases reflecting their importance. Prevention research is mentioned as a priority area in President Bush's February budget blueprint.

Other important programs needing increases are: the National Center for Health Statistics, NIOSH; health disparities demonstration research; and injury control.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The Coalition for Health Funding recommends an overall funding level of $6.7 billion for HRSA in fiscal year 2002. This is the total funding level that the Coalition believes is needed to provide adequate resources for the important programs that HRSA administers that address access to needed medical and health care services for medically underserved populations.

The Coalition is pleased that the President has expressed his support for the effort to double funding for the Consolidated Health Centers program over the next five years. Last year, Congress provided the first down payment on this goal bringing the current funding levels to $1.169 billion. The Coalition for Health Funding supports a second down payment in fiscal year 2002 to help reach the goal of building 1,200 new health center sites and doubling the patient capacity of the entire health center program over the next five years.

The Coalition's recommendation also includes increases for the programs of the Ryan White CARE Act. HIV/AIDS is an extremely serious epidemic facing Americans and people throughout the world. The programs of the Ryan White CARE Act target needed health care, and other support services, including expensive drug therapies, to Americans suffering from HIV/AIDS.

The Coalition supports an increase for the Title X family planning program in fiscal year 2002. This funding would support 4,600 family planning clinics across the United States. It would pay for comprehensive services including screenings for cancer, HIV, and other diseases as well as contraception, and teen pregnancy prevention including educational activities that encourage young people to postpone sexuality.

Preliminary information indicates the President's budget may cut funding for Graduate Medical Education for free-standing children's teaching hospitals which was a new initiative in fiscal year 2000, and received $235 million in funding in fiscal year 2001. This important program that trains physicians that provide direct care for children, needs to continue, and needs increased, not decreased, funding.

The Coalition also supports increased funding for the Children's Emergency Medical Services program which ensures that emergency care provided for children is appropriate for their specific needs, and funding at the authorized level for HRSA's new trauma care program.

The Coalition is disappointed that the Maternal and Child Health Block Grant has been level funded for the past several years at $710 million. This program provides comprehensive, preventive care for mothers and young children, as well as an array of coordinated services for children with special needs. MCH programs are facing increased demands for services due largely to two trends: continued growth in the numbers of uninsured that is outpacing targeted efforts, such as the Child Health Insurance Program, to cover them; as more eligible children for CHIP are identified, often by MCH outreach efforts, more children are identified as needing MCH services. This increased demand, and the findings of a recent Institute of Medicine report entitled, From Neurons to Neighborhoods, which concludes that new science about early childhood development demonstrates urgent need to expand the kind of services that the MCH Block Grant provides, the Coalition believes this program should be funded at its fully authorized amount in fiscal year 2002.

The Coalition is also very disappointed that the President's budget blueprint proposes to cut the Health Professions and Nursing Education Programs. These programs provide support to students, programs, departments and institutions to improve the racial and ethnic diversity, accessibility, and quality of the health and public healthffff workforce. In particular, these programs help meet the health care delivery needs of over 2,800 Health Professions Shortage Areas in this country, at times serving as the only source of health care in many rural and disadvantaged communities. The Coalition believes this program needs increased, not reduced, funding in fiscal year 2002.

The Coalition sincerely appreciates this opportunity to provide its fiscal year 2002 funding recommendations to the Subcommittee for the agencies and programs of the U.S. Public Health Service. The Coalition's recommendations for all of the public health agencies is provided in the accompanying table. The Coalition, and its member organizations, look forward to working with the Subcommittee in the weeks ahead to improve the health of all Americans.

DISCRETIONARY HEALTH PROGRAMS

[B.A. in millions of Dollars]

	Fiscal year		Difference	Percent
	2001 appropriation	2002 CHF recommendation		
CDC	$3,868	$5,000	+$1.1b	+29
NIH	20.3b	23.7b	+3.4b	+16.7
HRSA	5,557	6,700	+1.1b	+20
SAMSHA	2,958	4,057	+1.1b	+37
AHRQ	270	400	+130m	+48
FDA	1,217	1,399	+182m	+15
IHS	2,598	2,848	+250m	+9
OPHS	165	181	+16m	+9
Total Public Health	36,933	44,285	+7,352	+20

Prepared Statement of the Coalition of Northeastern Governors

The Coalition of Northeastern Governors (CONEG) is pleased to provide testimony for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies as it considers fiscal year 2002 and advance fiscal year 2003 appropriations for the Low Income Home Energy Assistance Program (LIHEAP). The CONEG Governors appreciate the support provided by the Subcommittee in maintaining this important program, and urge the Subcommittee to increase funding for both fiscal year 2002 and advance funding for fiscal year 2003 to the full authorized level. In addition, we are requesting that the full authorized funding authority be provided for each year to allow for the release of emergency funds for unforeseen circumstances, such as price spikes in natural gas or heating oil, severe weather and other potential emergencies.

During the current fiscal year, LIHEAP has played an essential role in making home energy affordable for the region's very low-income households—the elderly and disabled on fixed incomes, families with young children, and those making the difficult transition from welfare to work. Two-thirds of the region's LIHEAP recipients have annual incomes of less than $8,000 per year. For many of these households, annual income is not sufficient to pay high winter heating bills, even in periods of economic growth. Many low-income residents are forced to choose between heating their homes or purchasing food or vital medications.

The recent rise in winter heating fuel prices has hit these vulnerable citizens especially hard. Price volatility adversely affects the low-income households who, without disposable income to purchase fuels off-season, typically enter the market when demand and price are high. The percentage of household income spent on energy by low-income residents can be significant. Program funds are targeted to those households with high energy burdens, averaging 18 percent of household income—compared with 6.7 percent for all households.

This increase in the price of home heating fuels has created a heightened demand on the states' LIHEAP programs. The projected need far outweighs the available funding. States in the region have seen increases as high as 33 percent in their regular caseloads as well as significant increases in requests for emergency assistance from those households in imminent danger of a fuel service cut-off.

The $600 million in LIHEAP contingency funding provided by Congress in the fiscal year 2000 supplemental appropriations bill was essential in ensuring that low-income households could heat their homes this winter, and the states are deeply appreciative of Congress' action. Even with these contingency funds, the program currently serves less than 20 percent of citizens who qualify for LIHEAP assistance. While there will always be true crises that call for emergency funding, an increase in the regular LIHEAP appropriation for fiscal years 2002 and 2003 to the full authorized amount will enable the states to more fully implement cost-effective measures to meet the continuing energy needs of the region's most vulnerable citizens.

State LIHEAP programs could stabilize heating fuel prices for low-income households and expand the reach of limited program funds if an agency could achieve some form of price protection through contracting with retailers on a fixed or ceiling price basis when heating oil prices are most attractive. Today, these "pre-buys" are difficult to do, since the programs face the constraints of limited or no funds to carry forward to a new heating season, and the new funds are not available until October 1 of each year. A federal appropriation, and advance funding, to the full authorized level would allow states to manage the program resources in a manner to better take advantage of retail contracts.

As you know, the fiscal year 2001 Labor, HHS and Education appropriations bill did not contain advance fiscal year 2002 funds for LIHEAP. Enactment of advance funding is vital to the states' program planning activities for the coming heating season. In the Northeast, where the heating season begins in early October, states generally spend up to 70 percent of the LIHEAP funds during the first two quarters of the fiscal year. States must be prepared to begin their LIHEAP program as soon as the new fiscal year starts. Advance funding permits them to do this, even when Congress has not yet enacted the Labor, HHS and Education appropriations bill for the new fiscal year.

Our states have aggressively planned for a colder winter and higher heating fuel prices. LIHEAP programs opened early and states undertook aggressive outreach campaigns urging customers to conserve energy and explore fuel price protection options. States have designed their LIHEAP programs to make the most efficient use of funds by coordinating with weatherization and leveraging programs. In cooperation with federal officials and the winter fuels industry, CONEG conducted a winter fuels emergency simulation exercise to ensure that our states, federal agencies and the industry will be prepared to anticipate and effectively manage winter fuel supply emergencies which may arise.

These preparedness activities, while critical, cannot fully shield our lowest-income citizens from the impacts of higher heating fuel prices. Your support for increased LIHEAP appropriations to the full authorized level and the enactment of advance appropriations is urgently needed to enable our states to help mitigate the potential life-threatening emergencies and economic hardship that confront the region's most vulnerable citizens.

We thank the Subcommittee for this opportunity to share the views of the Coalition of Northeastern Governors, and we stand ready to provide you with any additional information on the importance of the Low Income Home Energy Assistance Program to the Northeast.

PREPARED STATEMENT OF COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

Thank you Mr. Chairman and Members of the Subcommittee for the opportunity to present written testimony for the record. My name is Charles Schuster and in addition to being a Professor of Psychiatry and Behavioral Neuroscience and Director of the Wayne State University Addiction Research Institute, I am the President of the College on Problems of Drug Dependence (CPDD). The CPDD, formerly the Committee on Problems of Drug Dependence, has been in existence since 1929 and is the longest standing group in the United States addressing problems of drug dependence and abuse. From 1929 until 1976, the CPDD was associated with the National Academy of Sciences, National Research Council. Now the CPDD functions as an independent organization with over 600 members representing all of the scientific disciplines and medical specialties concerned with understanding the etiology and consequences of drug abuse and based upon this understanding the development of effective prevention and treatment interventions.

As part of its function the CPDD serves as an interface among governmental, industrial and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field. CPDD also serves as a collaborating center for the World Health Organizations Drug Abuse Advisory Committee and members of the CPDD Board of Directors have served as an Expert Advisory Group to the Office of National Drug Control Policy.

Since 1938, a major focus of the CPDD's activities has been its sponsorship of an annual scientific meeting. This conference serves as a forum bringing together basic scientists, clinical investigators from industry, academia, and government. Representatives of regulatory agencies and other policy makers, as well as scientists and professionals in a number of diverse disciplines interested in the biochemical, behavioral, and public health aspects of drug dependence participate. This year I am pleased to note the Center for Substance Abuse Treatment/SAMSHA has supported the participation of community treatment practitioners. This support will enable us to bridge the gap between academic researchers and drug abuse treatment practitioners to facilitate the application of new science-based treatment and prevention interventions in community treatment programs.

The National Institute on Drug Abuse/NIH is a governmental organization that is very important to CPDD because it supports the overwhelming majority of the scientific research on the biopsychosocial problems associated with drug abuse and dependence. These research efforts are rapidly increasing our knowledge about the etiology and consequences of drug abuse and providing a science base for the development of more effective prevention and treatment interventions. There are a number of areas of NIDA sponsored research ranging from the basic to the applied that are making a difference. However, time permits me to mention only a few of these today.

NEUROTOXICITY

Many years ago my colleagues and I at the University of Chicago reported that high doses of methamphetamine (speed, crack) causes irreversible damage to dopaminergic and serotonergic neurons in the brains of laboratory animals. Although this uniform finding across diverse-animal species suggests that similar effects would be found in humans it is important to firmly establish this conclusion. Today, using modern techniques for the non-invasive study of the human brain (Positron Emission Tomography, functional Magnetic Resonance Imaging and Magnetic Resonance Spectroscopy) is allowing NIDA sponsored researchers to explore this premise and definitive answers are imminent. In addition, NIDA sponsored research is currently using these imaging techniques to determine the type of brain changes that take place when drug abusers are exposed to high doses of other drugs such as cocaine, MDMA (Ecstasy) and heroin, whether these changes are irreversible and their functional consequences. The recent emergence of the problems of teen-age abuse of MDMA and other "Club Drugs" exemplifies the ever-changing challenges which face the NIDA.

BEHAVIORAL TREATMENT INTERVENTIONS

Such basic knowledge informs and improves efforts to develop treatments of drug dependence. Treatments of all varieties and various combinations are important for promoting abstinence for the drug abuser and dependent patients. Behavioral treatments are one area of many where NIDA has been very successful and effective in adding to our "treatment toolbox". Behavioral treatments emphasize that treatment must address multiple factors in an individual's life that support drug use and rear-

range them so that they support abstinence. Such successful treatments have shown that teaching skills, supporting change, and providing incentives can produce both immediate and long lasting abstinence in the drug-dependent patient. NIDA sponsored researchers are applying these important innovations to an ever increasing array of conditions and patients. Among the most important of these is the pregnant addict. Behavioral treatments that promote abstinence in pregnant mothers not only help the mother, but prevent a plethora of problems in the developing baby. Such efforts show the success of developing treatments and exemplify the broad impact they can have not only today but also in tomorrow's generation.

NATIONAL DRUG ABUSE TREATMENT CLINICAL TRIALS NETWORK (NIDA–CTN)

Developing successful treatments are important, but so is the dissemination and utilization of those treatments. Over the past two years NIDA has established a network of 14 university-based research centers, each of which are affiliated with 5–10 community treatment programs (CTP's). Behavioral and pharmacological treatments, alone and in combination which have been shown to be efficacious in NIDA sponsored controlled clinical trials will be evaluated for their "usefulness" in these CTP's. Those that are found to be useful will be disseminated to treatment programs throughout the United States. In this way the NIDA–CTN will facilitate the utilization of the most effective treatments for all those seeking to overcome their drug dependence problems. If funding is available, we understand that NIDA plans on expanding this system to have an even greater impact on the quality of drug abuse treatment available throughout the country. The College urges you to support funding for NIDA at $991.7 million in the fiscal year 2002 Labor, Health and Human Services Appropriation Bill, which represents a 27.0 percent increase over current funding.

This increase will allow for the expansion of the CTN while at the same time providing the necessary funding for research which will lead to the development of new treatment interventions that the CTN will evaluate.

The members of the College on Problems of Drug dependence want to thank this Subcommittee for your steadfast support of the NIH in general and the National Institute on Drug Abuse in particular. We believe that the federal governmental investment in drug abuse research is extremely wise. Every individual in this country is effected either directly or indirectly by the problems associated with drug abuse. Economists estimate that drug abuse costs our society over $100 billion dollars each year. But dollars cannot portray the tragedies that drug abuse cause for the individual, their families and the communities in which they live.

I have seen the tragic consequences of my son's involvement with the criminal justice system because of his illicit drug use. The good news is that research has shown that drug abuse can be prevented and effectively treated. Clearly there is room for improvement in our ability to prevent and treat the problems of drug abuse/dependence. This is why additional research is needed. Basic research to better delineate the social and biological factors that make some young people vulnerable to the addictive properties of drugs of abuse. A thorough understanding of these etiological risk factors for drug dependence will make it possible to improve our prevention efforts especially for those who are most vulnerable for addiction. Basic research is essential for understanding what changes in the brain take place in the transition from sporadic abuse of drugs to the compulsive use characterizing drug dependence. This knowledge will help us to target the brain neurochemical systems that must be treated with medications if we are to reverse the addiction process.

Finally, basic research is needed to delineate the long term neurotoxic consequences of exposure to drugs of abuse so that we can develop therapies to assist individuals so afflicted to function optimally. Hopefully the insights provided by this basic research will lead clinical researchers in the development of new effective pharmacological and behavioral interventions for the treatment of all forms of substance abuse/dependence. Research has already shown that currently available empirically based prevention and treatment is the most cost-effective means of curbing drug abuse. Clearly supporting research that will further improve our ability to prevent and treat the problems of drug abuse will pay handsome dividends both financially and for the morale of our country. CPDD therefore asks this Subcommittee to seriously consider funding NIDA at $991.7 million for fiscal year 2002. We recognize that there are many competing demands for federal funds but strongly believe that this area is of the highest priority.

It must also be stated that the membership of the College on Problem of Drug Dependence is concerned about the adequacy of funding for drug abuse prevention and treatment services. We therefore request that you provide increased funding for the Center for Substance Abuse Prevention and the Center for Substance Abuse

Treatment to insure that they are able to provide the support necessary to provide all of our citizens the very best services possible.

Thank you for the opportunity to present the views of the membership of the College on Problems of Drug Dependence to this Subcommittee.

PREPARED STATEMENT OF COMMUNITY MEDICAL CENTERS, FRESNO, CA

Mr. Chairman and Members of the Subcommittee: My name is Dr. Philip Hinton and I am Chief Executive Officer of Community Medical Centers in Fresno, California. Community Medical Centers is a not-for-profit, locally owned healthcare corporation that is committed to improving the health of the community. I am pleased to provide the subcommittee with a request for assistance in securing federal monies for a critical project in the Central San Joaquin Valley that would improve healthcare delivery to the growing Hispanic and minority populations by creating a network of clinics accessible to the rural areas. These populations in the five county area of Fresno, Madera, Tulare, Kings and Mariposa face some of the most devastating and worst health outcomes in the state of California and in the nation:

—the third highest asthma mortality rate in the nation;
—the highest rates of teen pregnancy in the state;
—the highest incidence of diabetes among the Hispanic population
—late or no prenatal care for pregnant women
—greater likelihood for newborns to be of low birth weight than the rest of the state
—some of the lowest immunization rates in the nation (62 percent at age 2 versus 79 percent nationally)
—the highest rates of syphilis in the state.

These health outcomes are not acceptable and yet they exist because of the following reasons:

Limited access to care

—Low ratio of primary care providers to population. Fresno County has 178 physicians/100,000 population vs. 235/100,000 in the state.
—Virtually no specialist care located in rural areas
—Isolation of rural communities from urban areas and poor public transportation.

Financial constraints

—Many people are without health insurance
—Accessing healthcare in the urban areas results in a day's lost wages
—Lack of childcare providers means that patients must bring their entire family with them when they visit the clinic.

Educational issues concerning health

—Lack of understanding of preventive care
—Cultural barriers to addressing health issues before they become acute crisis

Language barriers

—Over 100 languages are spoken in the area

Coupled with high unemployment rates that are twice the state and three times the national average, and adults and children living below the poverty line hovering at 25 percent and 32 percent respectively, the statistics and indicators point to the need for aggressive action to address the tremendous health care needs of the population in this five county area.

Community Medical Centers proposes to address this health situation with a pilot project to improve the health of farm workers and residents of the rural communities who make up 41 percent of the population of the region.

Community Medical Centers has proposed developing a collaborative network that will include local healthcare providers, Federally Qualified Health Centers, county health and human services agencies, local hospitals, dentists, schools, churches and local communities. The network will work to aggressively deliver both preventive and primary health care to the people of the five county region. The new Regional Health Center on the campus of the Regional Medical Center in downtown Fresno will be the center for coordinating these activities. The new Regional Health Center is just one component of a more comprehensive, $210 million medical complex that will also include a new facility to house Level I burn and trauma services, emergency services, in-patient surgery, cardiac services and intensive care beds as well as a University of California San Francisco (UCSF) Medical Education and Research Center to house the teaching program. The Regional Health Center will deliver primary and specialty care, offer easy access to higher level care in an inpatient and

outpatient setting, and access the faculty and residents of the UCSF-Fresno Medical Education Program.

This $35 million project will:

—Improve access to the rural areas by partnering with existing centers and local healthcare providers to provide access for all patients and utilize and coordinate mobile health care units to go into the areas that are under-served. In addition, provide trained bilingual personnel to qualify people for health care programs and educate them about preventive care.

—Focus on preventive care and high prevalence diseases by offering asthma education and management programs; early diagnosis, dietary and medical management of diabetes; teen pregnancy prevention programs; prenatal care; screenings for cancer, diabetes and high blood pressure; and dental and mental health services.

—Result in a healthier community by providing primary care to a significant portion of the population and reducing their dependency on hospital emergency rooms for these services; improve people's quality of life and health thereby reducing hospital admissions for asthma, diabetes, hypertension and complications associated with these diseases; reduce the number of premature births.

—Realize significant savings in medical costs by focusing on the health needs of the population and emphasizing prevention and disease management as opposed to depending on hospitalization for primary care. We predict a 20 percent decrease in emergency room visits and hospitalization that would result in a significant savings of $18 million per year.

The human statistics point to the need to address this situation now before it progresses to a crisis. Community Medical Centers is working with the County of Fresno to contribute $17.5 million of state and local monies toward this pilot project. These monies, coupled with an additional $17.5 million from the federal government, would provide key funding support and ensure completion of this critical health care initiative facing our community.

We have identified the HHS Health, Resources and Services Administration (HRSA) Buildings and Facilities earmark in the fiscal year 2002 appropriation bill for Labor/HHS/Education as a source of funds. We understand that this program is specifically designated for buildings and facilities, and we request your assistance in securing as much of the needed $17.5 million as possible through this program account for the Regional Health Center to be housed on the downtown campus in Fresno. This past year, we were pleased to be the recipients of $851,000 of Federal support for this project. The funding was provided by the fiscal year 2001 Department of Health and Human Services Appropriation Act (Public Law 106–554).

We appreciate your attention to this matter, and we hope that you will favorably consider our request to improve healthcare delivery to the Central San Joaquin Valley in California.

PREPARED STATEMENT OF THE COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS

FULL FUNDING FOR THE PUBLIC HEALTH THREATS AND EMERGENCIES ACT

The Public Health Threats and Emergencies Act (PHTEA) is landmark legislation that was signed into law on November 13, 2000. The PHTEA builds on three years of funding, provided by Congress, to prepare the nation for bioterrorist attacks by strengthening the nation's public health system at the local, state and federal level. The PHTEA was introduced after a series of bipartisan Congressional forums, Committee hearings and a GAO report all of which established that our public health system is not prepared to detect or respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to antimicrobial agents, and acts of bioterrorism. CSTE contributed to the development of the PHTEA at every phase, and strongly supports funding the Act at the authorized level of $534 million.

The PHTEA has four major components as follows: (1) $100 million for building public health capacity with this amount expected to rise in future years; (2) $40 million for antimicrobial resistance; (3) $215 million for Bioterrorism preparedness; and (4) $180 million for CDC's facilities renovations. I will focus commentary on two components, building public health capacity and bioterrorism preparedness.

Building Public Health Capacity by Strengthening Infrastructure.—The Public Health Capacities provision of PHTEA has three main sections. Section 319A requires the Secretary of HHS, by November, 2001, to establish reasonable capacities, including needed personnel or workforce, that are appropriate for effective response

to major public health threats. These capacities would include, for instance, the ability of a state or local health department to: recognize the clinical signs and epidemiological signs of significant outbreaks of infectious disease; identify the disease-causing pathogens rapidly; organize and implement an effective medical response for those infected and prevention measures for those in danger of exposure; and communicate relevant information about the threat rapidly to other health departments, the CDC and to the provider community. Section 319B requires the Secretary, by November, 2001, to award grants to states to perform an evaluation of the extent to which state and local health departments can achieve the needed capacities. Finally, Section 319C provides grants to state and local health departments to address the identified gaps in their capacities—again with a focus on building capacity to identify, detect, monitor and respond to threats to the public health. Funds for filling gaps in capacities can be used to train public health personnel; develop, enhance, coordinate or improve participation in an electronic network for rapid disease information dissemination; develop plans for responding to public health emergencies coordinated with all levels of government; and enhance laboratory capacity and facilities.

Part of public health capacity building reflects CSTE's efforts, since 1994, to develop a comprehensive, state-based National Public Health Surveillance System (NPHSS). Congress has begun to support components of this system through the Health Alert Network (HAN) and the National Electronic Disease Surveillance System (NEDSS). However, there are other components that address the need for flexible, coordinated, and efficient surveillance (or health tracking) systems and that define the methods of surveillance in a changing health environment. These issues are discussed more thoroughly in the NPHSS section below.

Bioterrorism Preparedness.—For the past three years, Congress has provided funding specifically to address the greatest public health threat of all—bioterrorism. The PHTEA provides a more coherent framework for addressing this very real threat, one that experts believe will happen, it is just a matter of when. Some national security officials believe the United States will experience a major bioterrorist incident within the current decade.

The PHTEA ensures federal coordination of bioterrorism preparedness by creating interdepartmental task forces and working groups. Grants are made available to state and local health departments, but also to hospitals, clinics and primary care facilities, for the following purposes: (a) training of health care professionals and public health personnel to recognize the symptoms and epidemiological characteristics of exposure to a potential bioweapon; (b) rapid and accurate identification of potential bioweapons; (c) coordinating medical care for individuals exposed to bioweapons; (d) facilitating and coordinating rapid communication of data generated from a bioterrorist attack between national, state, and local health agencies and health care providers.

BUILDING THE NATIONAL PUBLIC HEALTH SURVEILLANCE SYSTEM

Epidemiologists working in public health agencies are responsible for monitoring trends in health and devising prevention programs that enable the entire community to be healthy. The science of epidemiology and surveillance, or health tracking, provide the basis for appropriate public health practice. Public health assessment includes surveillance, epidemiologic studies, program monitoring of diseases, risk factors for disease, health hazards, and preventive actions. Surveillance enables public health officials to:

—Recognize outbreaks and intervene to prevent additional cases;
—Identify priority health problems/needs so that resources can be appropriately allocated;
—Identify high-risk communities and groups to effectively target programs;
—Monitor the effectiveness of public health programs; and
—Identify issues that need further scientific study to devise preventive strategies.

These core activities of public health agencies are critical to the success of public health efforts, but have historically had no stable funding source and are often the first to suffer in state funding cutbacks. Funding restrictions in categorical federal programs have also contributed to a fragmented approach to surveillance at the state and local level. CSTE recommends that all federal funding for public health programs recognize and adequately fund epidemiology, assessment and surveillance as core required activities for public health programs. States should also be given flexibility to combine and integrate categorical funds for this purpose. This will help build the National Public Health Surveillance System (NPHSS) which CSTE conceptualized and has been advocating for among its various local, state, and federal partners.

In addition to support for core public health surveillance, CSTE supports the establishment of a national electronic public health surveillance, or health tracking, system that encompasses development of standards and criteria from which all programmatic surveillance systems would be built. CSTE views this overarching electronic system (NEDSS) as an important component of a National Public Health Surveillance System. Several CDC programs have well-developed surveillance systems that meet the needs of the program, but are not easily linked to increase the body of knowledge of the public's health. There is critical need for an over-arching model for integrated public health surveillance that assumes collaboration and integration of data collection efforts and use of surveillance resources across program and Center lines both at the federal and state levels. More effective integration of surveillance and health information systems could increase the power of public health agencies to make effective use of available information as economically as possible. In practical terms, an integrated health tracking system allows the detection and monitoring of infectious disease outbreaks and environmental hazards that involve more than one local or state jurisdiction such as the recent West Nile Fever outbreak.

Most importantly, a comprehensive, integrated, electronic surveillance, or health tracking, system present in every state and operational at the local, state and national level is the nation's best defense against a serious bioterrorism threat. It is a critical component of public health infrastructure that will significantly strengthen core public health capacity.

For the past two years, Congress has provided specific resources to begin implementing the National Electronic Disease Surveillance, or Health Tracking, System (NEDSS). In fiscal year 2000, $20 million was provided for this project at CDC and, in fiscal year 2001, $35 million, but since $5 million of this was earmarked for specific projects only $30 million was provided to CDC to continue building NEDSS nationally. Currently, under the fiscal year 2000 extramural grants, the first round to date, all 50 states have received some NEDSS funding with 42 states receiving Assessment and Planning grants averaging $86,000; 12 states receiving Element Development grants averaging $315,000 and two states, New York and Oregon, receiving Charter Site grants averaging $1,113,000 each. It is important to note that fully 35 states applied for Element Development grants, which include features such as web browser-based data entry, HL 7 messaging, and integrated data repository, but in large part due to resource constraints, only 12 received funding. Similarly, CDC received 12 Charter Site applications, but only had resources to fund two. Clearly more resources are needed to help states build a national electronic health tracking system. CSTE strongly supports $50 million in fiscal year 2002 for the NEDSS project as a critical public health capacity building component as provided within the Public Health Threats and Emergencies Act.

INCREASED SUPPORT FOR STATE CONDUCTED HIV CASE SURVEILLANCE, OR TRACKING

HIV case surveillance, or tracking, is a critical defense against the spread of AIDS, but currently depends on under-funded state and local health departments where funding for on-going AIDS surveillance (tracking) has been level or declining for several years. CDC estimates 200,000 250,000 persons are living with HIV (not AIDS) in non-HIV reporting states. Several recent developments have intensified the need for increased support for state and local health departments to conduct appropriate HIV case surveillance: (1) in December, 1999, CDC issued HIV case surveillance guidelines, but no additional funds were provided to states despite the fact that HIV case surveillance costs twice as much as AIDS surveillance; (2) the newly re-authorized Ryan White CARE Act (Public Law 106–345) includes new provisions that that seek to include HIV data in the formula that determines how many Federal resources each state will receive; (3) the September, 2000 Institute of Medicine report, "No Time To Lose: Getting More from HIV Prevention," recommended that sentinel surveillance also be expanded to provide additional information on HIV incidence. None of these important recommendations and developments can be responded to without additional resources for states.

For the 2000 and 2001 grant cycle for state cooperative agreements with CDC to conduct HIV surveillance, states requested twice the amount than they were awarded—a 40 percent gap in funding at a time when the need for HIV case surveillance data is intensifying and its benefit as a tool to target prevention efforts and reduce transmission of the disease is clear. CSTE strongly supports a $45 million increase in fiscal year 2002 to strengthen state and local health department HIV surveillance (tracking) systems.

ADDRESSING IDENTIFIED STATE AND LOCAL ENVIRONMENTAL HEALTH CAPACITY DEFICIENCIES

CSTE concurs with the Pew Environmental Health Commission's findings and supports their recommendations to commit significant national resources to enhance the National Public Health Surveillance System (NPHSS) so that, in addition to the ongoing efforts to monitor infectious diseases, the public health community can begin to track all chronic diseases and conditions like asthma, birth defects, and various forms of cancer. To advance the understanding of environmental disease, the NPHSS needs to include an ability to investigate disease links to environmental exposures. Much of the NPHSS will need to be based in state and local health departments where the data is generated, but allow aggregation for national assessment of progress toward the 2010 Healthy People goals. However, a comprehensive data system is not enough. Sufficient public health expertise capacity must also be present to interpret data, evaluate environmental health problems, and advance solutions. Both data collection and timely local response are a fundamental duty of state government, but experience has shown value-added benefits from federal partnerships. The scope of environmental public health activities is broad, ranging from assurance of the quality and integrity of public food, water and waste disposal systems to protecting the environment from manmade pollutants.

As a down payment on implementation of a nationwide health tracking system which will include chronic disease and its link to environmental exposures, CSTE urges Congress to provide an additional $20 million in fiscal year 2002 to expand environmental health capabilities within state health departments. Two agencies provide the bulk of the federal support for state environmental public health: the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH); both are administered by CDC. The Pew Commission has called for merging ATSDR and the NCEH under HHS at the CDC. ATSDR provided nearly $9 million in fiscal year 2001 to 28 states to assess environmental threats to communities. This program focus needs additional funding to reach all states, and provide each state with sufficient support.

The NCEH has been unable to provide core support for state environmental public health, but does provide substantial technical and laboratory assistance and categorical support to address issues such as childhood lead poisoning and emerging environmental threats such as asthma. CSTE urges the Subcommittee to increase support for CDC's asthma program from its current funding level of $25 million to $50 million. In spite of significant advances in the diagnosis and treatment of asthma, an improved understanding of the environmental triggers of asthma attacks, the health burden of asthma in the United States is increasing at epidemic proportions. Asthma affects more than 14 million Americans, of which five million are children. Over 5000 persons died from asthma in 1995, and asthma accounts for nearly 500,000 hospitalizations each year. The health care costs associated with asthma exceeded six billion dollars in 1990, and is currently $11 billion. Experts predict that those costs could climb to more than $18 billion by the year 2020.

Asthma control and prevention requires a long term, multifaceted approach that includes patient education, surveillance, and control programs. These programs have not been available due to a lack of resources at the state level. CDC's asthma program needs increased funding.

RESTORING AND INCREASING FUNDING FOR THE PREVENTIVE HEALTH/HEALTH SERVICES BLOCK GRANT

This program was cut $15 million in fiscal year 2000, a ten percent reduction, and level funded in fiscal year 2001. State health officials have indicated that $210 million is needed to enable them to respond to identified health problems that gaps in discretionary program funding prevent them from addressing, and unexpected health crises, such as West Nile Virus, or an environmental hazard. The PHHS Block Grant provides the only source of flexible funding for state health departments to address health problems they have specifically targeted under Healthy People 2010 goals, such as cardiovascular diseases and injury, but do not have sufficient, or sufficiently flexible, discretionary funds, to reach specified goals. In addition, up to five percent of total Prevention Block Grant funding is used to support basic public health activities including routine epidemiological surveillance, or health tracking. It seems contradictory to the public health community to support bioterrorism preparedness including building epidemiological capacity in state and local health departments and then threaten the net positive effect of this support by cutting the block grant funding ten percent and then locking in the cut through level funding.

SUPPORT FOR THE BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM

The Behavioral Risk Factor Surveillance System (BRFSS) is an essential component of an overarching public health surveillance, or tracking, system. It the only source of state level behavioral data, but is used at every level of government to inform intervention programs, policy decisions and budget direction for chronic and other diseases. It is the source of data for 24 of the 73 chronic disease indicators, six areas of the Healthy People 2010 leading health indicators and serves as the core source of surveillance, or health tracking, for multiple public health programs across the entire CDC. The BRFSS is currently in its 17th year of operation and is the largest continuous telephone survey in the world. It is flexible, timely and allows for state-to-state and state-to-nation comparisons of data. The BRFSS is able to address emerging health issues and fewer resources are required to run BRFSS than is required to run in-person interviews. The state-based telephone surveys are used to monitor health behaviors and knowledge regarding tobacco use, physical inactivity, poor diet, alcohol use, violence, risky sexual behaviors, and lack of preventive services (i.e. screening and immunizations).

In spite of all the data that BRFSS provides and the role these data play in the development of intervention programs and policy decisions, CDC funding for BRFSS is discretionary and averages $62,000 per state. Although states support a majority of the costs of BRFSS data collection, few are able to analyze and translate the data into long-term disease prevention and control programs and policies due to a lack of resources.

Current funding for BRFSS is $1.9 million. CSTE believes that BRFSS should be a discrete line item in the CDC budget and that funding should be doubled to $3.8 million in fiscal year 2002 to ensure adequate funding for all states.

The Council of State and Territorial Epidemiologists appreciates the opportunity to provide its fiscal year 2002 funding recommendations to the Subcommittee. Our members look forward to working with the Subcommittee to strengthen these areas of public health activity that CSTE believes are so critical to enhancing and protecting the health of the American public.

PREPARED STATEMENT OF THE CROHN'S AND COLITIS FOUNDATION OF AMERICA

INTRODUCTION

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Crohn's & Colitis Foundation of America (CCFA). CCFA is a non-profit, voluntary organization dedicated to finding the cure for Crohn's disease and ulcerative colitis. Throughout its 34 year history, CCFA has sponsored basic and clinical research of the highest quality. The Foundation also offers a wide range of educational programs for patients and healthcare professionals, and provides support services to assist people in coping with these chronic intestinal diseases.

My name is Jean Kouris, I live in Berea, Ohio, a suburb of Cleveland, and I am honored to represent the people of this country who suffer from Crohn's disease and ulcerative colitis. These are serious diseases that affect the gastrointestinal (GI) tract. Because they behave similarly, Crohn's and colitis are known as inflammatory bowel disease, or IBD. They can cause severe diarrhea, cramping abdominal pain, fever, and rectal bleeding. Complications of IBD can include arthritis, osteoporosis, anemia, liver disease, and colon cancer. Crohn's and colitis are not fatal, but they can be devastating. We do not know their cause, and we have no cure.

I am all too familiar with these diseases because my son Nathan is one of the up to one million Americans who suffer from IBD. Nathan has the dubious distinction of being among the youngest of children diagnosed with Crohn's disease. And while his age at diagnosis is unusual, the manifestation and course of the disease itself has not been. His nine short years have been a study in endurance, determination, the healing power of medicine and the healing power of prayer.

When Nathan was about seven weeks old, I arrived to pick him up at the end of a workday. The sitter told me that he had cried inconsolably for most of the day, drawing his legs up as if he was in pain. "There's something wrong with your baby," she said. The dutiful first-time mother, I took him to see the pediatrician that evening. Admittedly he was smiling and happy on my lap in her office, and her explanation was that some babies just had a harder time separating from their mothers when they went back to work.

Shortly thereafter, when he started passing bloody stools, I was told this was fairly common, and to put him on a "lactose-free" diet. By age six months he had been referred to a pediatric gastroenterologist, who put him on medication and scheduled

him for a colonoscopy. When the biopsy results came back I was told that he had something "not usually seen in babies this age."

Over the next few months Nathan's condition continued to deteriorate, and I became increasingly disenchanted with this particular physician. I first saw the words Crohn's disease when I picked up Nathan's biopsy results to take to another doctor for a second opinion. While waiting for the day of the appointment, Nathan, who was now eleven months old and otherwise developing normally, became so weak he could not stand up.

Three months later Nathan was put on "total parenteral nutrition" (TPN). TPN is a special liquid food mixture administered intravenously. Around this time, I remember saying to the doctor "I'm afraid he's going to die," and she responded "I'm not saying he won't, but right now we're a million miles away from that." That was the right thing for her to say to me as a mother, but I learned later that she had cried privately, afraid too that he would not make it.

For the next nine months I kept a bag packed, at the ready to head for the hospital if one of his twice-daily temperature readings was elevated. That was a trip I made too many times to count, as Nathan spent more than 90 days in the hospital during that time.

We have endured the comments of unknowing strangers, like the woman who referred to him as "a baby on a leash" and one who scolded my husband for "overfeeding that poor child." The reality was that he was seriously malnourished, but so bloated from the TPN and steroids that his eyes had become mere slits.

I took pictures, as every baby book should have the full complement of about a million and a half photos before age two. I took pictures of Nathan in the hospital, Nathan with his favorite nurses, Nathan pulling the TPN pack in a little red wagon, Nathan bare-chested with the Broviac showing. I took pictures because he was a charming child, always smiling and happy, a fun-loving baby who effervesced with a joy for life.

Nathan is nine now. He has achieved a measure of medical stability, and last summer, for the first time in his life, he actually went three months between doctor visits! He plays baseball and football, and takes piano and horseback riding lessons. He collects Poke-mon and does all the things most nine-year-old kids do.

I know that throughout his life he will have good times and not so good times. But Nathan has the spirit of a warrior and that's what helps him get through the difficult days. I also know that a cure is possible. I envision a world without Crohn's disease and ulcerative colitis. I hope you do too.

If we are to find the cause of, and cure for IBD, we must investigate all of the exciting possibilities that are being made known to us. To take advantage of these opportunities, CCFA has developed long-standing partnerships with NIH—specifically the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID)—and the Centers for Disease Control and Prevention (CDC).

RECOMMENDATIONS FOR FISCAL YEAR 2002

NATIONAL INSTITUTES OF HEALTH

Mr Chairman, together with NIAID, NIDDK supports the majority of IBD research at NIH. We were pleased that the Committee again last year recognized CCFA's IBD research agenda, entitled "Challenges in Inflammatory Bowel Disease," in its report.

Although we have made significant progress in recent years in the fight against Crohn's disease and ulcerative colitis, IBD remains among the most challenging disorders affecting the digestive tract. IBD patients and their families are pinning their hopes for a better life on medical advancements made through NIH and CCFA sponsored research. For this reason, CCFA supports the goal of the doubling the NIH budget by fiscal year 2002 and joins with the Ad Hoc Group for Medical Research Funding in recommending a 16.5 percent increase for NIDDK, NIAID, and NIH overall in fiscal year 2002. Moreover, the CCFA encourages the subcommittee to increase IBD research funding within NIDDK and NIAID at the same rate as NIH overall.

Throughout its 30-year existence, CCFA has recognized the importance of working closely with NIH. A primary principal of the Foundation's research program is to provide investigators with seed money to generate enough preliminary data to compete for NIH grants. And indeed, at last count, 40 of 57 IBD researchers funded through NIDDK and NIAID were former CCFA grant recipients.

Some of the most promising IBD research by the NIH has focused on translating findings from studies conducted on animal models to humans with IBD. These animal models have enabled researchers to form the current hypothesis that Crohn's

disease and ulcerative colitis are caused by a malfunctioning immune system, wherein components of the patient's immune system overreact to normal intestinal bacteria.

We know that people are susceptible to this malfunction because of their genetic makeup but further research is necessary to determine which bacteria are responsible, how these bacteria interact with the intestine's immune system, and which immune system components are involved.

Mr. Chairman, I am pleased to report that due in part to CCFA's Basic Research Agenda and our partnerships with NIDDK and NIAID, research findings are being translated with greater speed into new therapies for IBD patients. According to an industry report, the total sales of pharmacological therapies to treat IBD is expected to increase to nearly $1 billion in 2008, and the most dramatic increase will be in the sale of biologic therapies that target various proteins in the immune system.

By working together we have begun to alleviate the intense pain suffered by people with IBD, but there is a great deal more that needs to be accomplished. Our progress thus far gives us tremendous hope for the future, however, the study of new and promising research pathways depends upon increased federal funding for IBD research at NIH.

Finally, CCFA is excited by NIDDK's recent announcement that Dr. Stephen James, a leading IBD researcher, has joined the institute as the deputy director of its Digestive Diseases and Nutrition Division. We look forward to working with Dr. James in the search for improved clinical therapies, and a cure for IBD.

CENTERS FOR DISEASE CONTROL AND PREVENTION

IBD Surveillance Program

Mr. Chairman, as I have mentioned previously, CCFA estimates that "up to one million" people in the United States suffer from IBD. Unfortunately, we do not have an exact number: Due to the complicated nature of these diseases, patients may remain undiagnosed or misdiagnosed for several years. Given the recent advancements in treatment for these diseases and the increased risk that IBD patients have for developing colorectal cancer, CCFA is pleased that the Committee again last year recommended that CDC initiate a nationwide surveillance and epidemiological program with respect to IBD.

CCFA believes that generating improved epidemiological information on the IBD population is essential if we are to provide our patient community with the best possible care. We look forward to working with CDC this year on a comprehensive IBD epidemiological program. We ask that the subcommittee continue to support this important initiative in fiscal year 2002.

Colorectal Cancer Prevention

Finally, Mr. Chairman, in addition to coping with either Crohn's disease or ulcerative colitis, many IBD patients are at high risk for developing colorectal cancer. As you may know, colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States and the second leading cause of cancer-related deaths. Because people who have suffered from IBD for more than eight years are susceptible to this disease, CCFA has a long history of actively promoting the benefits of colorectal cancer screening.

Although colorectal cancer is almost entirely curable when detected early, studies have shown a tremendous need to: (1) inform the public about the availability and advisability of screening and (2) educate healthcare providers about screening guidelines. CDC's National Colorectal Cancer Roundtable is actively working to address these challenges by partnering with organizations like CCFA to implement a national public awareness campaign emphasizing the importance of screening and early detection. CCFA encourages the subcommittee to provide CDC with $15 million in fiscal year 2002 (an increase of $6 million over fiscal year 2001) for this vital campaign.

IBD RESEARCH AND SURVEILLANCE COORDINATING COMMITTEE

Mr. Chairman, because NIH and CDC are engaged in numerous research and public health activities related to IBD, CCFA recommends that the Department of Health and Human Services establish an Inflammatory Bowel Disease Research and Surveillance Coordinating Committee to ensure that the Federal government has a focused and coordinated plan for addressing IBD.

CCFA recommends that the Coordinating Committee be comprised of representatives from NIDDK, NIAID, the National Institute of Child Health and Human Development, CDC and other Public Health Service agencies as appropriate. The Committee would be charged with developing and implementing a comprehensive IBD

strategy in collaboration with the IBD community. We ask that the subcommittee join us in supporting the establishment of a Coordinating Committee in fiscal year 2002.

Mr. Chairman, thank you for the opportunity to present the views of the Crohn's and Colitis Foundation of America.

PREPARED STATEMENT OF THE CURE FOR LYMPHOMA FOUNDATION

INTRODUCTION

It is my pleasure to submit this statement regarding funding for the National Institutes of Health (NIH) in fiscal year 2002 and priorities for lymphoma research. I am a volunteer representing the Cure For Lymphoma Foundation (CFL), a nonprofit organization that funds research on Hodgkin's disease and Non-Hodgkin's lymphoma (NHL); provides educational materials and support services to individuals with lymphoma and their families; and engages in advocacy activities to advance a cure and improve the quality of care for those with lymphoma.

In November 1997, two weeks before my 38th birthday, I was diagnosed with follicular non-Hodgkin's lymphoma, an indolent cancer with a life-expectancy of seven to ten years. At that time, I was advised that because this disease was incurable, the best treatment strategy would be to "watch and wait" or defer treatment until I experienced further progression of my disease. As the mother of two young children, receiving this diagnosis and treatment recommendation certainly sharpened my focus on the disease and the advances in the treatment of lymphoma. During the next two years, I became involved in the activities of CFL and became an amateur researcher monitoring each and every advancement in lymphoma research and treatment. I felt one of my strongest contributions to CFL could be participating in public policy activities, attempting at every opportunity to create the very best climate for lymphoma research.

By November of 1999, my disease had progressed to the point where treatment became necessary and I participated in a clinical trial of a vaccine for the treatment of lymphoma but achieved only a brief remission. Currently, I am preparing to enroll in a second clinical trial, this time hoping to secure a longer remission through a combination therapy using monoclonal antibodies. It is my hope, in this statement, to convey both the exciting opportunities for lymphoma research and the sense of urgency that must be brought to this research and its funding. Those of us living with lymphoma will accept no less.

INCIDENCE OF LYMPHOMA

The Director of the National Cancer Institute (NCI) proudly reported this year that the incidence of most cancers is declining. This achievement is to be applauded. However, the situation for lymphoma is different. Since the 1970's, incidence rates for NHL have increased dramatically, making it one of the fastest rising cancers in the United States. The number of persons diagnosed with NHL has doubled since the 1970's, and NHL is the second rising cancer in incidence and death rates in the United States. The reasons for the increased incidence of NHL are not understood. This is a matter that deserves more attention, and CFL recommends a coordinated and aggressive research enterprise directed toward strengthening our understanding of the reasons for the increase in incidence of lymphoma.

LYMPHOMA RESEARCH ADVANCES AND OPPORTUNITIES

The nation's investment in basic research has deepened our understanding of lymphoma and contributed to enhancements in treatment, with many more therapeutic improvements expected. These advances include:

—Use of genetic analysis techniques to identify subpopulations of lymphoma patients who respond more favorably to chemotherapy. NCI-sponsored researchers have developed a lymphochip, which utilizes microarray technology and has allowed researchers to identify two subtypes of B-cell lymphoma. This discovery has significant implications, because further development and commercialization of the lymphochip will allow physicians to accurately diagnose patients and predict whether they may be effectively treated with chemotherapy or not, depending on their lymphoma subtype.

—Advances in immunology that have led to the development of a monoclonal antibody for the treatment of indolent B-cell NHL and may be the first of a group of therapies that use the body's own immune system to fight cancer.

—Cancer vaccines that employ immunotherapy to rally the body's defense against the diseases are currently being tested in trials across the country.

—New therapies combining different modalities, such as immune therapy and radiation, to fight the disease.

PROGRESS REVIEW GROUP ON LEUKEMIA, LYMPHOMA, AND MYELOMA

The NCI recently convened a meeting of extramural scientists, physicians, and advocates in a Leukemia, Lymphoma, and Myeloma Progress Review Group (LLM–PRG) that analyzed the current NCI portfolio of research on blood-related cancers and opportunities and barriers to research on these cancers. The report of the LLM–PRG is not yet complete, but a preliminary draft summarizing the work of the advisory panel captures the wealth of research opportunities that are available to researchers on blood-related cancers and identifies strategies for capitalizing on all those research avenues. We believe the unique contribution of the LLM–PRG may be proposals for innovative cooperative public-private sector research and development endeavors, and we applaud the willingness of the group to consider aggressive research strategies and structures.

Because advances in the treatment of blood-related cancers often provide insights into the treatment of all other cancers, the LLM–PRG report should be of particular importance not only to NCI but also to the Congress.

FISCAL YEAR 2002 RECOMMENDATIONS FROM CFL

CFL believes this is a critically important moment in lymphoma research which must be maximized by an appropriate federal response. CFL recommendations are listed below.

—Congress should sustain progress toward doubling the NIH budget in the five-year period from fiscal year 1999 to fiscal year 2003. We applaud the commitment of the Congress in providing substantial increases in funding for NIH in fiscal year 1999, 2000, and 2001 and urge that you provide an increase of 16.5 percent in fiscal year 2002. A boost of this magnitude is necessary to ensure that the five-year goal can be met.

—The Subcommittee should include language in its report that requires NCI to respond to the recommendations of the LLM–PRG when it appears before the Subcommittee to defend its fiscal year 2003 budget. CFL believes the LLM–PRG report may make a special contribution in identifying opportunities for public-private sector cooperation, and NCI should be directed to pay particular attention to these recommendations and its ability to implement collaborative programs of this sort.

—The Subcommittee should also include language in its report that requires NCI and the National Institute of Environmental Health Sciences to coordinate their investigations of the possible links between environmental exposures to toxins and the development of lymphoma.

—The Centers for Disease Control and Prevention (CDC) should be directed to enter into discussions with lymphoma researchers regarding the collection of lymphoma incidence and survival data through the CDC cancer registries program. In order to aid the lymphoma research effort, CDC cancer registries should collect lymphoma data by subtype.

PREPARED STATEMENT OF THE DIGESTIVE DISEASE NATIONAL COALITION

Mr. Chairman, thank you for the opportunity to submit testimony regarding fiscal year 2002 appropriations for the National Institutes of Health and the Centers for Disease Control and Prevention. before you today. I am Dr. Maurice Cerulli, a practicing gastroenterologist and Chief of Gastroenterology at The Brooklyn Hospital Center and president of the Digestive Disease National Coalition (DDNC). Founded in 1978, the DDNC is a voluntary organization comprised of 25 professional and patient organizations concerned with the many disease of the digestive tract. The Coalition has as its goal a desire to improve the health of the millions of Americans suffering from both acute and chronic digestive disorders.

Mr. Chairman, the social and economic impact of digestive disease is enormous. Digestive disorders afflict approximately 62 million Americans, resulting in 50 million visits to physicians, 10 million hospitalization, 230 million days of restricted activity, and nearly 200, deaths annually. The total cost associated with digestive diseases has been conservatively estimated at $60 billion a year.

On behalf of the DDNC, I would like to thank the subcommittee for its past support of digestive disease research and prevention programs at the NIH and CDC. With respect to the coming fiscal year, the DDNC joins the Ad Hoc Group for Medical Research Funding in recommending a 16.5 percent increase for the National In-

stitute of Diabetes and Digestive and Kidney Disease (NIDDK), the National Institute of Allergy and Infectious Diseases (NIAID) and the NIH overall. These increases will keep on track, for the final 2 years, the initiative to double the NIH budget over a 5 year period.

SPECIFIC RECOMMENDATIONS FOR FISCAL YEAR 2002

Inflammatory Bowel Disease.—Up to one million people in the United States suffer from Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD). These are serious diseases that affect the gastrointestinal tract causing bleeding, diarrhea, abdominal pain and fever. Complications of IBD can include anemia, ulcers of the skin, eye disease, colon cancer, liver disease, arthritis, and osteoporosis. Crohn's disease and ulcerative colitis are not usually fatal, but they can be devastating. We do not know the cause, and we have no cure.

In recent years we have made significant progress in the fight against IBD. In 1998, the FDA approved the first drug ever specifically for Crohn's disease. The DDNC encourages the subcommittee to continue its support of IBD research at NIDDK and NIAID at a level commensurate with the overall increase for each institute.

Given the recent advancements in treatment for these diseases and the increased risk that IBD patients have for developing colorectal cancer, the DDNC believes that generating improved epidemiological information on the IBD population is essential if we are to provide patients with the best possible care. Therefore, the DDNC, and its member organization the Crohn's and Colitis Foundation of America, encourage the CDC to initiate a nationwide IBD surveillance and epidemiological program in fiscal year 2002.

Endoscopic Research.—There continues to be tremendous potential for the development of new diagnostic and therapeutic procedures for gastrointestinal disorders. Without surgery, using endoscopes, we can find bleeding ulcers and stop the bleeding; we can take out stones that are blocking the bile duct; and we can cut out colon polyps to prevent colorectal cancer. The Clinical Outcomes Research Initiative (CORI) program is allowing us to link more than 50 centers around the country to assess the outcomes of endoscopic therapies. The gastroenterology community looks forward to working with the NIDDK to expand its endoscopic research program and we encourage the subcommittee to support this important effort.

Hepatitis C: a Looming Threat to Health.—It is estimated that 4 million Americans are infected with the Hepatitis C Virus (HCV). Unfortunately the majority of infected individuals are unaware that they have contracted the disease. In 1997, more than 10,000 people died from hepatitis C and the CDC estimates that the death rate will triple by 2010 unless there is additional research, education and effective public healthy interventions. Moreover, liver failure from HCV now accounts for more than half of all the liver transplants performed in the United States and is the leading cause of liver cancer.

The DDNC joins with the liver disease community in recommending an increase of $15 million in fiscal year 2002 for CDC's Hepatitis C Prevention Strategy program. This new funding will expand the number of states with CDC sponsored hepatitis C prevention coordinators from 16 to 50. In addition, we recommend an appropriation of $40 million (an increase of $17 million over fiscal year 2001) for CDC's Prevention Research Centers program.

Finally, Surgeon General David Satcher drafted a "Dear Citizen" letter last year warning American about the silent epidemic of HCV. The letter provided important educational information on HCV as well as action people can take to determine whether or not they are infected. The DDNC encourages the subcommittee to work with the Surgeon General's office in fiscal year 2002 to facilitate the distribution of this important correspondence to all Americans.

Pancreatic Cancer.—Last year, an estimated 28,300 in the United States were found to have pancreatic cancer and approximately 28, 200 died from the disease. Pancreatic cancer is the fourth leading cause of cancer death in men and women. Only 2 out of 10 patients will live one year after the cancer is found and only a very few will survive five years. Although we do not know exactly what causes pancreatic cancer, several risk factors linked to the disease have been identified:

—Age: Most people are over 60 years old when the cancer is found;
—Sex: Men have pancreatic cancer more often than women;
—Race: African Americans are more likely to develop pancreatic cancer than are white or Asian Americans;
—Smoking
—Diet: Increased red meat and fats
—Diabetes

The National Cancer Institute has established a Pancreatic Cancer Progress Review Group charged with developing a detailed research agenda for the disease. The DDNC encourages the subcommittee to provide an increase for pancreatic cancer research at a level commensurate with the overall percentage increase for NCI.

Colorectal Cancer Prevention.—Colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States and the second leading cause of cancer-related deaths. Colorectal cancer affects men and women equally. Although colorectal cancer is preventable and curable when polyps are detected early, a General Accounting Office report issued in March 2000 documented that less than 10 percent of Medicare beneficiaries have been screened for colorectal cancer. This report revealed a tremendous need to: (1) inform the public about the availability and advisability of screening; (2) educate health care providers about colorectal cancer screening guidelines.

CDC's National Colorectal Cancer Screening Awareness Program is addressing these needs by partnering with organizations like the DDNC and its coalition partners (AGA, ASGE, ACG, UOA) to develop an advocacy agenda emphasizing the value of early detection. The digestive disease community hopes that this relatively new program will do for colorectal cancer screening rates what the CDC's Breast and Cervical Cancer Screening Program has done for mammography and Pap smear screening compliance.

The DDNC has seen first-hand the ambitious agenda that CDC and its partners have developed to reduce the incidence of colorectal caner. We are convinced that we can make a significant impact on screening rates across the country if given adequate resources. Therefore, the Coalition encourages the subcommittee to provide CDC with $15 million in fiscal year 2002 (an increase of $6 million over last year) for this important program.

Mr. Chairman, thanks to support provided by this subcommittee in past years the NIDDK has been able to make important advances in the understanding and treatment of digestive diseases and improve the quality of life of many digestive disease patients.

One digestive disease that concerns us greatly is irritable bowel syndrome (IBS) a disorder that affects an estimated 35 million Americans. Many people with IBS suffer in silence, unable to speak about the disease even to their family members. The medical community has been slow in recognizing IBS as a legitimate disease and the burden of illness associated with it. Patients often see several doctors before they are given an accurate diagnosis.

Once a diagnosis of IBS is made, medical management is limited because the medical community still does not understand the physiologic mechanism of the disease. Living with IBS is a challenge. Trying to learn how to manage the symptoms is not easy.

There is a loss of spontaneity when symptoms may intrude at any time. Plans made often need to be changed. IBS is unpredictable. One can wake up in the morning feeling fine and within a short time encounter abdominal cramping to the point of being doubled over in pain and unable to function.

The unpredictable bowel symptoms may make it next to impossible to leave home. It is difficult to ease pain that may repeatedly occur periodically throughout the day. One becomes reluctant to eat for fear that just eating a meal will trigger symptoms all over again. IBS has a broad and significant impact on a person's quality of life. It strikes individuals from all walks of life and results in a significant toll of human suffering and disability.

While there is much we don't understand about the causes and treatment of IBS, we do know that IBS is a chronic complex of symptoms affecting as many as one in five adults. In addition;

—It is reported more by women than men.

—It is the most common gastrointestinal diagnosis amonggastroenterology practices in the United States.

—It is a leading cause of worker absenteeism in the United States.

—It costs the U.S. health care system an estimated $8 billion annually.

Mr. Chairman, much more can still be done to address the needs of the nearly 35 million Americans suffering from irritable bowel syndrome and other functional gastrointestinal disorders. We understand the challenging budgetary constraints that this subcommittee is operating under, yet we hope you will carefully consider the tremendous benefits to be gained by supporting a strong research and education program for irritable bowel syndrome at NIH and CDC. Mr. Chairman, on behalf of the millions of digestive disease sufferers, we appreciate your consideration of the views of the Digestive Disease National Coalition.

PREPARED STATEMENT OF THE DORIS DAY ANIMAL LEAGUE

Mr. Chairman and members of the Subcommittee on Labor, Health and Human Services, Education and Related Agencies Appropriations, thank you for the opportunity to submit testimony on behalf of the 300,000 members and supporters of the Doris Day Animal League requesting appropriations for the National Institute of Environmental Health Sciences' (NIEHS) National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Test Methods (NICEATM) for Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) activities for fiscal year 2002. This entity, ICCVAM, was permanently authorized in 2000.

FUNCTION OF ICCVAM

The ICCVAM performs an invaluable function for regulatory agencies, industry, public health, and animal protection organizations by assessing the validation of new, revised and alternative toxicological test methods that have interagency application. After appropriate independent peer review of the test method, the ICCVAM recommends the test to the federal regulatory agencies that regulate the particular endpoint the test measures. In turn, the federal agencies maintain their authority to incorporate the validated test method as appropriate for the agencies' regulatory mandates. This streamlined approach to assessment of validation of new, revised and alternative test methods has reduced the regulatory burden of individual agencies, provided a "one-stop shop" for industry, animal protection, public health and environmental advocates for consideration of methods and set uniform criteria for what constitutes a validated test method. In addition, from the perspective of animal protection advocates, ICCVAM can serve to appropriately assess test methods that can refine, reduce and replace the use of animals in toxicological testing. This function will provide credibility to the argument that scientifically validated alternative test methods, which refine, reduce or replace animals, should be expeditiously integrated into federal toxicological regulations, requirements and recommendations.

HISTORY OF ICCVAM

The ICCVAM is currently composed of representatives from the relevant federal regulatory and research agencies. It was created from an initial mandate in the NIH Revitalization Act of 1993 for the NIEHS to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use." In 1994, NIEHS established the ad hoc ICCVAM to write a report that would recommend criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to federal agencies and the scientific community. Through a series of public meetings, interested stakeholders and agency representatives from all 14 regulatory and research agencies, developed the NIH Publication No. 97–3981, "Validation and Regulatory Acceptance of Toxicological Test Methods." This report has become the sound science guide for consideration of new, revised and alternative test methods by the federal agencies and interested stakeholders.

After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS' NICEATM. Representatives from federal regulatory and research agencies and their programs have continued to meet, with advice from the NICEATM's Advisory Committee and independent peer review committees, to assess the validation of new, revised and alternative toxicological methods. Since then, two methods have undergone rigorous assessment and are deemed scientifically valid and acceptable. The first method, Corrositex, is a replacement for animal-based dermal corrosivity tests for some chemicals. The second, the Local Lymph Node Assay, is a reduction and refinement of an animal test for the skin irritation endpoint. The open public comment process, input by interested stakeholders and the continued commitment by the federal agencies has led to ICCVAM's success. It has resulted in a more coordinated review process for rigorous scientific assessment of the validation of new, revised and alternative test methods.

REQUEST FOR APPROPRIATIONS

On December 19, 2000, the "ICCVAM Authorization Act" which makes the entity a permanent standing committee, was signed into Public Law No. 106–545. For the past few years, the NIEHS has provided approximately $1 million per fiscal year to the NICEATM for ICCVAM's activities. In order to ensure that federal regulatory agencies and their stakeholders benefit from the work of the ICCVAM, it is impor-

tant to fund it at an appropriate level. I respectfully urge the Subcommittee to support an appropriation for the NIEHS's NICEATM for ICCVAM's activities at $3 million for fiscal year 2002. This appropriation request includes all FTEs, funding for independent peer review assessment of test methods and meetings of the ICCVAM and other activities as deemed appropriate by the Director of the NIEHS.

REQUEST FOR COMMITTEE REPORT LANGUAGE

I also respectfully request the Subcommittee consider the following report language for the Senate Labor, Health and Human Services, Education and Related Agencies Appropriations bill:

"The Committee supports the assessment of scientific validation of new, revised and alternative toxicological test methods by the ICCVAM. The Committee directs the regulatory and research agencies, including the National Institute of Environmental Health Sciences, Food and Drug Administration and Environmental Protection Agency, to use the expertise and credibility of the ICCVAM for these assessments to streamline their individual consideration of new, revised and alternative toxicological test methods. The Committee also urges the federal regulatory and research agencies to incorporate scientifically validated new, revised and alternative test methods into their regulations, requirements and recommendations in an expeditious manner."

Thank you for the opportunity to submit this request on behalf of the Doris Day Animal League.

PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

Chairman Specter, thank you for the opportunity to describe for the Subcommittee how dystonia has affected our lives and our recommendations for fiscal year 2002 federal funding of dystonia research.

My name is Rosalie Lewis, president of the Dystonia Medical Research Foundation. Three of my four sons have dystonia, and my fourth son is a carrier of the DYT1 gene which is responsible for generalized dystonia that begins in childhood. As there is no cure for dystonia, and only in the past thirty years has research given way to treatments other than brain surgery, my sons have had some benefit from oral medication and botulinum toxic injections. Although we are fortunate to have these treatments available, the various drugs have significant cognitive side-effects.

Dystonia is a neurological movement disorder characterized by involuntary muscle contractions and postures. There are several different types of dystonia, including: focal dystonias, affecting specific parts of the body, such as the arms, legs, neck, jaw, eyes, vocal cords; and generalized dystonia, affecting many parts of the body at the same time. Some forms of dystonia are genetic and others are caused by injury or illness. Dystonia does not affect a person's consciousness or intellect, but is a chronic and progressive physical disorder for which, at this time, there is no cure. We believe that some form of dystonia affects about 300,000 people in North America.

In the past few decades, dystonia researchers have made several exciting scientific advancements and have been able to rapidly turn laboratory and clinical research into diagnostic examinations and treatment procedures, directly benefitting those affected. Genetics, in particular, is opening up new understanding into the cause and pathophysiology of the disorder. Thus far, 12 dystonia related genes have been identified. In 1997, the DYT1 gene for childhood onset dystonia was identified, and we now have a genetic test available for this particular type of dystonia.

RESEARCH, AWARENESS, AND SUPPORT

It is an exciting time to be involved in dystonia research and awareness. Researchers are becoming more interested in movement disorders and dystonia at the National Institutes of Health (NIH), and research is yielding promising clues for better understanding and management of this disorder.

One way the Dystonia Foundation has advocated for more research on dystonia, is by funding "seed" grants to researchers. Thus far, the Dystonia Foundation has funded 338 grants, and 3 fellowships, totaling more than $17 million. Due to our advocacy there is a growing number of talented researchers dedicated to understanding the biochemistry of dystonia, genetic causes, new therapeutics and the ramifications of an epidemiology study.

Another primary goal of the Dystonia Foundation is education of both lay and medical audiences. Every year the Foundation conducts several medical workshops and regional symposiums to present, discuss, and disseminate comprehensive med-

ical and research data on dystonia. In January, 2001 NINDS co-sponsored a genetics and animal models meeting, designed to involve not only prominent researchers but inviting junior investigators to participate in the discussions. Additionally, in October 1996, the NIH was one of our co-sponsors for an international medical symposium, which featured 60 papers on dystonia and 125 representatives from 24 countries. Our next major international symposium is scheduled for September, where again we anticipate NINDS to co-sponsor the meeting.

Since 1995, over 3,000 educational medical videos have been distributed to hospitals, medical and nursing schools, and at medical conventions. Now, we have a children's video to increase public awareness of this devastating disorder. Media awareness is conducted throughout the year, and especially during Dystonia Awareness Week, observed nationwide from October 14 through 20, 2001.

The Dystonia Foundation has over 200 chapters, support groups, and area contacts across North America. In addition, there are 15 international chairpersons whose mission is to increase awareness, children's advocacy, development, extension, the Internet, leadership, medical education, an on-line news group, and symposiums. Furthermore, patient symposiums are held regionally to provide the latest information to dystonia patients and others interested in the disorder. Last year we held over eight regional symposiums reaching approximately 2,000 affected families.

DYSTONIA AND THE NATIONAL INSTITUTES OF HEALTH

The Dystonia Medical Research Foundation recommends an increase to $23.7 billion or 16.5 percent for NIH overall, and a 16.5 percent increase for NINDS and NIDCD or $1.37 billion and $350 million respectively. This increase reflects a request to double the NIH budget in five years. However, we request that this increase for NIH does not come at the expense of other Public Health Service agencies.

Dystonia is the third most common movement disorder after Parkinson's and tremor, and effects six times more people than better known disorders such as Huntington's, muscular dystrophy and ALS or Lou Gehrig's Disease. We ask that NINDS fund dystonia-specific extramural research at the same level that it supports research for other neurological movement disorders.

We urge the Subcommittee to recommend that NINDS provide the necessary funding for extramural research and a large scale dystonia epidemiological study and increase its efforts to educate the public and medical community about dystonia though cosponsorship of workshops and seminars. We also encourage the Subcommittee to support NIDCD in its efforts to revamp its strategic planning process by implementing a Strategic Planning Group which will help NIDCD as they: consider applications for high program priority; develop program announcements and requests for applications; and develop new research areas in the Intramural Research Program.

The ultimate goal of the Dystonia Foundation is a cure for dystonia. Until that goal is realized, we are hungry for any knowledge about the nature of dystonia and for more effective treatments with fewer side-effects. We have amassed many exceptional and diligent researchers, committed to our goal, and our top priority is funding their very important research. But the Foundation cannot do it alone. We need federal support through NIH, NINDS, and NIDCD to continue to fund good research and eliminate this debilitating disease.

I would like to introduce Mr. Peter Cohen.

Thank you Rosalie, my name is Peter Cohen and I have dystonia. Because of this neurological disorder, I have difficulty walking, standing, writing, and driving a car, just to mention a few daily activities I can't take for granted. Dystonia affected me first when I was a teenager, I developed muscle spasm and tremors. By my late twenties it became increasingly difficult to walk, my neck would turn involuntarily, and the tremors had spread to much of my body.

As these physical changes worsened over time, dystonia began to affect my professional and personal life. It became virtually impossible for me to read, write, type or sit in a comfortable working position, and I was forced to give up a successful career as an attorney. Furthermore, it became increasingly difficult to be in social situations. I felt physically and emotionally awkward because of the challenges presented by dystonia. I started isolating myself because I was ashamed of my appearance.

For the past couple of years I have tried to move beyond this shame. I look forward to a day when there is a cure for this debilitating disorder and I can fully participate in life.

Thank you Peter, Chairman Specter, we ask that you aggressively support medical research, specifically for movement disorders and brain research. By doing so,

you are doing a tremendous service for myself and my family, for Peter, and to the hundreds of thousands of people and families affected by dystonia.

Thank you very much.

THE DYSTONIA MEDICAL RESEARCH FOUNDATION

The Dystonia Medical Research Foundation was founded 25 years ago and has been a membership-driven organization since 1993. Since its inception, the goals of the Foundation have remained the same: to advance research for more effective treatments of dystonia and ultimately a cure; to promote awareness and education; and support the needs and well being of affected individuals and their families.

PREPARED STATEMENT OF EASTER SEALS

Easter Seals is a national nonprofit service organization dedicated to helping children and adults with disabilities achieve independence. Collectively, Easter Seals assists more than one million people annually through a national network of 105 affiliates. Easter Seals appreciates the opportunity to report on the success of "Early Childhood Development Project for the Mississippi Delta Region (Delta Project)," and to recommend that $1.6 million be allocated in fiscal 2002 to conduct the project's fifth and final year.

To date, the Delta Project has provided essential services to 7,000 children with disabilities who would otherwise have gone without needed evaluation and therapy services. Hundreds of Delta families have received counseling, training, and support that helps parents understand and promote their child's development. Delta Project staff have provided technical assistance and training to hundreds of child care workers, early intervention and health department professionals, teachers, therapists, doctors, and others to enhance competencies for better helping children with disabilities develop and learn. The Delta Project is committed to building lasting local capacity for improved service to children with disabilities and associated developmental and educational results. Delta project activities are conducted collaboratively with state and local health and education agencies and other providers, and do not duplicate or supplant available services.

DELTA PROJECT RATIONALE AND DESIGN

Children with disabilities in the Mississippi Delta are not receiving the appropriate early intervention and education services that they need to maximize development and learning. Proportionately lower family incomes, fewer public resources, shortages of pediatric personnel and specialized services, and inadequate support systems for families and staff are among the factors contributing to this situation. Geographic isolation, caused by wide dispersal of residents and community resources, poor roads, and lack of transportation, make it difficult for families to access services locally and out-of-region, and impede the ability of service providers to be available as needed. As a result, increased attention and supports are needed to promote more effective implementation of the Individuals with Disabilities Education Act (IDEA) in Delta communities, as well as other rural areas across the country.

The Delta Project is demonstrating strategies for building local capacity to improve early intervention and education services and enhance developmental and educational results for children with disabilities in the Delta regions of Arkansas, Louisiana and Mississippi. It offers a nationally-significant, replicable model for overcoming chronic gaps in local services and addressing parental and personnel preparation needs.

The Delta Project was officially launched in October 1998, with significant project activities appearing in targeted Delta communities in Arkansas, Louisiana and Mississippi in January 1999. Project implementation is occurring in phases, reflecting annual appropriations and U.S. Department of Education funding cycles. To date, Congress has approved a total of $3.725 million for this five-year initiative. A final appropriation of $1.6 million is recommended for fiscal 2002, to enable Easter Seals to provide full-scale services, training, and technical assistance in 45 Delta counties and parishes, and to report overall project findings. No further requests to earmark Education Department funds for this initiative will be made after 2002. To the extent necessary, Easter Seals will sustain needed capacity-building efforts using existing public and private funds.

The Delta Project is bringing needed expertise, technical assistance, and support to local families, educators and service providers, and community decision-makers that are currently lacking in the Delta. Major goals of the Delta Project are:

—Improve child find activities.
—Improve the quality and availability of appropriate early intervention and childhood development services for Delta region children with disabilities.
—Increase parent information and skills to better promote child development and learning.
—Increase the capacity of local educators and service providers to better serve children with disabilities and their families.
—Increase the ability of community decision-makers to create solutions to improve access to appropriate services for children with disabilities.

The Delta Project achieves these goals through collaboration with state and local health and education personnel, parents of children with disabilities, and local decision-makers, by:

—providing training and technical assistance to teachers, other education personnel, public health practitioners, child care workers and others to elevate their skills and ease in assisting children with disabilities and families;
—providing training and support to families with children with disabilities to promote increased understanding of child development and parent-child activities that advance child development and learning;
—facilitating collaboration and problem-solving among local agencies, community resources and decision-makers to improve services and results for children with disabilities; and,
—offering short-term, otherwise unavailable evaluation and essential services for children with disabilities.

DELTA PROJECT STATUS & RECENT ACTIVITIES

Although Easter Seals is seeking final year funding for the Delta Project in fiscal 2002, the project is programmatically at its mid-point in terms of implementation and capacity building effect. A summary of significant accomplishments and selected activities during the past six months (October 1, 2000 to March 31, 2001) follows.

Over the past two and one-half years, the Delta Project has proven an effective catalyst for necessary change in Delta communities. Significant accomplishments include:

—Dramatically enhanced child find efforts through capacity building with Head Start agencies, child care providers, physicians, local health departments and other service agencies. For example, in East Carroll Parish, Louisiana, these efforts resulted in the identification and referral of ten children with developmental delays for services. This may not seem noteworthy until contrasted with previous years during which no children with developmental needs were found, despite the birth of hundreds of children annually in an at-risk environment of crushing poverty, teen pregnancy, and inadequate pre-natal care. In Bolivar County, Mississippi, project staff collaborated with Head Start to screen 282 preschool children for developmental delay and other needs, of whom 49 were referred for additional testing.
—Substantial increase in access to early intervention services in the Delta because of developmental screenings, evaluations, and short-term therapy services provided by Project staff. A total of 438 children received short-term therapy services from project staff across the three-state region. It is important to note that these services meet not only the immediate needs of specific children, but also address personnel and parent needs as well. In Arkansas, for example, the majority of children were referred by school personnel triggering direct service to children, accompanied by consultation on classroom programming, behavioral issues, and augmentative communications needs. In many instances, parents were included in these consultations.
—Increased competency of nearly 400 Delta health and education professionals to better understand and serve children with disabilities through participation in 15 project training sessions that addressed topics of greatest concern. For example, two tri-state training conferences were held in Little Rock; "Communication Development with Autistic Spectrum Disorder," held in October 2000 and "Managing Children's Behavior in a Positive, Developmentally Appropriate Way" in February 2001. A workshop was held in Greenville, Mississippi in late march 2001 entitled "Sensory Processing: From Definition to Intervention," which was attended by 53 professionals and paraprofessionals from the three-state Delta region.
—Higher level of knowledge and skills development among Delta parents due to project training and support. For example, three parent workshops on Early Brain Development were conducted in Morehouse and Richland Parishes, Louisiana, that helped 47 parents understand early brain development and its rel-

evance to their child's abilities and needs. In Arkansas, project staff helped hundreds of families, including 40 parents who received individualized consultations on developmental milestones, home activities to enhance development, positioning techniques, feeding strategies, and effective use of assistive technology.

—Greatly increased awareness of child development needs and services in the Delta through distribution of materials, participation in agency initiatives, presentations, and use of the media. For example, the project developed and distributed 2,881 copies of a basic child development letter titled "Is Your Child on Track," which helps parents, personnel, and others to better understand child development milestones, recognize potential delays, and to facilitate evaluations, as appropriate. Delta project staff regularly contribute to health and education agency decision-making, such as First Connections in Arkansas, Children's Coalition in Louisiana, and First Steps in Mississippi, and Interagency Coordinating Committees in all three states. Community contacts with faith groups, community groups and the media are a regular part of Delta Project outreach.

The Delta Project is fully operational in 45 counties and parishes, representing the entire area originally targeted based on need, as follows:

—*Arkansas*.—Arkansas, Ashley, Bradley, Chicot, Crittenden, Cross, Desha, Drew, Lee, Lincoln, Mississippi, Monroe, Phillips, Poinsett, and St. Francis.

—*Louisiana*.—Avoyelles, Catahoula, Concordia, East Carroll, East Feliciana, Franklin, Livingston, Point Coupee, Madison, Monroe, Richland, St. Helena, Tensas, West Carroll, and West Feliciana.

—*Mississippi*.—Adams, Bolivar, Coahoma, Claborne, De Soto, Humphreys, Issaquena, Jefferson, Leflore, Sunflower, Sharkey, Tunica, Warren, Washington, and Wilkerson.

Note.—Project staff are currently conducting a comprehensive needs assessment in parishes and counties listed in italics. Planning and coordination services will be available in these targeted areas this fiscal year, and full project services will be implemented beginning October 2001.

Project offices are located in Little Rock, AR, Monroe, LA, Covington, LA, and Greenville, MS. Easter Seals Arkansas based in Little Rock serves as project headquarters, coordinating project services in Arkansas and overseeing region-wide training, technical assistance, evaluation, and reporting activities.

Highlights for the period, by state, characterize the Delta Project's fundamental and lasting contribution to addressing chronic needs at the local and national levels.

In Arkansas, selected accomplishments during the past six months include:

—Educated 30 mothers attending a Lee County WIC (Women, Infants and Children) Clinic about developmental milestones and potential indications of developmental delay, and guidance on accessing needed services.

—Assessed 81 children for developmental delay, with one-third being referred to the early intervention program.

—Initiated 171 contacts with social, health, educational, parenting, and therapy providers in the Delta to enhance child find efforts; 27 contacts were with physicians and 85 visits were made to Head Start and community child care centers.

—Participated in health fairs in Monroe and Desha counties and provided information to about 375 people on child development and early intervention.

—Surveyed 772 therapists in the three-state Delta region regarding practices and attitudes on delivering school-based therapy services in the classroom (inclusionary) versus on a "pull-out basis. Therapists generally favored services outside of the classroom, while administrators and teachers supported an inclusionary approach.

In Louisiana, selected accomplishments during the past six months include:

—Boosted child find results in chronically underserved areas, with 40 percent of the children assessed by project staff referred to the early intervention program.

—Met with LSU Shreveport medical staff address concerns that children referred to ChildNet for early intervention services after medical treatment were not entering the system or accessing needed services. Project staff worked out a solution, whereby project staff will facilitate the referral process between LSU and ChildNet and support ChildNet in reducing service delays.

—Collaborated with Child Search Coordinators to identify and address barriers to raising awareness among parents regarding the benefits of early intervention.

In Mississippi, selected accomplishments during the past six months include:

—Established a collaborative relationship with the Delta Area Health Education Centers and Delta Medical Society to schedule presentations by project staff and disseminate project information.

—Moved project office from Jackson to Greenville to better access and support local early intervention and education systems serving children with disabilities.
—Aided development of a proposal by Part C leadership to increase Medicaid payment for early intervention services that has been submitted to the governor for review.
—Scheduled regional training conferences for therapists, teachers, and parents to be held in Greenville, MS in spring 2001 on sensory processing, inclusion or intrusion, and therapeutic interventions.

Detailed information on Delta Project activities and findings are described in a mid-year report to the U.S. Department of Education, submitted May 2001.

Delta Project accomplishments and outcomes are evaluated by the University of Alabama's Civitan International Research Center, based in Birmingham, Alabama. The Civitan International Research Center is a University-Affiliate Program with research and evaluation expertise in early childhood development and programs serving children with disabilities in the Mississippi Delta Region. Civitan conducts an independent evaluation of the Delta Project, including site visits, throughout the year. During the past six months, evaluation staff conducted project site visits in Arkansas on January 30–31, 2001; in Mississippi on February 22–23, 2001; and Louisiana on March 8–9, 2001. Civitan reports its findings to the U.S. Department of Education on a semi-annual and annual basis. Easter Seals is pleased that evaluation findings to date are favorable.

Easter Seals greatly appreciates the Subcommittee's strong support for initiating and continuing the "Early Childhood Development Project for the Mississippi Delta Region." The Delta Project is beginning to have a dramatic, positive, and lasting impact in Arkansas, Louisiana, and Mississippi. It is generating valuable lessons and techniques for use in underserved areas throughout the country. Investment of $1.6 million in fiscal 2002 will support final year operations in the three-state region, evaluation and reporting, and the dissemination of findings and recommendations. Proposed statutory and report language for fiscal 2002 is attached for your information and use. Thank you for supporting the Delta Project.

EARLY CHILDHOOD DEVELOPMENT PROJECT FOR THE MISSISSIPPI DELTA REGION

The following statutory and report language is proposed for use in the fiscal 2002 Appropriations Bill for Labor-HHS-Education for the U.S. Department of Education, Office of Special Education and Rehabilitative Services, Special Education programs IDEA Research and Innovation.

FISCAL 2002 APPROPRIATIONS STATUTORY LANGUAGE

"Of the funds provided, $1,600,000 shall be available for Easter Seals Arkansas "Early Childhood Development Project for the Mississippi Delta Region."

REPORT LANGUAGE TO ACCOMPANY FISCAL 2002 APPROPRIATIONS BILL

"The Committee continues to be concerned about unmet needs among children with disabilities in rural areas, particularly the Mississippi River Delta, and the lack of adequate support in these areas for parents, school personnel, child care staff, and health providers to overcome chronic barriers to effective local service delivery. The bill addresses these concerns by providing $1,600,000 to continue the Early Childhood Development Project for the Mississippi River Delta Region to be carried out by Easter Seals Arkansas in Arkansas, Louisiana and Mississippi. The Committee recognizes that this multi-year project provides unduplicated early intervention and early childhood services to children with disabilities ages birth through twelve years, assists parents, and builds lasting local capacity to better provide and coordinate such services to maximize developmental and educational results. Valuable solutions generated by this project will be available for replication across rural America."

DELTA PROJECT—SUMMARY OF SERVICES

[October 1, 2000–March 31, 2001]

	Arkansas		Louisiana		Mississippi		Total Children Seen For Period	Total Number of Visits For Period
	Number of Children Seen	Number of Visits	Number of Children Seen	Number of Visits	Number of Children Seen	Number of Visits		
Evaluations	42	52	15	15	11	31	68	92
Consultations	29	29	3	3	.....	.....	32	32
Screenings	32	1	.....	.....	282	.....	314	1
Therapy:								
OT	.....	.....	13	137	.....	.....	13	137
PT	.....	.....	.....	.....	1	4	1	.....
SLP	.....	.....	20	203	.....	.....	20	203
Other	.....	.....	4	54	.....	.....	4	54
Total	103	82	41	412	294	35	438	529
	Number of Individuals Trained	Number of Trainings Conducted	Number of Individuals Trained	Number of Trainings Conducted	Number of Individuals Seen	Number of Trainings Conducted	Total Trained	Total Trainings Conducted
Inservice	205	9	126	5	53	1	384	15
Parent Training/Consultations	38	42	114	114	15	35	167	191
Total	243	51	240	119	68	36	551	206

PREPARED STATEMENT OF THE EPILEPSY FOUNDATION

The Epilepsy Foundation is the national voluntary organization that works for people affected by seizures through research, education, advocacy and service. Founded in 1968, its national office is based in Landover, Maryland. The national office and its network of more than 60 affiliates across the country provide many direct services to individuals and families, including: community education; employment assistance; recreation; professional education conferences; assisted living; and case management and counseling.

The Epilepsy Foundation supports medical research to find better treatment and an eventual cure for epilepsy, and works with federal government agencies and Congress to advance the interests of people with epilepsy.

Epilepsy is a neurological condition characterized by recurrent, unprovoked seizures. At least 2.3 million people currently have epilepsy; the number of people affected by epilepsy, family members, teachers, care givers, employers is an exponentially far larger number. A recent CDC study in Texas found 1.8 percent of adults had been diagnosed with epilepsy or seizures. Approximately 181,000 new cases of epilepsy occur each year; 10 percent of all Americans will experience seizures in their lifetimes.

MEDICAL RESEARCH ADVANCEMENT

The Epilepsy Foundation actively supports the efforts of Congress to double funding for the National Institutes of Health. We are pleased that NIH maintains strong bi-partisan support and has enjoyed significant increases in funding. These investments in our nation's health are paying dividends. In the last decade considerable progress has been made in identifying genes associated with epilepsy and in developing medications, devices and surgical treatments.

Almost a year ago, participants in a historic scientific conference predicted that prevention and a cure for epilepsy are only a generation away. Now the scientific community is working on next steps and ways to measure progress toward those goals. The conference, "Curing Epilepsy: Focus on the Future", was sponsored by the National Institute for Neurological Disorders and Stroke (NINDS), which is the primary federal sponsor of epilepsy medical research. The Epilepsy Foundation was one of the co-sponsors. NINDS, together with scientific experts have developed a set of benchmarks and priorities to guide future research.

Specifically, the conference and the benchmarks look at how epilepsy begins, ways of identifying people at risk and how to develop treatments that will prevent epilepsy in those people as well as continuing the search for new therapies, free of side effects, to prevent seizures. Clearly there are significant opportunities for advancements in epilepsy research.

THE IMPACT OF SEIZURES

Despite this progress and hope for the future, epilepsy remains a chronic condition that usually requires a lifetime of medical treatment. As many as 44 percent of people with epilepsy continue to have seizures despite treatment; 56 percent have early or delayed seizure control with treatment. Currently, there is no cure for epilepsy.

A recent cost study estimates that the cost of epilepsy, focussed on its most narrow measures, the direct medical costs, and the indirect costs as identified by the impact on earning and home production, is $12.5 billion annually.

The consequences of seizures continue to be severe and life altering, even among people with well-controlled seizures. Their impact spans employability, income levels, education, marriage, fertility, life expectancy and life style. The Texas study showed high levels of pain, anxiety, poor health, depression, and fatigue among adults living in the community, to the degree that their quality of life was negatively affected about 40 percent of the time.

Twenty five percent of all people with epilepsy are unemployed; among those who are partially or poorly controlled, unemployment approaches 50 percent. Marriage and fertility rates are reduced in people with epilepsy, there is an increased risk of brain damage and increased mortality and stigma remains a fact of life for too many people fueling discrimination and isolation from the mainstream of life.

Children with epilepsy are at special risk of learning difficulties. Studies have documented deficits in language, visual-spatial function, problem solving, and adaptive behaviors, even in the absence of co-morbidity. Children with epilepsy have unique difficulties when compared to those with other chronic illnesses such as asthma and diabetes; achievement scores are lower, there are problems with self-concept, depression, and behavior. These studies demonstrate the critical importance of

early recognition and treatment, as well as the often unanticipated consequences that a diagnosis of epilepsy can have.

RESEARCH AND PUBLIC HEALTH RECOMMENDATIONS

The Epilepsy Foundation supports the doubling of the NIH budget. We expect that the NINDS will update Congress and the epilepsy community on the progress being made to implement the recommendations from the conference entitled "Curing Epilepsy: Focus on the Future." Continuing to invest in basic and clinical research is crucial to meeting our goal of preventing and curing epilepsy. However much more needs to be done to address the impact of epilepsy and to improve the quality of life of those living with the disorder. Experts agree that timely recognition of seizures and effective treatment can reduce the risk of subsequent brain damage, as well as disability and mortality from injuries incurred during a seizure and from recurring seizures.

In 1993 Congress recognized this need and directed the Centers for Disease Control and Prevention (CDC) to develop an epilepsy program within the National Center for Chronic Disease Prevention and Health Promotion. As a result, the CDC initiated a number of activities including a public health campaign geared toward teen awareness and education, a project with the Agency for Healthcare Research and Quality to develop provider education materials and surveillance and prevention research activities to better analyze trends in access to care, levels of care and other demographic variables.

In 2000, Congress expanded the program by passing the Children's Health Act of 2000. The goals for this program include progress in research, epidemeology and surveillance, early detection, improved treatment, public education and expansion of interventions to support people with epilepsy and their families in their communities. The Children's Health Act of 2000 also authorized a new program within the Health Resources and Services Administration. HRSA is directed to create grants to improve access to health and other services regarding seizures; and to gear projects toward encouraging early detection and treatment for those living in medically underserved areas.

This agenda is much larger than current resources for the program. In fiscal year 2001, Congress appropriated $4 million for the CDC epilepsy program. Additional resources will be needed in order to expand the reach of the program into local communities and to fulfill the legislative intent.

FISCAL 2002 FUNDING RECOMMENDATIONS

Epilepsy research funded by the National Institute of Neurological Disorders and Stroke is vital to continuing the fight against epilepsy. The promise of future breakthroughs in epilepsy research can only be achieved by increased funding for epilepsy research and prevention programs. The Foundation urges Congress to increase the federal commitment to epilepsy research by allocating sufficient funding for the NINDS, the Centers for Disease Control and the Health Resources Services Administration.

—*Epilepsy Program at the Centers for Disease Control and Prevention*.—The Epilepsy Foundation supports a $3 million dollar increase in funding for the CDC epilepsy program.

—*Health Resources and Services Administration*.—The Epilepsy Foundation supports an initial investment of $3 million in order to create demonstration projects to improve access to health care for people with epilepsy.

—*Doubling the National Institutes of Health Budget*.—The Epilepsy Foundation supports the efforts to double the funding for the NIH, particularly the National Institute of Neurological Disorders and Stroke (NINDS). In keeping with this effort, we support an increase to $1,370.6 million for NINDS in fiscal year 2002. The Foundation urges Congress to support a major expansion of epilepsy research within NINDS. In 1999, NINDS spent $74 million on epilepsy research. We are seeking a commitment to double that amount by fiscal year 2005.

Thank you for the opportunity to submit testimony to the Subcommittee. We look forward to working with you in the 107th Congress.

PREPARED STATEMENT OF THE FACIOSCAPULOHUMERAL MUSCULAR DYSTROPHY SOCIETY

Mr. Chairman, it is a great pleasure to submit this testimony to you today.

My name is Daniel Paul Perez, of Lexington, Massachusetts, and I am testifying today as President & Chief Executive Officer (CEO) of the Facioscapulohumeral

Muscular Dystrophy Society (FSH Society, Inc.) and as an individual who has this devastating disorder.

We are excited to report that during the past several months, the National Institutes of Health (NIH) have announced a series of initiatives to accelerate research on Facioscapulohumeral Muscular Dystrophy (FSHD). For the first time since its inception, the NIH has requested grant applications whose purpose is to explore and develop research that will broaden the base of knowledge on FSHD. We are indebted to you, Senator Arlen Specter, as well as Representative John Porter, Chairman U.S. House of Representatives Subcommittee on Labor, HHS, Education and Related Agencies, formerly of U.S. House of Representatives, as well as the directors and staff of the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) at the NIH for this progress.

The FacioScapuloHumeral (FSH) Society, incorporated in 1991, solely addresses specific issues and needs regarding facioscapulohumeral muscular dystrophy (FSHD). We provide public awareness of FSHD by providing information, referral, education, and advocacy on FSHD. Additionally, the FSH Society offers assistance and support to patients, families, physicians, and other professionals. The Society publishes a newsletter with information about advances in research, political action effecting FSHD research and profiles of people with FSHD. We have awarded $650,000 in grants toward the prevention, cause and treatment of FSHD for research projects, post-doctoral and research fellowships and provided training support to institutions and fellowships to individuals in the field of FSHD research worldwide. The FSH Society promotes collaborative research and collects and disseminates research information. The Society organizes and sponsors annual international and national scientific meetings on FSHD as well as annual international and national patient network day meetings.

FSHD is a neuromuscular disorder that is inherited genetically and has an estimated frequency of one in twenty thousand (1/20,000). FSHD affects 12,500–37,500 persons in the United States. The major consequence of inheriting this disease is that of a clinically unpredictable and progressive and severe loss of skeletal muscle, with the usual pattern of initial noticeable weakness of facial, scapular and upper arm muscles and subsequent developing weaknesses of other skeletal muscles. Retinal and cochlear disease can often be associated with FSHD although the pathogenesis and causative relationship to FSHD remains completely unknown. FSHD wastes the skeletal muscles and gradually but surely brings weakness and reduced mobility. Many with FSHD are severely physically disabled and spend the last 30 years of their lives in a wheelchair. The toll and cost of FSHD physically, emotionally and financially is enormous. FSHD is a life long disease that has an enormous cost-of-disease burden and is a life sentence for the innocent patient and involved persons and their children and grandchildren as well.

We are in an unprecedented time with the publication of the entire human genome sequence. We have spent an enormous amount of money in genomic research that is coming to fruition and we hope to begin to realize the payoff for this investment. However, this chapter is not closed and we are not done with understanding FSHD. FSHD is a complex and difficult disease and the mechanism of this disease is tightly bound to the next steps for genome research. FSHD is an enormously rich disease to study with its involvement in telomeres, repeats, chromosomal "cross-talk", new protein and DNA models for transcription of the genome, and many other new areas outlined for investigation by the entire genome community as critical areas for the next steps to understanding how the human genome and physiome works. FSHD may well be the only human disease that can be used as a model for the next generation of novel genomic inquiry.

A decade of progress in FSHD has led to the discovery of a novel genetic phenomena of crossover of subtelomeric DNA between chromosomes (4 and 10) in both normal individuals and diseased individuals and to the discovery that facioscapulohumeral muscular dystrophy may be the only human disease caused by a deletion-mutation causing a position effect variegation (PEV). PEV causes DNA in one part of the genome to affect DNA in other parts of the genome. In FSHD, DNA at the very end of the chromosome (telomere) interferes with DNA upstream towards the center (proximal) of the chromosome. Despite remarkable genetic insight and immense progress by a small team of scientists worldwide, the nature of the gene product(s) remain enigmatic and the biochemical mechanism and cause of this common muscle disease remains absolutely unknown and elusive.

FSHD, in particular, and muscular dystrophy in general appear to be of little interest to the pharmaceutical industry, biotechnology industry and Wall Street. No privately or publicly owned company is currently pursuing FSHD research. Unlike Alzheimer's, Parkinson's disease or breast cancer with hundreds of millions of re-

search dollars from the NIH supplemented by the enormous investments from the pharmaceutical and biotechnology sector, FSHD has nowhere to go in the private sector. We rely totally on NIH funding and that of voluntary health organizations which raise research funds from the public, to advance knowledge in this field.

Neuromuscular and muscle disease has one of the highest cost-of-disease burdens in the U.S. economy. Yet, of $20.5 billion annually given to NIH, approximately $19 million is spent on all muscular dystrophy research and, of that amount, conservatively $450,000 is currently being spent on the third most prevalent and third largest dystrophy, FSHD. Clearly, the muscular dystrophies are significantly underfunded by NIH. In last year's testimony, we reported the NIH had not responded to the past three years of House and Senate Reports accompanying the appropriations bill Language. We are pleased to report a very different picture this year.

The FSH Society with the NINDS, the NIAMS and the and the NIH Office of Rare Diseases (ORD) held "The 3rd International Conference on the Cause and Treatment of FSHD" on Monday, May 8, 2000. The research community, the clinical community, the observers and the NIH related experts agreed that it was a truly outstanding, top-rate and excellent meeting. We successfully assembled the leading FSHD researchers from all over the world at the NIH in Bethesda, Maryland where they shared their findings with each other and the NIH. The Directors and Staff at the NIH developed an excellent program to aid in the development of a portfolio for FSHD. The Research Planning Conference held Tuesday, May 9, 2000 generated a multitude of ideas on how to move forward on the FSHD agenda.

The May 9, 2000 baseline of recommendations by expert scientific panel on FSHD for evaluating priorities is as follows and to date the NIH is beginning to accomplish the sixteen items listed in this set. Recommendations for future directions, organized by topic, are listed as follows:

A. Molecular Processes; 1. Characterize the molecular pathogenesis of FSHD; elucidate the role of the repeats associated with the disease as well as what causes their deletion; 2. Determine the relationship between repeat length and its effect on the degree to which disease is manifested (penetrance); 3. Determine the gene sequence and whether the repeats are acting as suppressors or insulating units; 4. Clarify how similarity of regions on chromosomes 4 and 10 may relate to FSHD.

B. Tissue Changes; 5. Characterize changes in muscle as the disease develops; 6. Determine basis of differential involvement of muscles; 7. Explore the role of inflammation in FSHD; 8. Study properties of muscle cells derived from affected tissue.

C. Possible Therapies; 9. It was speculated that it may become possible to repair the disease locus by selected and targeted addition of 3.3 kb repeats to the disease locus on chromosome 4; 10. The modification of cultured FSHD regenerative muscle cells that would reverse their higher sensitivity to oxidative stress. Such cultured cells, with better ability to respond to oxidative stress, might then be used for treatment of patients.

D. Population Based Studies; 11. Establish patient registries and recruit additional families for study; 12. Determine if a nonstandard locus produces FSHD.

E. Resources; 13. Create new animal models; 14. Facilitate use of differential gene and protein expression techniques; 15. Promote development and use of noninvasive imaging techniques; 16. Enhance formation of clinical and basic research consortia.

Each year anew the FSH Society defines, at the request of the entire international and global molecular genetics and clinical research community, the most crucial issues in FSHD research today and in the coming several years—these following nine areas represent the majority of efforts to be made given recent advances in technology, science and understanding of FSHD.

A. An International clinical and molecular data (resource) base. Although a complicated issue for several reasons (homogeneity of clinical and genetic data, access etc.), presence of such a facility should greatly improve; 1. our insight in the natural history, and genotype-phenotype relationships as support for patient counseling and management; 2. the availability of biological material (DNA, cell lines, muscle biopsies etc.) for research purposes; the design of (homogeneous) clinical trials.

B. Non-chromosome 4q families; large enough to allow linkage analysis and gene isolation. Identification of a second FSHD gene should greatly facilitate the identification of crucial (rate-limiting) molecular pathways. This might help direct our thinking on (gene) therapy.

C. Large scale profiling of thousands of components to identify molecular pathways leading to FSHD and targets amenable for intervention. Attention should be given to; 1. RNA (transciptomics). RNA reflects the steady-state transcription situation, but might be only a meager reflection of the true (patho)biology. This work is ongoing in several centers; 2. Protein (proteomics). The protein components reflect the real biological executive situation. Proteomics is much more complicated than

transcriptomics, but may give much more information; 3. Metabolites (metabolomics). In the near future, we will have technologies at our disposal to identify and quantify metabolites, the individual steps (substrates) of metabolic pathways. These compounds may crucially determine the actual pathology and phenotype.

D. Cellular and animal models. It is very likely that the generation of cellular and animal models will be pivotal, not only for the generation of therapeutic means, but also to help identifying the molecular basis of FSHD itself. In all likelihood, several approaches have to be followed; 1. Transgenic mouse models. Two different approaches can be envisaged: models for individual candidate genes, identified in the chromosome 4q region or elsewhere and general models in which large genomic regions of chromosome 4q and chromosome 10q, including the telomeres are transferred and integrated, preferably at mouse telomeres. These latter models will approximate the human situation and allow studies on the cause and consequences of the inter- and intra-chromosomal interactions and rearrangements in relation to FSHD; 2. Other animal models. For specific questions on position effects variegation etc., simpler models, like Drosophilia, and yeast may be very useful.

E. Chromatin structure in and adjacent to the region where the FSHD deletions occur. Including; 1. factors predisposing to illegitimate recombination; 2. abnormally expressed genes in FSHD.

F. Better understanding of abnormalities of the small blood vessels of the retina at the back of the eye in FSHD patients. Including; 1. why children with a more severe or even sporadic form of FSHD are more likely to develop this symptomatic form of retinal disease; 2. an unidentified additional genetic peculiarity which renders some FSH individuals peculiarly susceptible to symptomatic retinal disease; 3. whether retinal, cochlear and skeletal muscle abnormalities in FSH represent different effects of the same mutation or otherwise are the results of abnormalities of adjacent genes; 4. the possibility that such pleitropic effects are mediated by inflammation and/or "environmental" factors.

G. Clinical, molecular genetic study and genotype/phenotype correlation of facioscapulohumeral muscular dystrophy phenotype and facioscapuloperoneal muscular dystrophy phenotype.

H. Clinical trials. It is likely that new clinical trials will be launched on basis of hints in other (muscular) disorders. Access to well characterized (e.g. with respect to clinical phenotype and genetic constitution) patients cohorts is crucial for proper evaluation.

I. Molecular pathway based therapy. Increasing insight in the molecular pathways of FSHD, already available and hopefully even more so in the near future, will form the rationale for novel treatment strategies. It is difficult to predict whether these efforts will be DNA-based or pharmacological. In any case, such experimental approaches have to be developed in (transgenic) animal models; another argument for investing in versatile models.

The NIH has the tremendous capacity to quickly enhance research in the above project areas through its intramural and extramural research programs. The FSH Society and Congress have been repeatedly informed that the NIAMS has invested considerable resources into the newly formed Laboratory of Physical Biology (LPB) at the NIAMS to strengthen its intramural program on muscle diseases and in FSHD muscular dystrophy research. The LPB mission is to study of biological systems using leading-edge physical approaches, and muscle contraction, regulation, structure, and function. The NINDS also has a considerable resource to offer with its intramural research staff and programs. Additionally, the NINDS and NIAMS staff are currently consulting with members of the extramural community to build a research portfolio on FSHD. This year should bring a concerted effort by the NIH NINDS/NIAMS, the National Institute for Human Genome Research (NIGHR) and its NIH Intramural Sequencing Center (NISC) to accelerate extramural research by offering and bridging intramural resources with the extramural community of researchers and clinicians thereby making the above research viable. The NIH has begun to make great progress in its extramural programs covering FSHD and the immediate proactive inclusion of intramural resources and programs will help rapidly accelerate solutions and understanding of FSHD.

On November 8, 2000, the first of the three major announcements was made by NIH as "Exploratory Research on Facioscapulohumeral Muscular Dystrophy". On December 11, 2000, the second announcement was made on the establishment of a National Patient Registry at the University of Rochester Medical School for FSHD and Myotonic muscular dystrophy. On January 4, 2001, the third announcement was made for a three year program "Therapeutic and Pathogenic Approaches for the Muscular Dystrophies."

We are delighted with these steps towards finding solutions for FSHD. We note with cautious optimism that the NIH has begun the process to establish a portfolio in the causes and treatment of FSHD as called for in the past three years of House and Senate Report Language. However, we are only beginning the process. Difficult work lies ahead involving establishing population databases, developing research resources such as a mouse model, understanding the molecular process, understanding tissue changes, the development and clinical trials of possible therapies and population based studies.

Mr. Chairman, we are watching with interest the response of the scientific community to the announcements of NIH referenced above. We are concerned that, despite these announcements, the exciting scientific questions about this disease and progress in genomics and the tremendous need of patients for therapies, that the response of the scientific community will be less than optimal. We hope we are wrong. We are concerned that there is not an attitude of confidence that FSHD, muscular dystrophy or muscle biology is of significant importance at NIH over the long term to justify the investment by researchers in this field. After all it has taken the FSH Society since 1994 to encourage Congress and NIH to move this far, we feel the Committee should consider earmarking funding in this area sufficient to encourage researchers to make a commitment to pursue this difficult and often frustrating area of investigation.

We request that the Committee consider earmarking an amount of not less than fifteen (15) million dollars for FSHD research.

The men, women and children who live with the daily consequences of this devastating disease are your friends, neighbors, fellow taxpayers and contributors to the American way of life. With an historic 88 percent employment rate and an average educational achievement level of 14 years, we personally bear our burden of the health care costs and training expenses to prepare for and maintain financial and personal independence. We appeal to you today to take our hard earned tax dollars commensurate with our numbers and valuable contributions to American Society and we urge the United States Government to allocate a proportion of our tax burden toward research on FSHD.

Mr. Chairman, we trust your judgement on the matter before us. Please remember, we need your help to ensure that the sun is rising on FSHD and all other muscular dystrophies.

Mr. Chairman, again, thank you for providing this opportunity to testify before your Subcommittee.

PREPARED STATEMENT OF THE FOUNDATION FOR ICHTHYOSIS & RELATED SKIN TYPES

Mr. Chairman and members of the Subcommittee: The Foundation for Ichthyosis & Related Skin Types (F.I.R.S.T.) wishes to thank the members of this subcommittee for your past support of the National Institutes of Health (NIH) and the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS). We appreciate the opportunity to provide written testimony regarding funding for skin disease research and the budget for NIAMS. F.I.R.S.T. is requesting that the budget for the NIH/NIAMS be increased by 16.5 percent, which will keep the NIH on track to doubling the budget by fiscal year 2003.

In 1992 a member of F.I.R.S.T. testified before this committee regarding the need for a national registry for ichthyosis and related disorders. Today, as a direct result of your interest and support, we have the National Registry for Ichthyosis and Related Disorders. The Registry's funding was just renewed for another four years and was expanded to include molecular diagnosis. The registry helps generate researcher interest in ichthyosis, and provides investigators with an essential tool—a pool of affected individuals with a confirmed clinical diagnosis. The availability of this pool of information results in significant savings in research time and dollars, which would have normally been spent identifying eligible patient populations.

F.I.R.S.T. is a voluntary organization dedicated to providing support, information, education and advocacy for individuals and families affected by ichthyosis. F.I.R.S.T. supports research into causes, treatment and a cure for ichthyosis.

Ichthyosis is a family of genetic skin diseases characterized by dry, thickened, scaling skin. These diseases are caused by genetic defects that are usually the result of genetic inheritance. Currently, there is no cure for ichthyosis, and there are no truly effective treatments.

Some forms of ichthyosis cause the skin to be very fragile and blister easily. Scaling and flaking are continuous. The skin is tight and cracked. The palms and soles can be thick, making something as simple as holding a pencil or as natural as walk-

ing difficult and painful. Overheating is dangerous and infections are a constant threat.

Our children are sometimes hospitalized for infections. Simple medical procedures are complicated. Days and activities are planned around skin care. Stares and questions from strangers are common. While the physical aspects of ichthyosis are obvious, the blows to ones self-esteem can be even more damaging. Currently, ichthyosis is a life-long battle. Hopefully, this will change in the future.

We recognize this Subcommittee's strong history of bipartisan support for medical research funding and the NIH. Recently new genes have been discovered for several types of ichthyosis and related skin types. Darier's disease, although not strictly an ichthyosis, was found to be caused by mutations involving the ATP2A2 gene. Another ATPase gene, ATP2C1, encoding another calcium pump was found this year to be the cause of Hailey-Hailey disease. Patients with this condition have more problems with blistering, but lesser problems with scaly skin than patients with Darier's disease.

Two new genetic defects affecting the synthesis of cholesterol have now been linked to ichthyosis. The affected enzymes, sterol 4 demethylase and sterol 7,8 isomerase, were first shown to cause ichthyosis-like conditions in laboratory mice. Cholesterol is an essential component of the plasma membrane that surrounds each cell, and also of the membranes lying between the cells of the stratum corneum. In these outer skin layers, cholesterol acts to prevent too much evaporative loss of water from the interior of the body to the drier atmosphere. Subsequently, several patients with the Conradi-Hunermann-Happle syndrome, a condition that affects only females and causes an ichthyosiform erythroderma in a swirling pattern during infancy, along with abnormalities affecting the eye, bones and other tissues, have mutations in the gene for sterol 7,8 isomerase. And patients with CHILD syndrome, a condition also only affecting females in a pattern of abnormalities but is limited to only one side of the body, have had mutations affecting the sterol 4 demethylase in some cases and the sterol 7,8 isomerase in others.

Several new causes of palmar plantar keratoderma (PPK) (thickened outer skin mostly restricted to palms and soles) were identified this past year. Striate PPK (bands of thickened skin along the digits) was linked to mutations affecting two proteins, desmoglein I and desmoplakin, that are constituents of desmosomes. Papillon Lefevre syndrome is a palmar plantar keratoderma with severe periodontitis (inflammation of the gums). This condition was found to be due deficiency of a protease (enzyme that digests proteins), Cathepsin. The last of the genetic breakthroughs this past year were the identification of connexin gene mutations in two scaling skin disorders. One of the skin diseases caused by a connexin mutation (connexin 31 protein, encoded by the gap junction protein beta-3 gene) is Erythrokeratodermia vanablis. Not all patients with EKV have been found to have mutations in this gene, implying that other genes may cause the same disease pattern. Also patients with different mutations in this same gene do not have skin disease, but instead are deaf. Mutations affecting another connexin, Connexin 26, also cause deafness and some of these patients, in addition to deafness, have Vohwinkel's PPK.

We are excited about this progress, and about the current research into gene therapy. We are hopeful about the possibility for an effective treatment or cure on the horizon, but at this point it is still just hope. We continue to be frustrated by the lack of effective treatment options.

Three years ago, this country embarked on a commitment to double the National Institutes of Health (NIH) budget in five years. F.I.R.S.T. requests that funding to the NIH continually be increased to stay on track with that plan. It is very important to support this initiative because the NIH is where most of the country's important research originates. Research that involves any new discovery for any skin disease is beneficial to all skin diseases. Since skin diseases are so closely related, eventually these advancements will filter across the board and possibly lead to discoveries in our particular disease, ichthyosis. It is critical for fundamental research to be continued as well. Even though each particular skin disease group wants their particular disease to be the focus of increased research, it is difficult to study any of these diseases if the basic function of skin cells is not mastered.

Last year, Congress passed the Clinical Enhancement Act to provide a loan repayment program for medical school graduates. F.I.R.S.T. asks that funding for this program be supported and increased.

Young doctors are faced with enormous medical school loans after graduation. Because of this debt, many young doctors choose professions that provide higher salaries, which will help them reduce their debt quicker. By supporting and increasing funding for the Clinical Enhancement Act, this program will become stronger and encourage young doctors to choose a career path in research. F.I.R.S.T. also requests

that federal appropriators support funding for a workshop to study and record the current yearly medical costs related to skin diseases in this country.

If the NIH is to unlock the mysteries of disease, translate the recent research discoveries into new treatments for the bedside, it is necessary that the appropriation for the NIH be a sizable, sustained and stable effort. We hope that you will keep the faith with your constituents, and provide the needed funds to the NIH.

On behalf of our members, those with ichthyosis and their families, we thank this Congressional Subcommittee for their time and attention.

PREPARED STATEMENT OF FAMILIES OF SPINAL MUSCULAR ATROPHY

Mr. Chairman and members of the Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies, Families of Spinal Muscular Atrophy wishes to thank you for this opportunity to submit written testimony for the record.

Mr. Chairman and Members of the Subcommittee, let me begin by asking a question, what would you do if you were told your 10-week-old son or daughter would not live to see his/her second birthday? Or, if your child were beginning to walk, and then for some reason, unknown to you, regressed to only crawling then eventually only sitting? For families who have a child diagnosed with Spinal Muscular Atrophy these are not hypothetical questions, these are real situations faced everyday.

Spinal Muscular Atrophy (SMA) is the number one genetic killer of children under the age of two. SMA is a vicious, debilitating genetic disease that affects individuals indiscriminately and is more widespread than anyone realizes. One in every forty people carries the gene that causes SMA and one in every 6,000 babies is born with SMA. Due to the various forms of SMA, the disease onset can be at any age.

SMA is a neuromuscular disease that affects the anterior horn cells. Through great collaborative effort the scientific field has identified the gene that causes SMA as well as determined the missing protein and are well on their way to replacing it. By replacing this missing protein it is hopeful that the disease will be eradicated and that some damage might be repaired. With this knowledge and additional National Institutes of Health (NIH) funding through the National Institute of Neurological Disease and Stroke (NINDS), this information will not only lead to a cure for SMA, but will also open doors through this new technology to be used for other motor neuron and neuromuscular diseases.

Families of S.M.A is a 100 percent volunteer organization whose mission is to fund research, support families and create awareness. Through the efforts of Families of S.M.A. scientists from all over the world meet once a year to discuss and share the progress made in research. Most recently we have asked that NINDS explore areas of promising research, which were identified at the 2000 Families of SMA International Workshop. This includes the development of a SMA basic and clinical research portfolio through all available mechanisms, as appropriate, including clinical trails of drug compounds capable of activating SMN2 expression.

We wish to thank NINDS for their support in the Multi-Center Creatine Study, but the continued development of a SMA research portfolio is critical. In the very near future SMA will be involved in drug development and/or stem cell therapy or gene replacement therapy. The participation of NINDS in this endeavor is most important. We ask the committee to encourage NINDS to explore areas which will be identified at the 2001 Families of S.M.A. International Workshop which is being held in June.

Mr. Chairman, on behalf of all the individuals suffering from the various forms of SMA, thank you for your continued, strong leadership for the bipartisan effort to double the NIH budget over five years. Providing the NIH with a $3.4 billion increase in funding this year is critical to individuals with SMA.

Thank you.

FACT SHEET ABOUT SPINAL MUSCULAR ATROPHY (SMA)

The Disease

Spinal muscular atrophy (SMA), the number one genetic killer of children under the age of two, is a group of inherited and often fatal diseases that destroys the nerves controlling voluntary muscle movement, which affects crawling, walking, head and neck control, and even swallowing.

Who is Affected

SMA is one of the most prevalent genetic disorders.

—One in every 6,000 babies is born with SMA. Of children diagnosed before age two, 50 percent will die before their second birthday.

—SMA can strike anyone of any age, race or gender.

—One in every 40 people carries the gene that causes SMA. The child of two carriers has a one in four chance of developing SMA.

Types of SMA

—Type I, or Werdnig-Hoffman Disease, is the most severe form of SMA. Children with Type I tend to be weak and lack motor development, rendering movement difficult. Children afflicted with Type I cannot sit unaided and have trouble breathing, sucking and swallowing. Type I SMA strikes infants between birth and six months.

—Type II, is slightly less severe. Type II patients may be able to sit unaided or even stand with support and usually do not suffer from feeding and swallowing difficulties. However, they are at increased risk for complications from respiratory infections. Type II SMA affects infants between seven and eighteen months old.

—Type III, also known as Kugelbert-Welander Disease, is the least deadly form of childhood-onset SMA. Type III patients are able to stand, but weakness is prevalent and tends to eventually sentence its victims to a wheelchair. Type III SMA strikes children after the age of eighteen months, but can surface even in adulthood.

—Type IV, is the adult form of the disease in which symptoms tend to begin after age 35. Symptoms usually begin in the hands, feet and tongue, and spread to other areas of the body.

—Adult Onset X-Linked SMA, also known as Kennedy's Syndrome or Bulbo-Spinal Muscular Atrophy, occurs only in men. Facial and tongue muscles are noticeably affected. Like all forms of SMA, the course of the disease is variable, but in general tends to progress slowly.

SMA does not affect sensation and intellectual activity in patients. It commonly is observed that patients with SMA are unusually bright and sociable.

Testing

Prenatal counseling is available to couples who are carriers of SMA or who have lost a child to SMA.

PREPARED STATEMENT OF THE HEPATITIS FOUNDATION INTERNATIONAL

Chairman Specter and members of the Committee. I am Thelma King Thiel, Chairman and Chief Executive Officer of the Hepatitis Foundation International (HFI), representing the Board of Directors and members of 425 patient support groups across the nation, the majority of whom suffer from chronic viral hepatitis.

We commend the Committee for allocating initial funds that have enabled CDC to make tremendous strides in efforts to understand hepatitis and to control it through universal immunization and education programs.

Although all five types of viral hepatitis are preventable, we are currently dealing with an "epidemic of discovery", people who are already infected with the hepatitis C virus because of lack of information about transmission, appropriate vaccines and effective treatments to stop the spread to others. Hepatitis B has been eclipsed by hepatitis C even though we have effective tools to eradicate hepatitis B. Lack of funds and integrated prevention activities contribute to the ongoing transmission of hepatitis B that claims 5,000 lives each year. If high risk individuals who attended STD clinics, or those who have been incarcerated had been vaccinated against hepatitis B in the early 1980s when the vaccine was approved, we would not be dealing with the large numbers of individuals who are chronically infected and in need of liver transplants today. It is time to make a major investment in immunization and preventive education to bring these diseases under control. All newborns, young children, young adults, and especially those who participate in high-risk behaviors must be a priority for immunization initiatives. We need to provide effective preventive education in our elementary and secondary schools to help children avoid the ravages of health problems resulting from viral hepatitis infection.

The Hepatitis Foundation International has worked closely with the Centers for Disease Control and Prevention through cooperative agreements in addition to contributing private funds for specific projects. HFI provided significant independent support and co-sponsored the Hepatitis C Teleconference for healthcare providers in 1997. Collaboration with CDC has enabled the Foundation to develop and distribute thousands of award winning videos and innovative, effective educational materials nationwide dealing with liver wellness, hepatitis and substance abuse prevention. Many of these items are available in several languages. Teachers, healthcare providers, public health officials, personnel in corrections and juvenile detention centers, governmental and non-governmental agencies all need these tools. Funding is

needed to duplicate and distribute many more to those on the front line in the battle against hepatitis and substance abuse.

Prevention can save lives today. We need to train health care professionals in effective communication and counseling techniques. We need public awareness campaigns to alert individuals to assess their own risk behaviors. We need to motivate them to seek medical advice . . . to encourage them to be immunized against hepatitis A and B . . . and to stop drinking any alcohol if they have participated in risky behaviors that may have exposed them to hepatitis C.

Mechanisms are in place to provide screening, referral services, medical management, counseling, and prevention education for those who have HIV/AIDS. Funds must be made available to expand all of these services, including immunization, to those who are infected by hepatitis viruses.

HFI recommends an increase of $15 million for further implementation of CDC's Hepatitis C Prevention Strategy. This increase will further the development of state-based prevention programs by increasing the number of state health departments with CDC funded coordinators from 16 to 51 covering each state and by implementing demonstration projects to evaluate ways to integrate hepatitis C and hepatitis B prevention efforts into existing public health programs. HFI recommends that $10 million be added to CDC's budget to train and maintain hepatitis coordinators in every state to implement prevention and management strategies.

The CDC Prevention Research Centers Program plays a critical role in reducing the human and economic costs of disease. CDC should be commended for its decision to fund the most meritorious applications in the fiscal year 2001 competition, regardless of geographic location of the applicants with respect to other Prevention Research Centers. Preventive education is cost effective. CDC estimates that for every $1 spent on school-based drug and alcohol, tobacco, and sexuality education, $14 are saved in avoided health care costs.

CDC currently funds 24 prevention research centers at schools of public health and schools of medicine across the country. An additional two centers will be selected using a portion of the $23 million the Congress dedicated to the program in fiscal year 2001. However, core funding for prevention centers has been decreasing since this program was first funded in 1986 from an average of $800,000 per center to $580,000 in fiscal year 2000.

In order to continue to build this flagship CDC extramural research program, HFI requests Congress to increase the core funding to $40 million for Prevention Research Centers in fiscal year 2002.

Past investment in NIH has led to an explosion of knowledge that has advanced understanding of the biological basis of disease and development of strategies for disease prevention diagnosis, treatment, and cures. Countless medical advances have resulted in a direct benefit to the lives of all Americans. NIH-supported scientists remain our best hope for sustaining the momentum in the pursuit of scientific opportunities and new health challenges. Research studies to learn why some HCV infected individuals resolve their infection spontaneously may prove to be life saving information for many who are currently infected. The answer may provide a cure for others.

To achieve the proposed doubling of the NIH budget over the five-year period from fiscal year 1999 to fiscal year 2003, the Hepatitis Foundation International joins with Congress and the new Administration in supporting an appropriation of $23.7 billion for NIH in fiscal year 2002 representing a 16.5 percent increase. HFI also recommends a comparable increase of 16.5 percent in hepatitis research funding at the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Allergy and Infectious Diseases. An additional $4 million is needed to extend and expand the HALT–C to study the pathogenesis and treatment of hepatitis C and to understand why some patients respond to treatment and others do not.

A significant portion of increases for these Institutes should be earmarked to conduct studies among groups of patients that have been neglected in overall research initiatives. They include:

—African Americans—to identify reason why they do not respond to antiviral agents in the treatment of chronic hepatitis C.

—Children and Adolescents—Pediatric liver research lacks appropriate funding to address the many diseases, including viral hepatitis, that affect children.

—Renal Dialysis Patients—Many are HCV infected and outcomes of treatment need more investigation.

—HIV/HCV Positive Patients—Co-infections need special investigation

—Hemophilia Patients—Co-infection with HIV needs further study.

Victims of hepatitis suffer emotionally as well as physically. They experience discrimination in employment, strained personal relationships and severe depression

when treatments fail to control their illness as well as during their treatment. We look forward to working in collaboration with CDC, NIH, health departments and other voluntary organizations to bring viral hepatitis under control.

I would be happy to answer any questions you may have. Thank you for providing this opportunity to present our testimony.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

We appreciate the opportunity to provide testimony to the Labor, Health and Human Services, and Education Subcommittee on two funding items of great importance to The Humane Society of the United States (HSUS) and its 7.7 million supporters nationwide. As the largest animal protection organization in the country, The HSUS urges the Committee to address these priority issues in the fiscal year 2002 budget:

—$6 million for planning and construction to launch the national chimpanzee sanctuary system authorized by Public Law 106–551;

—$3 million to expand the work of the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), authorized by Public Law 106–545, coupled with Committee Report language encouraging federal agencies to avail themselves of ICCVAM's expertise and efficient review process.

CHIMPANZEE SANCTUARIES

We are very pleased that Congress last year enacted H.R. 3514 (Public Law 106–551), the Chimpanzee Health Improvement, Maintenance, and Protection Act, which authorized up to $30 million to establish and operate a federal chimpanzee sanctuary system for chimpanzees no longer used in medical research. Introduced by Senators Bob Smith (R-NH) and Richard Durbin (D-IL) and Representative Jim Greenwood (R-PA), this legislation earned the bipartisan support of 24 cosponsors in the Senate and 143 cosponsors in the House. It had the endorsement of more than 100 scientists, many of whom are renowned experts in the field of chimpanzee research. The legislation was approved by unanimous voice vote in both chambers and was signed into law on December 20, 2000.

This common-sense statute is designed to help animals who are deemed by the Secretary of Health and Human Services to be "surplus" for medical research, but who are still being warehoused in expensive federally-supported laboratory cages. As determined by the Congressional Budget Office (CBO), the sanctuaries envisioned by this law will provide a much higher quality of life for these animals. They will also serve American taxpayers well, by saving millions of dollars over the course of the next several years ($4 million annually, after initial construction costs). These savings are primarily due to the fact that sanctuary facilities, which offer a more naturalistic environment and opportunities for social interaction, can be built and operated at significantly lower cost than laboratory facilities. Housing chimpanzees in sanctuaries is estimated to cost $8–$15 per day per animal, compared to the $20–$30 per day per animal that the federal government currently spends to house them in lab cages. In addition, the statute creates a public-private partnership, requiring private sector matching dollars to complement the federal government's share (the private match is 10 percent of construction costs and 25 percent of operating costs).

The statute follows the recommendations of a National Research Council (NRC) report commissioned by the National Institutes of Health (NIH) and released in 1997, "Chimpanzees in Research: Strategies for Their Ethical Care, Management, and Use." In 1986, NIH launched an initiative to breed chimpanzees—mistakenly thought to be useful models for AIDS research—creating a surplus of several hundred chimpanzees who are no longer used in medical research. According to the NRC report, the government is spending more than $7 million annually on maintenance of chimpanzees. The report recommends a breeding moratorium and opposes euthanasia of chimpanzees as a means of population control, noting that "[s]ome of the best and most caring members of the support staff, such as veterinarians and technicians would, for personal and emotional reasons, find it impossible to function effectively in an atmosphere in which euthanasia is a general policy, and might resign." The report also specifically recommends: "The concept of sanctuaries capable of providing for the long-term care and well-being of chimpanzees that are no longer needed for research and breeding should become an integral component of the strategic plan to achieve the best and most cost-effective solutions to the current dilemma."

To implement this law in a timely and efficient way, we respectfully request that the Committee direct NIH to allocate $6 million in fiscal year 2002 for planning and

construction of the national chimpanzee sanctuary system. In recognition of budget constraints, this requested funding level falls well below the $11 million outlays that CBO projected for the first year of the system. But we believe it is enough to ensure that implementation will move forward quickly, so that the chimpanzees and taxpayers can begin to benefit as Congress intended.

INTERAGENCY COORDINATING COMMITTEE FOR THE VALIDATION OF ALTERNATIVE METHODS (ICCVAM)

We are also very pleased that Congress enacted H.R. 4281 (Public Law 106–545) last year by unanimous voice vote in both chambers. This legislation, introduced by Senator Mike DeWine (R-OH) and Representatives Ken Calvert (R-CA) and Tom Lantos (D-CA), earned the bipartisan support of 5 Senate cosponsors and 73 House cosponsors, and was signed into law on December 19, 2000. This statute strengthens and makes permanent the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM). We hope the statute will increase acceptance of more animal-friendly test methods by streamlining the process by which these methods are validated and easing institutional barriers within federal agencies that discourage their use.

ICCVAM performs an invaluable function for regulatory agencies, industry, public health, and animal protection organizations by assessing the validation of new, revised and alternative toxicological test methods that have interagency application—including methods that replace, reduce, and refine the use of animals in testing. After appropriate independent peer review of a test method, ICCVAM provides its assessment of the test to the federal agencies that regulate the particular endpoint that the test measures. In turn, the federal agencies maintain their authority to incorporate the validated test method as appropriate for the agencies' regulatory mandates. This streamlined approach to assessment of validation of new, revised and alternative test methods has reduced the regulatory burden of individual agencies, provided "one-stop shopping" for industry, animal protection, public health and environmental advocates to consider test methods, and set uniform criteria for what constitutes a validated test method.

ICCVAM arose from an initial mandate in the NIH Revitalization Act of 1993 for the National Institute of Environmental Health Sciences (NIEHS) to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use." In 1994, NIEHS established an ad hoc ICCVAM to write a report that would recommend criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to federal agencies and the scientific community. Through a series of public meetings, interested stakeholders and agency representatives from 14 regulatory and research agencies developed NIH Publication No. 97–3981, "Validation and Regulatory Acceptance of Toxicological Test Methods." This report has become the "sound science" guide for consideration of new, revised and alternative test methods by the federal agencies and interested stakeholders. After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS' National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Representatives from federal regulatory and research agencies have continued to meet, with advice from NICEATM's Advisory Committee and independent peer review committees, to assess the validation of new, revised and alternative toxicological test methods.

Since then, two methods have undergone rigorous assessment and been deemed scientifically valid and acceptable. The first method, Corrositex, is a replacement for animal-based dermal corrosivity tests for some chemicals. The second, the Local Lymph Node Assay, is a reduction and refinement of an animal test for the skin irritation endpoint.

The open public comment process, input by interested stakeholders, and the continued commitment by various federal agencies have led to ICCVAM's success so far. Now, with enactment of Public Law 106–545, ICCVAM is poised to accomplish even more in terms of streamlining the validation of other new, revised and alternative test methods. For the past few years, NIEHS has provided approximately $1 million annually to NICEATM for ICCVAM activities. In order to ensure that federal regulatory agencies and their stakeholders can more fully benefit from the work of ICCVAM, we respectfully urge the Committee to direct NIEHS to allocate $3 million for ICCVAM activities in fiscal year 2002. Funding at this level will cover FTEs, independent peer review assessment of test methods, meeting expenses, and other activities as deemed appropriate by the Director of the NIEHS. In addition, we respectfully request inclusion of the following Committee Report language:

"The Committee directs that $3 million from the National Institute of Environmental Health Sciences budget be allocated to the National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Test Methods for Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) activities during fiscal year 2002. The Committee supports the assessment of scientific validation of new, revised and alternative toxicological test methods by the ICCVAM. The Committee directs the regulatory and research agencies, including, but not limited to, the National Institute of Environmental Health Sciences, Food and Drug Administration and Environmental Protection Agency, to use the expertise and credibility of the ICCVAM for these assessments to streamline their individual consideration of new, revised and alternative toxicological test methods. The Committee also urges the federal regulatory and research agencies to incorporate scientifically validated new, revised and alternative test methods into their regulations, requirements and recommendations in an expeditious manner."

Again, we appreciate the opportunity to share our views and priorities for the Labor, Health and Human Services, and Education Appropriation Act of fiscal year 2002. We hope the Committee will be able to accommodate these two requests affecting animals across the United States. Thank you for your consideration.

PREPARED STATEMENT OF THE HUNTINGTON'S DISEASE SOCIETY OF AMERICA

SUMMARY OF RECOMMENDATIONS

The Huntington's Disease Society of America ("HDSA") urges Congress to increase funding for medical research on neurodegenerative diseases and disorders, especially Huntington's Disease ("HD"), through budgetary increases to the National Institutes of Health ("NIH").

Specifically, HSDA encourages Congress to provide at least a 16.5 percent increase over fiscal year 2001 for NIH, raising the funding levels from $20.3 billion to $23.7 billion, as recommended by the Ad Hoc Group for Medical Research Funding. Within NIH, HDSA recommends at least a commensurate increase for the National Institute of Neurological Disorders and Stroke ("NINDS"), the National Institute of Mental Health ("NIMH"), and the National Institute on Aging ("NIA"), each of which support a modest portfolio of HD research. These increases would allow for further research on the diagnosis, treatment and cure for HD, a debilitating and devastating neurodegenerative disease.

HUNTINGTON'S DISEASE SOCIETY OF AMERICA

HDSA is a national voluntary non-profit health organization dedicated to finding a cure for Huntington's Disease while providing services and support for those living with HD and their families. Founded in 1967, HDSA promotes and supports both basic and clinical HD research, aids families throughout the continuum of HD, and educates the public and healthcare professionals about HD.

Private donations coupled with the tireless fundraising efforts of HDSA chapters around the country make the HDSA Research Grants program possible. These grants help innovative research projects develop sufficiently to attract funding from other sources, particularly the NIH, which do not provide funds for projects in their early stages of development.

HUNTINGTON'S DISEASE

HD is an inherited degenerative brain disorder that results in the loss of both mental faculties and physical control. It is caused by the mutation of a single gene. The disease afflicts approximately 30,000 Americans, while 150,000–200,000 Americans are at-risk of inheriting it from a parent. Each child of a parent with the HD gene has a 50/50 chance of inheriting the disease. Every person who inherits the HD gene will eventually develop the disease. HD does not skip generations; if one does not inherit the gene, one cannot pass it on. HD affects as many people as Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's disease) or Cystic Fibrosis.

Symptoms of HD may affect cognitive ability or mobility and include depression, mood swings, forgetfulness, clumsiness, involuntary twitching and lack of coordination. As the disease progresses, concentration and short-term memory diminish and involuntary movements of the head, trunk and limbs increase. Walking, speaking and swallowing abilities deteriorate. Eventually the person is unable to care for him or herself. Death often results from complications such as choking, infection or heart failure.

The costs to society are both direct and indirect, and include medical expenses, loss of productivity in the workplace by patients and caregivers (oftentimes spouses or children), disability claims, and long-term care expenses. On an annual basis, the direct and indirect costs of HD to society total over $2 billion.

RESEARCH RECOMMENDATIONS

Once thought of as a rare disease, HD is now considered to be one of the more common hereditary diseases. Although HD is classified as a more common hereditary disease, researchers have yet to discover an effective treatment to slow the progression of HD or a cure for this deadly disease. Over the past decade, there have been breakthroughs in HD research and researchers continue to aggressively build upon these advancements. The outlook for treating and curing HD has never been more promising.

In 1993, researchers identified the gene that causes HD. Such a discovery has made possible a predictive test for HD. Individuals at-risk for HD can now find out whether they carry the gene before symptoms arise. This discovery has been a springboard for laboratory research. It has led to the creation of a mouse model of Huntington's Disease, referred to as a "transgenic" mouse. The HD gene is inserted into mouse DNA, thus causing the mouse to develop HD symptoms. Using transgenic mouse models, researchers have identified and characterized pathogenic hallmarks; the aberrant events that occur in the brain cells of the subjects with HD.

In an effort to transform basic research data and determine how it can be applied to treat or cure HD in humans, clinical trials must be established. Patients with HD and their families are desperately depending on the positive outcomes of these clinical trials to improve their quality of life. However, prior to commencement of clinical trials, researchers must employ the technology of high throughput screens for drug development. This technique rapidly tests a very large number of compounds to see if they have a desired positive effect. Compounds that have a positive effect then go through more research to determine if they could become a viable drug therapy for human clinical trials.

HDSA appreciates the commitment that Congress has made to double the NIH budget by fiscal year 2003. Medical research endeavors and America's patients are benefiting tremendously from this five-year effort. This initiative will pay dividends for decades to come. However, despite the fact that HD is considered one of the more common hereditary disease, the NIH Office of Budget estimates that only one-third of 1 percent of NIH's sizeable $20.3 billion budget will be dedicated to HD research in fiscal year 2001. The level of NIH resources allocated to HD research is inadequate, especially considering the recent substantial increases in the NIH budget. NIH must elevate the priority level of HD research.

HDSA recommends that Congress urge the NINDS, NIMH, and NIA to increase RO1 funding for HD and other neurodegeneration research by 15 percent for fiscal year 2002. Using such an increase in resources, researchers will develop more models of HD, including fruit fly models and worm models, and will test compounds and genes which may ameliorate or prevent HD. Additionally, researchers hope to target the aberrant events that occur in brain cells of subjects with HD and test approaches to prevent or mitigate these adverse occurrences.

HD serves as a prototype disease caused by the mutation of a single gene. Therefore, advances made in the understanding and treatment of HD will increase scientists' ability to derive the mechanism and therapeutic approaches for several similar diseases, including Alzheimer's Disease, ALS and Parkinson's Disease.

CONCLUSION

HD continues to take a huge emotional and financial toll on America's families. HDSA appreciates Congress' commitment to biomedical research and to the NIH in recent years. However, more effort is needed. Congress must maintain the momentum, and in some cases, devote even more resources. HDSA is grateful for the opportunity to present its views on fiscal year 2002 appropriations. Please contact Barbara Boyle, HDSA National Executive Director/CEO, at (212) 242–1968, if you have further questions.

PREPARED STATEMENT OF THE IMMUNE DEFICIENCY FOUNDATION

Mr. Chairman, thank you for the opportunity to submit testimony on primary immune deficiency disorders and the need for continued research and education on these diseases.

Primary immune deficiency diseases are inherited disorders in which parts of the body's immune system are missing or do not function properly. The World Health Organization has identified more than 70 different primary immunodeficiency diseases. These disorders are very under diagnosed, but we believe that more than 45,000 Americans, of all races, ages, and gender. Fortunately, most primary immune deficient patients, once diagnosed, are able to maintain their health through infusions of a pooled plasma derivative known as intravenous immuneglobulin (IGIV) every three to four weeks for the rest of their life. However, if primary immunodeficiency diseases are not properly diagnosed and treated, they can lead to serious illness and early death.

The Immune Deficiency Foundation (IDF) is the national non-profit, charitable organization dedicated to improving the health of primary immune deficient patients through research and education. Headquartered in Towson, Maryland, IDF was founded in 1980 by a group of parents of primary immune deficient children who wanted to focus attention on the needs of primary immune deficient patients, physicians, and researchers.

IDF provides a wide variety of patient and family services, medical research and education, and advocacy for issues related to these diseases. Specifically, the Foundation acts as an information clearinghouse for newly diagnosed patients and provides these individuals with an opportunity to interact with other primary immune deficient patients and families. Oftentimes, the most reassuring call a parent of a newly-diagnosed child will make is not to a doctor or hospital, but to one of our local patient representatives with his or her own children playing loudly in the backyard. This opportunity to speak directly and frankly to another parent in a similar situation often is the first chance to seek support and results in a level of comfort that with proper treatment their child can grow up with a near-normal life.

The foundation is also active in medical research to try to better define and diagnose these diseases. While we search for these longer-term answers, we are also looking to improve current treatment options for patients as well as improve understanding of these diseases within the medical community. Because primary immune deficiency is a rare disease, we focus on providing educational opportunities such as visiting professorships and grand rounds for physicians and medical students who might otherwise not be exposed to this knowledge. The foundation is also working through an NIH grant that I will discuss in more detail later to help better identify the range and occurrence of these diseases.

Finally, IDF has a very active public policy program that focus on blood safety issues, patient reimbursement for treatment, and advancing scientific knowledge regarding primary immune deficiency diseases.

Mr. Chairman, I am both a patient, a physician, and the newly elected Chairman of the IDF Board of Trustees. My case is representative of a typical immune deficient patient. I was diagnosed with Common Variable Immunodeficiency 10 years ago, following years of repeated infections, which were unresponsive to antibiotics, and undiagnosed by numerous physicians who happened to be colleagues of mine. This led to numerous unsuccessful surgeries resulting in permanent lung and sinus damage. Prior to my diagnosis, a day was considered successful if I had enough energy to get out of bed. Following appropriate diagnosis and treatment with IGIV, I was able to return to my medical practice and developed a new lease on life.

In my testimony, I would like to highlight three areas of importance to the IDF and the primary immune deficiency community we represent: (1) National Primary Immune Deficiency Surveillance Program. (2) Primary Immune Deficiency Research at the National Institutes of Health. (3) Primary Immune Deficiency Registries at the National Institute of Allergy and Infectious Diseases.

NATIONAL PRIMARY IMMUNE DEFICIENCY SURVEILLANCE PROGRAM

Mr. Chairman, because primary immune deficient patients are the only patient population that require life-long infusions of IGIV to maintain their health, the Immune Deficiency Foundation has been working to establish a national surveillance study of this group to evaluate the short and long term effects of IGIV use. The establishment of this surveillance initiative is vitally important because although primary immune patients have been treated with IGIV for over 20 years, a prospective study on adverse events associated with its use has not been performed.

IDF's surveillance program would provide valuable epidemiological data on the potential risks of IGIV therapy, and conditions which might predispose patients to adverse events. In addition, this initiative would benefit other IGIV users by serving as an early warning system should study participants be exposed to new and emerging pathogens.

IDF's proposed surveillance study would focus on the following:

—Identifying and characterizing adverse events
—Determining their prevalence and incidence
—Determining whether there are specific risk factors for adverse events such as: (1) Certain primary immunodeficient diseases (e.g., Common Variable Immunodeficiency vs. X-Linked Agammaglobulinemia); (2) Pre-existing medical conditions (e.g., renal and/or cardiac disease); and (3) More common with some preparations than with others (e.g., different brands and different formulations).

Mr. Chairman, IDF has been working with the plasma fractionation industry, the Food and Drug Administration, and the Centers for Disease Control and Prevention to establish this new surveillance program, and we are grateful for the subcommittee's support of this partnership last year as we developed the details of this project. Now that the program is nearing the end of the planning stage, we ask that you continue to support this important public health initiative by encouraging CDC to work with us again in fiscal year 2002. Moreover, we ask that you encourage the National Institutes of Health to support this effort as well.

PRIMARY IMMUNE DEFICIENCY RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH

Mr. Chairman, I would like to take this opportunity to thank the subcommittee for its longstanding support of biomedical research at the National Institutes of Health. IDF remains committed to the goal of the doubling the NIH budget by fiscal year 2003. Specifically, IDF encourages the subcommittee to continue its support of primary immune deficiency research at the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), and the National Cancer Institute (NCI).

In recent years, NIAID sponsored research has shed new light on the genetics of primary immunodeficiencies. NIAID investigators are using this information to develop new gene-based therapies for many primary immune disorders. This cutting-edge research has given patients hope that improved therapies, and eventually a cure, for these diseases may be on the horizon. Primary immune deficiency research also benefits people suffering from other disorders, such as autoimmune diseases and cancer, due to its acute focus on the functions of the immune system.

Recognizing the promise that biomedical research holds for improving the quality of life for primary immune deficient patients, IDF joins with the Ad Hoc Group for Medical Research in recommending a 16.5 percent increase for NIAID, NICHD and NCI in fiscal year 2002.

PRIMARY IMMUNE DEFICIENCY CLINICAL REGISTRIES PROGRAM

Mr. Chairman, since 1997, IDF has contracted with NIAID to construct and maintain registries of 8 primary immunodeficiency diseases including, Chronic Granulomatous Disease, Common Variable Immunodeficiency, DiGeorge Anomaly, Hyper IgM Syndrome, Leukocyte Adhesion Defect, Severe Combined Immunodeficiency, Wiskott-Aldrich Syndrome, and X-Linked Agammaglobulinemia. The goal of these registries is to assemble a comprehensive clinical picture of each disorder, including estimates of disease prevalence, clinical course, and complications.

This data is an invaluable resource for physicians conducting basic research on these disorders. For example, information from one registry (chronic granulamatous) is being used by four institutions to examine six different questions relating to various aspects of the disease. Further expansion of these registries is essential if we are to increase our understanding of additional primary immune deficiency disorders. IDF appreciates the subcommittee's longstanding support of the NIAID/IDF clinical registries partnership and encourages you to continue to support these important programs in fiscal year 2002.

Mr. Chairman, thank you once again for the opportunity to present the views of the Immune Deficiency Foundation.

PREPARED STATEMENT OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA'S (IDSA)

IDSA appreciates the opportunity to provide testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education concerning fiscal year 2002 funding for the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH)—particularly the National Institute of Allergy and Infectious Diseases (NIAID), the Office of AIDS Research (OAR) and the Fogarty International Center (FIC)—and for the Health Resources Services Administration (HRSA).

IDSA represents more than 6,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases.

Our members share a common focus on the epidemiology, diagnosis, prevention, investigation and treatment of infectious diseases. The discipline of infectious diseases is a subspecialty of both internal medicine and pediatrics, typically involving a two-to-three year fellowship and then board certification. Infectious diseases physicians care for patients with serious infections, including persons with HIV/AIDS, meningitis, heart valve infections, severe bone, joint or wound infections, and those with cancer or transplants who have life-threatening infections caused by unusual organisms. IDSA is the principal organization representing infectious diseases physicians.

Infectious diseases are the second leading cause of death and the leading cause of disability-adjusted life years worldwide (one disability-adjusted life year is one lost year of healthy life) and the third leading cause of death in the United States. The World Health Organization estimates that 1,500 people die each hour from an infectious disease. Diseases, such as AIDS, hepatitis, tuberculosis, malaria and pneumonia, as well as new and emerging infectious diseases, continue to cause unfathomable human suffering in this country and around the world. The real and potential implications on human lives and the escalating costs of health care in this country is staggering. CDC reports that should an influenza pandemic occur in the United States today with the ferocity of past ones, it would cause an estimated 89,000 to 207,000 deaths, 314,000–734,000 hospitalizations; and the economic impact would range from $71 billion to $167 billion.

Earlier predictions of the elimination of infectious diseases did not take into account changes in demographics and human behaviors and the extraordinary ability of microbes to adapt, evolve, and develop resistance to drugs. More than 35 newly emerging infectious diseases were identified between 1973 and 1999, and new infectious disease threats continue to be identified. The continual evolution of emerging and reemerging diseases, particularly the acceleration of the HIV/AIDS pandemic in developing countries, will heighten the global impact of infectious diseases in this century.

But the story is not all bleak. Advances made over the past century in infectious diseases treatment, prevention and research, particularly related to vaccines' development, and infection control have demonstrated the many benefits that biomedical research and public health may have in bringing these diseases under control. As the physicians who care for patients with serious and often life-threatening infections and as researchers who study drug resistance and are involved in development of new and better antimicrobial agents, our goal is to ensure that patients have access to state-of-the-art care and that the care provided is the most clinically appropriate for each patient.

We strongly believe that today's investment in infectious diseases prevention, treatment, and research will pay significant dividends in the future to the American people in dramatically reduced health care costs and improved quality of life for millions. As such, the Society has strongly advocated for appropriate funding for biomedical research, public health and infrastructure building. And, as infectious diseases do not recognize nor respect arbitrarily determined national borders, IDSA also adamantly supports United States' leadership in funding international collaborative efforts to fight transmission of infectious diseases through international research and infrastructure building in lesser-resourced countries.

NATIONAL INSTITUTES OF HEALTH

It is unlikely that we can overestimate the importance that the National Institutes of Health have had in advancing the continuum of disease knowledge now available. NIH is largely responsible for orchestrating current efforts in scientific discovery and for training future scientific leaders. The National Institutes of Allergy and Infectious Diseases (NIAID), NIH's Office of AIDS Research (OAR) and the John E. Fogarty International Center (FIC) are largely responsible for fulfilling those goals in the field of infectious diseases in the United States and around the world. NIAID-, OAR- and FIC-sponsored research and training in the areas of HIV/AIDS, sexually transmitted diseases, tuberculosis, malaria, new and emerging infectious diseases, antimicrobial resistance and genomics will significantly and favorable impact the health of millions of Americans and people of all countries.

We applaud Congress' and the Administration's commitment to increase support for NIH's programs and to double its budget by 2005. We can think of no more important investment than for the basic and clinical research that NIAID, OAR and FIC sponsors and conducts. We would note that, although the FIC's budget has increased substantially over the past several years reaching $50 million in fiscal year 2001, this amount is a small fraction of what is necessary to carry out the increasingly important international research and training that FIC supports around the

world. Thus, we recommend that you closely review FIC's budget with an eye toward providing a significant increase in funding for the Center in fiscal year 2002.

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC is the nation's prevention agency. Its important mission is to translate health information, including the results of NIH-sponsored research, into prevention programs that are effective in the diversity of our nation's communities. They do their work in partnership with state and local public health providers and other Federal agencies. CDC programs make public health work around the nation.

Increased surveillance and response, applied research, infrastructure building and training and prevention and control efforts are all necessary if we are to meet the challenges that infectious diseases will create in the years to come. CDC's Strategic Plan Preventing Emerging Infectious Diseases: A Strategy for the 21st Century continues to build domestic and global capacity for recognizing and responding to infectious diseases. Providing health departments with resources for building epidemiology and laboratory capacity has dramatically improved our ability to identify, investigate, and rapidly implement control measures in outbreak situations (such as with West Nile in the eastern United States and E.Coli, Salmonella and Listeria in other parts of the country).

Both NIH and CDC's work are inextricably linked. And, while we strongly support the Administration's proposed funding for NIH, we maintain that Congress' and the Administration's commitment to CDC must not waiver. Increased funding for NIH must not be appropriated at the expense of CDC and/or other public health programs. Thus, we support increased funding to enable CDC to implement the activities envisioned in its Strategic Plan. It is our best professional judgment, given the many unmet public health needs and missed prevention opportunities, that CDC funding should be increased to $5 billion, a $1.2 billion increase over fiscal year 2001 levels, to permit the agency to adequately fulfill its mission.

Moreover, the ever-evolving complexity of CDC's budget structure and the increased practice by Congress to dedicate particular funds for specific projects is a cause of great concern to the public health community and fiscal planners. A Pricewaterhouse/Coopers study has determined that CDC's budget structure is particularly inflexible and that this may have negative implications for public health. The General Accounting Office has concurred with these findings. We ask that Congress review this analysis and act accordingly to afford CDC the flexibility to effectively and efficiently carry out its public health mission.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Programs administered through the Health Resources and Services Administration serve as vital components of the nation's health care safety net. From funding for health professionals' training to resources for community health centers and HIV/AIDS services, HRSA funding provides vital resources that translate into health care for underserved and disenfranchised populations. Of particular interest to IDSA is funding for the Ryan White CARE Act, a program that funds medical care, drug therapy for HIV disease and HIV-related opportunistic infections, and ancillary services for uninsured and underinsured individuals, as well as training for health care providers. IDSA urges the Subcommittee to support generous funding for all Titles of the Ryan White Care Act so that biomedical and clinical research may benefit all Americans living with HIV disease.

SIGNIFICANT FUNDING NEEDS EXIST

Now, we would like to highlight a few specific public health and research areas where increased funding is needed.

Antimicrobial resistance

In the United States and around the world, many important human infections are becoming increasingly resistant to the antimicrobial drugs used to treat them. For example, CDC reports that in some areas of the United States, more than 30 percent of infections with pneumococci, the most common cause of bacterial pneumonia and meningitis, are no longer susceptible to penicillin. In the 1970s, all were susceptible. Moreover, nearly 30 percent of the bacteria that most frequently cause infections acquired in hospital intensive care units are resistant to the preferred antibiotic.

We must respond to the persistent problem of antimicrobial resistance by increasing research efforts, creating surveillance systems and developing strategies to ensure that newly developed and existing drugs are used effectively. An interagency task force, co-chaired by CDC, the Food and Drug Administration and NIH recently

released "A Public Health Action Plan to Combat Antimicrobial Resistance". The Plan outlines a number of surveillance, prevention and control, research, and product development action items. Increased funding is necessary to permit these agencies to move quickly to implement these critical action items. We also support full funding to implement the Public Health Improvement Act that was enacted last year.

Food safety

According to CDC, food-borne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. Hospital costs for these illnesses are estimated at more than $3 billion per year. Costs from lost productivity are estimated at $8 billion per year.

Through the National Food Safety Initiative, Congress has supported increased funding over the past several years, which has enabled the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) to move aggressively to reduce the impact of food-borne illness in this country. CDC, USDA, and FDA have developed and implemented critical, new research, surveillance, education and prevention efforts, under this initiative. We encourage Congress to continue to lead the way in this effort by increasing funding for the Food Safety Initiative.

Bioterrorism

The nation's public health infrastructure is not adequate to detect and respond to a bioterrorism event in this country. The potential for such an event increases with each passing day. Timely response to a bioterrorism event will absolutely depend upon a sound monitoring system at the community level. Such a system will require strong support for state and local public health infrastructure, particularly adequately equipped and staffed laboratories, and support as well for a program that cuts across all centers and programs at CDC. To this end, increased funding is needed to implement the activities authorized last year through the Public Health Improvement Act. Only through sufficient funding for assessments of local capacities to respond to an event, infrastructure development and training, vaccine research and development at NIH and coordinated response efforts across governments and health care organizations will we be able to anticipate problems, prioritize resources, and intervene effectively.

Vaccines and immunization

Immunizations are among the greatest public health achievements of the 20th Century. With the advent of vaccines for chickenpox, measles, whooping cough, polio, pneumococcal disease, hepatitis B, influenza and other infectious diseases, thousands of lives have been saved and disability and suffering averted with incredible cost savings achieved. Despite generally high coverage levels in the United States, pockets of under-immunized children, adolescents and adults remain at increased risk for contracting and transmitting vaccine preventable diseases. The global picture is much more ominous.

Additional funding is needed to shore up the nation's immunization infrastructure. In an Institute of Medicine report released last year, entitled Calling the Shots, experts agreed that unstable funding for state immunization programs threatens coverage for specific populations and age groups. In addition, according to CDC, immunization costs for more than 12 million Americans are not covered by public or private health insurance programs. This is shocking given the level of importance to public health and the demonstrated cost-effectiveness that have been realized as a result of the establishment of the National Immunization Program (NIP). Increased funding is critical to ensure that every individual may have access to appropriate vaccines.

Sufficient funding for CDC's programs to eliminate measles in the Western Hemisphere and to eradicate polio worldwide also is critical. The benefits of these programs are not limited to other countries; in the United States alone, the eradication of polio would result in a yearly cost savings of $230 million.

Finally, new vaccines' research and development will help us to prevent populations from becoming infected in the first place. Researchers at NIAID are working to develop vaccines for tuberculosis, HIV and Streptococcus pneumoniae, the leading cause of morbidity and mortality in infants and young children worldwide. NIH-sponsored research has proven successful in the past, most notably with the development of vaccines against Haemophilus influenzae type b (Hib) a bacterium that can lead to life-threatening meningitis and pneumonia in young children. Thanks to the work of NIH researchers, this vaccine reduced the number of cases of invasive Hib disease by 97 percent from 1987 to 1997. In order to repeat this success with

other diseases, we urge your continued support for vaccine research and development.

HIV/AIDS

A comprehensive funding strategy through NIH's Office of AIDS Research, CDC's prevention programs and HRSA's primary care services is the only appropriate response to the HIV/AIDS epidemic. Increased funding for AIDS through the Office of AIDS Research is critical. Through the research that it supports, the Office of AIDS Research holds the most promise for saving and improving many lives through the development of improved treatments for people living with HIV/AIDS and the development of an HIV/AIDS vaccine. CDC plays a key role in the fight against the spread of HIV/AIDS. With 40,000 new cases of HIV being diagnosed each year, this is no time for complacency. We strongly encourage increased investment in CDC's HIV/AIDS programs. These include the HIV/AIDS surveillance program that tracks the disease and informs the development of national and local prevention efforts; funding of community-based programs that design and implement prevention programs targeted at their communities; and the variety of programs funded through the Congressional Black Caucus (CBC). The CBC programs deserve special attention given the alarming increase of HIV/AIDS in minority communities. To adequately support these and other important programs, CDC funding for HIV/AIDS programs should be increased substantially. The Ryan White CARE Act administered under HRSA is the heart of the federal response to HIV/AIDS care. Generous funding for all titles of the CARE Act are necessary to maintain the significant reductions in HIV-related morbidity and mortality we have enjoyed in recent years.

Finally, IDSA strongly supports HHS' global AIDS efforts. Substantial increases are warranted for new research, treatment and prevention strategies, and public health infrastructure building in lesser-resourced countries. Our Society supports a robust and comprehensive U.S. response to the global HIV/AIDS pandemic. We will be advocating for increased funding in other federal budget accounts as well.

Thank you again for the opportunity to provide IDSA's views on these important matters to the subcommittee. Please let us know if you require any additional information.

PREPARED STATEMENT OF THE JOSLIN DIABETES CENTER

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to appear before you to present Joslin Diabetes Center's proposal to improve the access to and quality of health care for people with obesity and type 2 diabetes and to reduce costs and increase savings for these health care outlays by establishing a new paradigm for the prevention and treatment of obesity and type 2 diabetes.

Obesity is a major risk factor for the development of type 2 diabetes and insulin resistance and a major cause of morbidity and mortality in the Unites States:

—1 in every 2 Americans is overweight and the prevalence of obesity has increased 57 percent in the last 10 years.

—Obesity disproportionately affects minorities—60 percent of African-American, Mexican-American, and Native-American women meet the criteria for being overweight and between 33–37 percent are obese.

—Obesity in children and adolescents is increasing at an alarming rate, leading to the occurrence of type 2 diabetes in these groups.

Equally foreboding for the future well-being of our country, the startling rise in obesity is driving an emerging epidemic of diabetes in the United States:

—Diabetes in the United States increased by 6 percent in 1999.

—Over 90 percent of diabetes is type 2 (adult-onset), and 90 percent of people with type 2 are obese.

—The Centers for Disease Control and Prevention reported that diabetes increased 33 percent nationally to 6.5 percent between 1990 and 1998.

—The rise in diabetes costs increased across all age groups but was most profound—about 70 percent—among people ages 30–39.

— For the rapidly expanding over-50 age group, the incidence of diabetes approaches 20 percent, and diabetes and its complications comprise 25 percent of Medicare costs.

Obesity is a risk factor for:

—Diabetes

—Cardiovascular disease—heart attack, stroke

—High blood pressure

—Sleep apnea

—Uterine cancer
—Breast cancer
—Colon cancer
—Gall bladder disease

With over 50 percent of the population obese, these risk factors underscore why this serious problem is emerging as an epidemic.

As the world's largest and most comprehensive independent diabetes research and patient care institution, Joslin Diabetes Center proposes the development of a pilot program to prevent and treat obesity and type 2 diabetes. Over 80 percent of people with type 2 diabetes would be "cured" if they could lose 10–20 pounds of weight. Unfortunately, 90 percent of these people with type 2 diabetes cannot successfully lose weight because obesity is a medical problem and not a moral fault.

To address the growing epidemic of obesity and type 2 diabetes, Joslin Diabetes Center would like to share technology, methods and experience through the development of a pilot demonstration project for the prevention and treatment of obesity and type 2 diabetes:

—To adapt Joslin's state-of-the-art Diabetes Outpatient Intensive Treatment Program for different ethnic, economic, social and age population groups.
—To demonstrate the effective long-term benefits of Joslin's Intensive Treatment and telemedicine protocols.
—To evaluate clinical strategies for prevention and treatment of obesity including the application of our growing knowledge of molecular mechanisms that increase appetite and of the role of leptin in obesity.
—To analyze different diets of people with type 2 diabetes.
—To advance Joslin's applied research results in the development of preferences for alternative food choices and lifestyles and community-level and school interventions to prevent obesity and the onset of diabetes.

Joslin's pilot project would demonstrate significantly improved prevention and treatment of obesity and type 2 diabetes, resulting in reduced costs, improved patient access and quality of life.

Specifically, we propose to initiate a pilot project of detection, prevention, and care of obesity and type 2 diabetes for a three-year period, utilizing training and validation exercises derived from Joslin's expertise and telemedicine infrastructure. The cost would be $3.6 million annually.

Through its Diabetes Outpatient Intensive Treatment Program, Joslin applies a new approach towards patients with diabetes. This approach focuses on two major areas: improving clinical outcomes in a practical, resource-efficient manner. Clinical outcomes have demonstrated improved metabolic control (and thus fewer long-term complications) and reduced patient stress resulting from having to treat their diabetes. The Program is focused on individual flexibility and was developed in a way to be more efficient in utilization of both patient resources and health-care resources.

Rather than rely on continued intensive involvement of health care providers throughout a patient's lifetime, we put the patient through a short, intensive course of training which not only leads to an immediate improvement in their metabolic control, but gives the patient the foundation to take care of themselves in the future. The Program also reduces the patient's diabetes-related stress by training the patients to care for their own diabetes, seeking other professional input when needed. This is more appealing to the patient, more efficient in the use of resources in the long-term, and produces good results.

With the proposed pilot project, Joslin is in the process of developing an alternative Outpatient Intensive Treatment Program for people with obesity and type 2 diabetes. The pilot project will establish and validate appropriate criteria, protocols and outcome guidelines for different ethnic, economic, social and age population groups.

Utilizing Joslin's JVN telemedicine infrastructure, Joslin Diabetes Center will design and develop a modularized medical outcomes-based Telemedicine Diabetes Intensive Treatment Program to provide a web-based Comprehensive Diabetes Management System. Integrating Joslin's JVN telemedicine infrastructure as a component of the CDC can link health care practitioners with the National Diabetes Education Program, targeting the segment of the population that suffers from the epidemic explosion of obesity and diabetes complications. Adaptation of Joslin's JVN system for treating obesity and type 2 diabetes can measurably improve patient access, compliance, education and motivation to further increase effective long-term individual and society health benefits.

Ongoing research at Joslin addresses how complex molecular mechanisms regulate body weight (hormones that control eating and appetite), how the fat cell functions as an endocrine cell, how leptin signaling the brain affects eating, and how

fat interacts with the beta cell to cause diabetes. Resulting new clinical strategies for prevention and treatment of obesity and diabetes complications will be incorporated as a component of the pilot project.

The three-year demonstration pilot will additionally provide the opportunity to broaden the clinical applications of promising bariatric surgery and medical therapy protocols for alleviating obesity and resulting diabetes complications. Evaluation of strategies for the prevention and treatment of obesity and type 2 diabetes will analyze long-term effects of gastric by-pass (bariatric) surgery, including clinical evaluation of people with gastric bypass surgery and the clinical evaluation of medical therapies to further refine Joslin's new paradigm of intensive treatment of obesity and type 2 diabetes.

The demonstration project will train health care providers, e.g. nurse educators and physicians, from and for different ethnic, economic, social and age population groups. Concurrently, Joslin will provide curriculum-based patient and provider education modules.

The proposed pilot project will demonstrate significantly improved detection, prevention and care techniques for obesity and type 2 diabetes, resulting in overall reduced costs, improved patient access, and improved quality of life. Furthermore, this demonstration of Joslin's new paradigm for obesity and type 2 diabetes health care will provide better clinical understanding and expertise, which can be effectively extended to benefit all people living with type 2 diabetes.

Thank you for this opportunity to appear before you today. I would be pleased to answer any questions you might have.

PREPARED STATEMENT OF THE JUVENILE DIABETES RESEARCH FOUNDATION INTERNATIONAL

Brayton James DiPietro

Before I begin, I would like to thank the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies for giving me the opportunity to share my story. My name is Brayton DiPietro and I am pleased to testify on behalf of the Juvenile Diabetes Research Foundation. I am in the eighth grade at St. Paul's Grade School in North Canton, Ohio. I also have diabetes and was diagnosed just after my eleventh birthday. I will be fifteen this June, so this summer will mark four years that I have had the disease.

I broke my leg on December 15 while sledding in my backyard. The doctors were unable to use any rods or pins in setting my break because people with diabetes run a high risk of infection. We also heal slower. For a person with diabetes, the entire process would have taken about one fourth as long.

Many people believe that the life of an individual with diabetes doesn't change dramatically once diagnosed. I am here to tell you that that is not true. Three or four times a day, I have to check my blood sugar by pricking my finger and give myself an injection of insulin. I have to think about every single thing that I eat and when I eat it. As a teenager, it won't surprise you that I would love to sleep in on a Saturday morning. However, if I do that it would throw of my blood sugar levels and it could take several days to get back on course.

Those, of course, are the good days. When I have the flu, I have to check my blood sugar constantly and my urine for ketones to make sure that I don't go into Ketoacidosis, a condition that could be fatal in less than 24 hours. When I play baseball, I have to check my blood sugar level every other inning to make sure I am maintaining proper blood sugar levels. Even taking these precautions, I have experienced loss of vision, dizziness, and general disorientation during a game.

I don't really know what I am going to be yet when I grow up. I know that I can't be a pilot for the Navy because of my diabetes. Can you imagine what would happen if I blacked out in a combat situation?

I have approximately 6,000 finger pricks plus an equal amount of insulin injections in the past four years. That doesn't even count regular drawing of blood tests at the doctor's office. While I wait for a cure, which I know will happen if you continue to generously support medical research at the National Health Institute and help ensure that juvenile diabetes research is adequately funded, the best thing that I can do is to continue to take proper care of myself, remain disciplined, and try to lead as normal a life as possible.

Back in Canton, I heard a lot about the not so good things that happen in Washington these days. I am really glad to have the opportunity to be part of a good thing that is happening in Washington. Your subcommittee's leadership in doubling the NIH budget by 2003 could allow me to live a fuller and healthier life. Thank you.

Steven DiPietro

Brayton's story is not unique. In one form or another, it is shared by each of the 16 million Americans who have diabetes. In addition to its personal burden, diabetes carries an extraordinary price tag—one in four Medicare dollars are attributable to individuals with diabetes, and the disease costs our nation more than $100 billion annually. If we could cure diabetes it could both solve the Medicare solvency problem and be a major boost to our economy!

As you may imagine, I am very proud of my son, who I witness each day persevere through his daunting, daily regimen of living with diabetes. I do my share in fighting juvenile diabetes by volunteering with my local chapter of the Juvenile Diabetes Research Foundation, where I currently serve as Board President. I am pleased that through our local walks, galas, and special events, JDRF will be able this year to allocate $120 million for juvenile diabetes research.

However, we can't do it alone. This is why your continued support for the bipartisan effort to double the NIH budget over five years and provide the NIH with a $3.4 billion increase in funding this year is critical to individuals with diabetes.

Last year, researchers announced that seven individuals with diabetes had been "cured" of the disease following the successful transplantation of insulin-producing cells. In my mind, the question is no longer whether we will cure diabetes, but when will it happen. Your support for doubling the NIH budget will make this happen sooner, and my family, and the millions of others who have diabetes want to thank you for making their hopes and dreams possible.

PREPARED STATEMENT OF THE KENNEDY KRIEGER INSTITUTE

Mr. Chairman, Members of the Committee, the Kennedy Krieger Institute in Baltimore, Maryland appreciates the opportunity to present its views on a number of important programs supported by the U.S. Department of Education; the National Institutes of Health and the Health Resources and Services Administration at the U.S. Department of Health and Human Services.

We would like to highlight the efforts of three federal agencies under your jurisdiction and the important work that they do to strengthen the capacity of programs, such as the Kennedy Krieger Institute, to make progress in the important areas of education and health.

THE KENNEDY KRIEGER INSTITUTE

The Kennedy Krieger Institute is an independent research institution located adjacent to Johns Hopkins University. The mission of the Institute is to focus solely on disorders related to the brain and central nervous system. Brain related disorders effect one in four adults and one in ten children at a cost to society of $400 billion per year. The overall goal of research at the Kennedy Krieger Institute is to understand the developing central nervous system through the study of relationships between genes, the brain and human behavior. Although the Institute has special expertise with regard to children, the research scope includes studies of changes in the brain and the central nervous system across the lifespan. The Kennedy Krieger Institute is a comprehensive resource for children with disabilities, recognized as a research facility and training center for health care professionals from around the world. The Institute treats a wide array of children with neurological diseases including, but not limited to, Down syndrome; attention deficit hyperactivity disorder; lead poisoning, autism; cerebral palsy; genetic and metabolic disorders, like fragile X syndrome, neurofibromatosis, tay sachs disease, tourette syndrome; spina bifida; degenerative brain disorders; mental retardation; and many others. Our Institute integrates cutting edge neurobiological and behavioral research efforts into a comprehensive program which includes inpatient and day treatment services; outpatient services; home and community services; and school programs for children with disorders of the brain. The Institute is well-known for its strong interdisciplinary research and care in many fields including medicine, psychology, education, physical and occupational therapy, audiology, speech and language therapy, social work, child development, nutrition and nursing.

BASIC AND CLINICAL RESEARCH

The Board of Directors, the researchers, health professionals and patients and families at the Kennedy Krieger Institute are all very grateful for the support that this Committee has provided to the NIH over the past several years. The resources that Congress has appropriated have enabled the research community to grasp re-

search opportunities that a decade ago we could not even have dreamed possible. This is making an incredible difference in the lives of the children that we treat.

We are currently experiencing an unprecedented appreciation of the benefits to health and life quality that can result from biomedical and behavioral research. Of particular note is the most welcome present and predicted increase in public sector funding for basic research and the dramatic, if not explosive, private sector investment in biology. With such appreciation and tangible support comes the responsibility to organize the scientific enterprise so as to produce effective interventions. And, our challenges are many.

Many children with developmental disabilities and neurological diseases display severe behavior problems. The mission of our basic and clinical research, clinical care, and educational programs is to improve the quality of life for these children and their families through a variety of mechanisms including:

—providing advanced and comprehensive treatment services;

—promoting the widespread dissemination of effective interventions; and

—improving treatment technologies through basic and clinical research.

With that said, we support treatment and research initiatives including but not limited to behavior programs, pediatric feeding disorders, neuroimaging, basic and clinical research efforts and training.

The National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological Diseases and Stroke support a number of important initiatives with regard to brain biology; neurobehavioral assessment and protocol development; translation studies related to cognition pathways of learning disorders from a developmental perspective; molecular sciences to further understand the molecular basis of many developmental disabilities; brain mapping; and other basic and clinical programs which are at the core of the programs conducted at the Kennedy Krieger Institute. Further, the National Center for Research Resources (NCRR) supports important neuroimaging studies for neuroscience, metabolic, behavioral, and other research. The Kennedy Krieger Institute receives funding from the NCRR for our neurobehavior research unit through a subcontract from the Johns Hopkins University General Clinical Research Center (GCRC). The support we receive is used to conduct studies related to functional imaging. We believe it is important for the Committee to consider an NIH National Imaging Network for Clinical Research that will enable NCRR to provide the resources to create links between the GCRC to the imaging center. This sort of infrastructure would be vitally important to facilitate and integrate research networks.

Clearly, multiple programs supported by the National Institutes of Health (NIH) enrich our capacity to address important basic and clinical research issues in the population that we serve. The work of this Committee ensuring a sustained commitment to these programs has enabled institutions, such as ours, to move forward at unprecedented speed. To that end, we urge the Committee to continue its efforts in support of the NIH.

Request.—The Kennedy Krieger Institute endorses the recommendation of the Ad Hoc Group for Medical Research Funding for fiscal year 2002 which recommends a $3.4 billion, or 16.5 percent, increase that will result in a total NIH budget of $23.7 billion in fiscal year 2002. This funding level is necessary to continue the congressional campaign to double the budget of the NIH by 2003.

EDUCATION

Our approach to severe behavioral problems in many children with developmental disabilities and severe behavior problems is multi-focused. The Severe Behavior Program provides comprehensive diagnostic evaluations, parent training and school consultative services. The linkage to the child's school and school district is imperative to develop and effectively implement effective strategies to deal with the behavioral problems many of our patients present with. This initiative is complemented by inpatient and outpatient behavioral management services for children who display severe destruction behavior.

The Kennedy Krieger Institute's Lower and Middle Schools, recipients of the US Department of Education's National Blue Ribbon Awards in 1996 and 1997, respectively, are recognized models in special education. Their track record includes: innovative models of education based upon current scientific understanding of brain functioning; creative integration of technology in the classroom; comprehensive curriculum tailored to unique needs of the student; and training in the field of special education.

Employment data for all youth in the United States are a national concern. Fewer students are graduating from high school adequately prepared to enter post-secondary program or secure competitive employment. Of particular concern are youth

with disabilities, who are consistently less successful than their non-disabled peers. It has been estimated that 70 percent of individuals with disabilities are either unemployed or underemployed.

The Kennedy Krieger high school program, which opened in September, 1999, provides a comprehensive approach to school-to-work transition for youth with serious learning, emotional, neurological, and developmental disabilities. The school-to-work curriculum at our Career and Technology High School is unique in that it will be the only program in the state to make career training the foundation of, and not merely a supplement to, the school's core curriculum. All of the students that attend the Kennedy Krieger Career and Technology High School demonstrate a serious disability, and 50 percent of these students come from families supported by federally-funded programs for children and families living below the poverty level. As the school's student population grows from the current enrollment of 125 to 200 students, it is anticipated that the percentage of students living below poverty will remain current if not increase.

Drawing on the most current educational, work-readiness, and industry standards, the high school staff develop partnerships with business and community groups to develop a state-of-the-art model that will result in economically and personally rewarding employment for youth with disabilities. The Career and Technology High School will take students challenged by severe learning, emotional, traumatic brain injury, and developmental disabilities and provide a school-to-work instructional model that addresses the needs of students with serious disabilities who have the potential to undertake meaningful employment. Students will graduate with the knowledge and work and social experience they will need for successful postsecondary employment in a specific career clusters including: Information Technologies; Hospitality; Tourism Construction and Manufacturing; Business and Finance; Arts and Graphics; and Communications. Programs supported by the Department of Education, including the Technology Innovation Challenge Grant program are critical to enable cutting edge programs such as our to fully develop our capacity to create model systems which can be applied nationwide. The strong support that this Committee has provided to these programs in the past have been a worthwhile investment and we urge your continued strong support.

Request.—The Kennedy Krieger Institute respectfully requests $2 million in program funding from the Department of Education's Technology Innovation Challenge Grant program to support the expansion of a dynamic performance-based curricula and instructional delivery options utilizing distance learning that connects educational and research programs. Students, teachers, parents, and other professionals will receive support through instructional software, performance databases, access to the Internet, and opportunities for self-directed learning.

MARCUS INSTITUTE, ATLANTA GEORGIA

The Kennedy Krieger Institute has embarked upon a collaboration and formal fiscal affiliation with the Marcus Institute, located in Atlanta, Georgia, to establish a national network of developmental services for children with disorders of the brain and their families. The foremost goal of this national initiative is to rally support and spearhead unified advocacy for individuals with developmental disabilities and severe and challenging behaviors so that they can experience a greater quality of life and participate as fully as possible in family, school, and community life.

Currently, the Marcus Institute is housed in leased space within a professional office park—a location woefully inadequate for the programs and specialized services provided to the severely disabled children served by the Institute. We are in the process of developing an 80,000 square foot facility near the Emory University campus and the Centers for Disease Control and Prevention. The new facility will allow the Institute to expand upon its mission to encourage and facilitate advanced research, training, and programming for children and adolescents with developmental disabilities and severe and challenging behaviors through the further refinement and expansion of the Marcus Behavior Center. This behavior center of excellence is devoted to providing the most advanced clinical treatments, training, and research so that services for the families of children with severe and challenging behavior are as effective and as comprehensive as possible.

The new Marcus Institute will include a school with a student population of approximately 50 children. The school will work with those children with the most acute emotional, behavioral, and psychological challenges to continue their educational process while receiving our specialized services and avoid additional difficulties when they return to their community school. The Marcus Institute school is designed continue their education while they are here, rather than permanently removing them from their community school.

Since 1993, the Marcus Institute has provided clinical services to more than 14,000 individuals, conducted research, and provided education and training programs. These services have been provided by developmental pediatricians, psychiatrists, behavioral, clinical and neuro-psychologists, neurologists, geneticists, nurses, physical, occupational, and speech therapists, social workers, special educators, and family support personnel.

The Marcus Institute in Atlanta and Kennedy Krieger Institute (KKI) in Baltimore have developed a partnership in which programmatic, research, and training expertise is shared to provide community-based treatments for children with developmental disabilities who display the most severe forms of behavior disorders, including aggression, self-injurious behavior, and pediatric feeding disorders. These behaviors pose a substantial risk to the individual(s), family members, and other care providers. Without appropriate treatment, these children are at substantial risk for health problems (and even death) and for lifelong placement in residential programs, which often costs $100,000 or more per year and millions of dollars over the individual's lifetime. The behavior programs at the KKI have been in existence for over 20 years. All children who receive these services show clear improvement and over 80 percent meet their primary discharge goals (compared with less than 2 percent for traditional outpatient mental health services).

The Marcus and Kennedy Krieger programs are unique not only in terms of their success levels, but also because the effectiveness of the treatment protocols used have been documented through systematic program evaluation data and through formal research studies published in refereed journals. The Marcus Behavior Center currently provides a continuum of consultative, outpatient, educational, and day treatment services for children with severe behavior disorders. Those with the most severe problems are seen in our intensive day treatment programs. Young children (usually below age 6) are admitted to the Feeding Day Treatment Program if they display behaviors such as food refusal or food selectivity (eating one or only a few foods) that necessitate medical interventions (e.g., gastrostomy tubes) to prevent malnutrition or death. School-aged children (ages 3 to 21) are admitted to the Severe Behavior Day Treatment Program if they have developmental disabilities and display severe self-injurious behavior (SIB), aggression, or property destruction that poses a significant risk to self, others, or the environment, which cannot be safely managed or effectively treated in a less intensive program.

Less severe cases are served through our outpatient and consultative programs, whereas the most severe cases are served through our day treatment programs. For example, SIB consists of repetitive motor responses that produce physical harm to the individual who displays the behavior. Typical forms of SIB include head banging, self-biting, head hitting, body hitting, scratching, eye poking, pica, and ear poking. SIB is extremely rare among individuals of normal intellectual functioning. It is seen in approximately 6 percent to 16 percent of individuals with mental retardation and autism.

As part of our collaborative effort, the Kennedy Krieger Institute is working with the Marcus Institute, the United States Congress, and State and local officials in Georgia as we establish this state-of-the-art facility in Atlanta.

Request.—We respectfully request $5 million in fiscal year 2002 funding through the Health Resources and Services Administration (HRSA) Construction account to provide assistance with the construction of a new, state-of-the-art health facility for the Marcus Institute. The Marcus Institute was created as a result of a generous donation by Bernie and Billie Marcus. It is known as a nationally recognized center for excellence for the provision of coordinated and comprehensive services for children and adolescents with developmental disabilities and severe and challenging behaviors. Our goal is to publicize any Federal grant to leverage additional dollars throughout the private sector. Funding at the $5 million level would provide 20 percent of the total cost of the campus.

CONCLUSION

The Kennedy Krieger respectfully requests the support of the Committee through the allocation of fiscal year 2002 funds for the following.

1. A continued commitment to the congressional campaign to double the NIH budget by 2003 by providing a $3.4 billion, or 16.5 percent, increase for NIH in fiscal year 2002, as advocated by the Ad Hoc Group for Biomedical Research funding. The continued investment in NIH will support a number of important research initiatives including brain biology, neurobehavioral assessment, and molecular sciences to further understand the molecular basis of many developmental disabilities.

2. The Kennedy Krieger Institute respectfully requests $2 million in program funding from the Department of Education's Technology Innovation Challenge

Grant program to support the expansion of a dynamic performance-based curricula and instructional delivery options utilizing distance learning that connect experiences between school and the workplace. This investment will permit severely disabled students to receive support through instructional software, performance databases, access to the Internet, and opportunities for self-directed learning.

3. We respectfully request $5 million through the Health Resources and Services Administration (HRSA) Construction account to provide assistance with the construction of a new, state-of-the-art health facility for the Marcus Institute in Atlanta Georgia. It is known as a nationally recognized center for excellence for the provision of coordinated and comprehensive services for children and adolescents with developmental disabilities and severe and challenging behaviors.

The Kennedy Krieger Institute thanks you for the opportunity to present our views.

PREPARED STATEMENT OF THE DRUG AND ALCOHOL SERVICE PROVIDERS ORGANIZATION OF PENNSYLVANIA

My name is Deb Beck and I am the President of the Drug and Alcohol Service Providers Organization of Pennsylvania (DASPOP), a statewide coalition of drug and alcohol prevention and treatment programs, practitioners, employee assistance programs, and drug and alcohol associations representing more than 365 organizations, programs and clinics, over 3,000 certified addiction professionals, 1,200 student assistance professionals, and 400 prevention specialists. Thank you for this opportunity to submit testimony in support of increased fiscal year 2002 funding for alcohol and drug treatment, prevention, and research programs in the Departments of Health and Human Services and Education.

Today I am representing the views of DASPOP, the State Associations of Addiction Services, which is composed of 27 state-based associations of treatment and prevention providers in 26 states, and the Legal Action Center, a non-profit law and policy firm that represents individuals in recovery from and struggling with alcohol and drug problems and AIDS.

Thank you, Mr. Chairman and members of the subcommittee, for last year's increases for alcohol and drug treatment, prevention, and research programs and your refusal to cut funding for these services. Funding is even more important in light of the recent sharp increases in ecstasy use among our youth and in marijuana use among young adults age 18 to 25. President Bush has recognized the need for expansion of these services through his campaign proposals for large increases in funding and his encouragement of even greater participation by faith-based organizations that meet appropriate standards. We urge the Congress to dramatically expand funding for the full continuum of drug and alcohol treatment, prevention, and effectiveness. Providing strong support for alcohol and drug treatment, prevention, and research is essential to maintaining and improving the health and well being of our nation. These programs save lives and money by decreasing alcohol and drug use, crime, health care costs, AIDS and welfare dependence, and by increasing employment.

TREATMENT AND PREVENTION NEEDS IN PENNSYLVANIA

Pennsylvania programs have been leaders in developing effective alcohol and drug treatment programs for women, youth, criminal justice offenders, and other underserved populations. However, despite the success of these programs, we are faced with a capacity crisis that needs attention. The annual waiting list for alcohol and drug treatment services in Pennsylvania is approximately 49,000 individuals, yet these individuals represent only a small portion of the actual number of persons in need of treatment services. And in spite of last year's increases for the Substance Abuse Prevention and Treatment (SAPT) Block Grant, this year in Pennsylvania we are expecting that waiting list to continue to grow as pressure on public treatment funds increases. Some factors that place a strain on these funds include:

—*Reduced Medicaid Coverage*.—Many individuals with alcohol and drug problems have lost their Medicaid coverage which helped to pay for their alcohol and drug treatment. Some individuals lost their coverage due to changes in Pennsylvania law, while others lost Medicaid coverage because of changes in federal law which made individuals with a primary diagnosis of alcoholism or drug dependence ineligible for SSI and Medicaid. These changes in eligibility have created a funding shortfall of more than $80 million.

—*Reduced General Support Funding*.—Fewer individuals are eligible for Medicaid coverage that pays for general health care services. When individuals without Medicaid enter alcohol and drug treatment and require medical care, alcohol

and drug treatment programs pay for the cost of the client's medical care by using general support funds that are not specifically earmarked for alcohol and drug treatment. This reduction in general support funding results in programs relying more heavily on funds dedicated expressly to treatment to provide alcohol and drug treatment services. These dedicated funds include the SAPT Block Grant.

—*Lack of Managed Care Coverage*.—Commercial managed care companies frequently deny coverage for alcohol and drug treatment, forcing individuals and families to seek treatment in the publicly funded alcohol and drug treatment system.

—*Increase in Purity of Heroin and Cocaine*.—In the last few years heroin has returned to popularity due in large part to the increased purity of the substance. This allows drug users that were fearful of injecting chemicals into their bodies to either smoke or snort the drug. In the past, the average purity of heroin was between 1 and 10 percent. Now authorities are noticing the percentage as high as 98 percent in Pennsylvania compared to a national average of 35 percent. There has also been a significant increase in the purity of cocaine, the most commonly used drug in Pennsylvania, with an average purity as high as 80 to 90 percent. The substantial increase in the purity of these drugs has put a severe strain on the public drug treatment system, as users of these purer drugs are more likely to quickly become addicts in need of treatment.

This increase in demand for treatment services, coupled with funding and benefit reductions, places even more pressure on the SAPT Block Grant to provide support for alcohol and drug treatment services. Increased fiscal year 2002 funding, especially for the SAPT Block Grant, is necessary in order for Pennsylvania to expand access to alcohol and drug treatment services, which save both lives and money.

Pennsylvania also has developed effective community-based prevention services that reduce the onset of alcohol and drug use among youth and other vulnerable populations. However, decreasing Safe and Drug Free Schools State Grants program funding will adversely impact many of these programs, requiring cuts in prevention services for youth. Increasing funding for effective, community-based alcohol and drug prevention programs is critical, especially in light of the recent sharp increases in drug use among middle-school youth. The State Grants program in the Safe and Drug Free Schools and Communities Act is a vital resource for these services.

RECOMMENDATIONS

For providers to supply these essential services in Pennsylvania and throughout the nation, we need your support. We urge Congress to adopt the following increases in fiscal year 2002 funding for alcohol and drug treatment, prevention, and research programs in the Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Education, and National Institutes of Health. These are wise investments that will provide desperately needed services in communities across the country:

—$2.0 billion for the Substance Abuse Prevention and Treatment Block Grant to continue closing the treatment and prevention gap.

—$350 million for the Center for Substance Abuse Treatment (CSAT) and $350 million for the Center for Substance Abuse Prevention (CSAP), including CSAP's High Risk Youth program, to expand Targeted Capacity Expansion programs that provide targeted, gap filling services and infrastructure tailored to address specific and emerging drug epidemics and/or underserved populations, and to support the continued translation of research into best practice through Knowledge Development and Application programs.

—$694 million for the Safe and Drug Free Schools and Communities Act program, with the increased funding ($50 million) allocated to the State Grants program to support local, community-based prevention initiatives.

—$341 million for research at the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and $991 million for research at the National Institute on Drug Abuse (NIDA).

TREATMENT AND PREVENTION REDUCE ALCOHOL AND DRUG USE AND HAVE PUBLIC SUPPORT

Numerous studies have demonstrated the effectiveness of treatment and prevention in reducing alcohol and drug use. As stated above, the National Treatment Improvement Evaluation Study (NTIES) evaluated CSAT's demonstration programs and found sustained reductions in drug use. Drug use declined by 51 percent for crack, 55 percent for cocaine, 47 percent for heroin, and 50 percent for marijuana for the 5,700 clients studied one year after completing treatment. NTIES also found

a 78 percent decrease in violent crime, 19 percent increase in employment, and 11 percent decrease in welfare dependence. Prevention has also been shown to be effective in reducing use. A recent study, conducted by the University of Washington's Washington Kids Count project, clearly demonstrates that the level of peer substance use in middle schools has a substantial impact on the academic performance of students across the state. The study found that on average, students whose peers had little or no involvement with drinking or drugs scored 18 points higher in the reading portion of the Washington Assessment of Student Learning (WASL) test and 45 points higher on the math section.

Prevention and treatment have been repeatedly shown to be cost-effective. The Office of National Drug Control Policy estimates that drug abuse and addiction cost this country at least $277 billion per year in deaths, medical emergencies, spread of infectious diseases, crime, homelessness, lost productivity, and other social costs. Expanded access to treatment and prevention would decrease this cost. A 1994 California study found that each $1 invested in drug and alcohol treatment and prevention saves taxpayers $7. These reductions in taxpayer costs were attributed to savings in criminal justice costs (22 percent), victim losses (40 percent), theft losses (69 percent), and health care costs (23 percent).

The public recognizes the value of treatment and prevention services. A 2000 survey found that 84 percent of poll respondents believed that at least half of the funding available to fight the drug problem in local communities should be spent on prevention, education, and treatment. Police have echoed the public's support for treatment. In a 1996 survey, police chiefs from around the country ranked drug abuse as the most serious problem in their communities and identified the shortage of treatment programs as the most serious limitation in their ability to address drug problems successfully.

CLOSING THE TREATMENT GAP IN OUR COMMUNITIES

Access to alcohol and drug treatment does not meet the current need for services. While between 13 million and 16 million people need treatment for alcohol and drug problems in any given year, only 3 million, or 20 percent receive treatment.

The need for treatment will only become greater in the future. A 1999 analysis of data from the National Household Survey on Drug Abuse (NHSDA) projected that the need for future treatment is expected to increase 57 percent because of increased marijuana first use and problems among the aging cohort of drug abusers who first started using illicit drugs during the 1970s.

INCREASED INVESTMENT IN PREVENTION PROGRAMS REQUIRED

To reduce the trend of increased alcohol and drug use by youth, especially middle-school aged youth, Congress must increase its investment in community-based prevention programs. A 1998 study found that drug use jumps 300 percent in the first year after elementary school. Furthermore, according to data from the Monitoring the Future Study, ecstasy use has significantly increased in 2000 among all students, with a 45 percent increase in use among 8th graders.

To effectively address this important problem, every adolescent should have access to alcohol and drug prevention services, but this is not the case nationwide. Providing universal access to effective community and school-based prevention services requires increased funding.

DRUG AND ALCOHOL TREATMENT, PREVENTION, AND RESEARCH FUNDING MUST BE EXPANDED

Substance Abuse Prevention and Treatment Block Grant—SAMHSA/CSAT

The majority of SAMHSA's funding for drug and alcohol treatment and prevention is sent directly to states through the Substance Abuse Block Grant. The Block Grant is the primary source of federal funding for alcohol and drug treatment and prevention services, accounting for over 40 percent of public funding for these services nationwide.

To help meet the pressing need for treatment and prevention services, we urge Congress to fund the Block Grant at $2.0 billion for an overall increase of $335 million of fiscal year 2002 funding.

SAMHSA/CSAT & CSAP—Balancing the Knowledge Development Application Program with the Need to Target Services to Underserved Populations and Emerging Drug Epidemics

Funding at the Centers for Substance Abuse Treatment and Prevention should be directed toward two major activities: services capacity expansion for populations at high risk or which have increased need for treatment and prevention services and

Knowledge Development and Application (KDA). Targeting service funding allows CSAT and CSAP to meet the evolving needs of communities by providing targeted, gap filling services and infrastructure tailored to address specific and emerging drug epidemics and/or underserved populations (e.g., methamphetamine, heroin, designer drugs, adolescents, specific racial and ethnic groups, exoffenders, homeless persons, and women on welfare.)

Investment in the application of research findings is also a key Federal responsibility, and CSAT and CSAP, as the lead Federal agencies in treatment and prevention, are singularly equipped to translate research findings into best practices for treatment and prevention programs.

For fiscal year 2002 we urge Congress to appropriate $350 million each for CSAT and CSAP, a $94 million increase for CSAT and a $175 million increase for CSAP.

Safe and Drug Free Schools and Communities Act—Department of Education

Research has demonstrated that school-based prevention programs that focus on personal and refusal skills development can significantly reduce alcohol and drug use. The Safe and Drug Free Schools program also provides critical intervention services by supporting student assistance programs that refer students who are beginning to use alcohol and drugs to appropriate services. These early intervention programs, which have no other source of federal funding, are critical to reaching youth at high risk early.

For fiscal year 2002 we urge Congress to appropriate $694 million for the Safe and Drug Free Schools and Communities Act program, a $50 million increase over fiscal year 2001, with the entire increase be directed into the States Grants program which supports local community prevention programs.

We also ask that Congress keep the funding for the Safe and Drug Free Schools and Communities Act program separate from the 21st Century Program. The combination of these two programs would dilute funding directed toward drug and alcohol prevention efforts.

Basic Research—NIH/NIAAA & NIDA

Research into the causes, costs, and "cures" of alcoholism and drug dependence is an important component of our field's continuum. This past year NIDA and NIAAA have been making great strides in research relative to alcohol and drug dependence. These breakthroughs have demonstrated that alcoholism and drug dependence research hones our knowledge about addiction and improves our ability to treat and prevent it.

To expand our knowledge of addiction and how best to treat and prevent it, we urge Congress to appropriate $341 million for NIAAA, a $79 million increase, and $991 million for NIDA, a $211 million increase.

CONCLUSION

Alcoholism and drug dependence continue to be among our Nation's most serious and costly public health problems. The programs I have discussed this afternoon are the first line of defense to protect our children from developing drug and alcohol problems, as well as the funding source of last resort to treat Americans who have already developed these problems. As a society, we must strengthen these programs. Thank you.

PREPARED STATEMENT OF THE LOVELACE RESPIRATORY RESEARCH INSTITUTE (LRRI)

It is proposed that the Department of Health and Human Services (DHHS) through its constituent agencies, support the renovation of the LRRI clinical facilities and purchase of necessary equipment to support LRRI maintain its high research and clinical standards, better provide appropriate data security.

LRRI has committed to a building campaign using $10 million in private funds to improve its laboratory facilities and equipment. LRRI's clinical study facility is in need of renovation to better accommodate the thousands of outpatients recruited for these studies and to better maintain security of their patient information. LRRI requests $2 million to help renovate this facility.

PROJECT IMPACT

LRRI, as a private non-profit research institute, places top priority on its ability to translate its basic science findings from animal models, into protocols designed to evaluate new approaches for treating respiratory disease. These protocols lead to new innovative techniques and approaches to health care.

LRRI conducts clinical studies requiring the recruitment of thousands of patients that provide the basis for making the link between genetic and cellular defects and clinical disease presentation and demographic characteristics. Currently, LRRI is conducting population-based genetic studies in:

—Chronic obstructive pulmonary diseases (COPD),
—Early detectors for lung cancer,
—Pulmonary fibrosis, and
—Mechanisms of asthma and other lung diseases in Hispanic and Native American children

Two events have greatly enhanced the ability to better understand the mechanisms of human disease in communities. One is the dramatic advance in molecular and cellular biology over the last 10 years, especially in human genetics. The other is the ability to collect and process data using advance computer systems and statistical techniques. This process called "molecular epidemiology" makes the link between genetic and cellular defects and clinical disease. LRRI has formed collaborations with national and local a private health providers to collect and manage patient data to carry out their "molecular epidemiological" studies. These partners include, the:

—Lovelace Health Systems (LHS),
—Albuquerque Veterans Administration Medical Center (VA),
—University of New Mexico School of Medicine (UNM), and the
—University of Miami School of Medicine (UMSM).

Given the nature of the clinical studies performed, LRRI's facility requires security mechanisms well beyond those of ordinary medical clinics. As one can well imagine, this facility is the repository of very sensitive personal data, including that linked to an individual's DNA. To carry out this responsibility for privacy and confidentiality, there is a need to renovate the facilities and equipment necessary to be physically and electronically impenetrable to all but those who have specific and authorized access.

The existing 8,000 sq. ft. facility was constructed in the 1950's and requires renovation and upgrades to provide a suitable, efficient, functional and secure facility. The proposed project would require reconfigured space, upgrades to meet current fire and safety codes, new interior finishes, new plumbing, upgraded electrical and a new heating, ventilation and air conditioning system.

The current clinical trials facility is occupied in part by other LRRI functions. Some of these functions will need to be relocated to provide the required additional space for the clinical studies. Unfinished space is being made available in the new research facility included as part of the $10 million LRRI campaign. The proposed project will include the completion of 8,000 square feet of the unfinished space for this purpose.

Accordingly, to meet this responsibility and to improve LRRI's ability to conduct its clinical studies, we respectfully request $2 million. The responsible Federal agency is the Health Resources and Services Administration (HRSA).

PREPARED STATEMENT OF THE LYMPHOMA RESEARCH FOUNDATION OF AMERICA, INC.

Chairman Specter, Ranking Member Harkin and esteemed members of the Subcommittee, thank you for this opportunity to present written testimony before you on behalf of the over 600,000 Americans living with lymphoma and on behalf of the Lymphoma Research Foundation of America (LRFA). LRFA is the foremost national nonprofit organization dedicated to funding lymphoma research and providing information, education and support to lymphoma patients and their loved ones.

The organization was founded in 1991 by Ellen Glesby Cohen, whose own experience battling non-Hodgkin's lymphoma led her to fully appreciate the pressing need for better, safer cancer treatments. To date, LRFA has awarded $3 million in support of 93 lymphoma research projects. Tragically, Ms. Cohen's battle with lymphoma ended in August of last year.

Lymphoma is a cancer that originates in and affects the body's immune system. Lymphoma occurs when cells that normally fight infection abnormally multiply and form tumors. Lymphoma strikes men, women and children of all ages, races and socio-economic backgrounds.

Three years ago, after a routine physical, my doctor told me that he was concerned about my white blood cell count. It had been high for a while, and he feared that I might have a form of cancer called Chronic Lymphocytic Leukemia (CLL). He calmed me by saying that people sometimes lived up to ten years with CLL without treatment, and referred me to an oncologist at Mayo Clinic for further evaluation.

After several days of testing at Mayo, the oncologist told me that I had a disease called Mantle Cell Lymphoma not CLL. I remember vividly that he could not look me in the eye when he told me there were no known effective treatments for it. I asked him how long I had to live. He said that I was in the last stage of the disease, that lymphoma was in every organ of my body, and I could have as little as six to 18 months to live.

Stunned, my wife and I felt lost. We knew nothing about lymphoma. That evening we walked to a bookstore and started to read. We learned that lymphoma is a cancer of the lymphatic system, a part of our immune system, and that there are two main types of lymphoma, Hodgkin's lymphoma, also known as Hodgkin's Disease, and non-Hodgkin's lymphoma (NHL). We learned that about 80 percent of people diagnosed with Hodgkin's disease, with treatment, survive for at least five years.

The prognosis is quite varied for non-Hodgkin's lymphomas, the category I am in, for NHL is a more complex group of cancers. There are more than 30 subtypes of non-Hodgkin's lymphoma that range from slow growing, or indolent, to highly aggressive. Some non-Hodgkin's lymphomas are considered curable. The majority are not curable, but are treatable. With mine, we discovered that statistically, whether you treat it or not, you live the same amount of time. In the complexity that I have described lays our challenge. No one knows what causes lymphoma.

According to "Cancer Facts & Figures" published by the American Cancer Society (ACS), the number of newly diagnosed cases of lymphoid malignancies in 2001 is estimated to be 89,600 with a 50 percent average mortality rate for all lymphomas. The ACS also reports that the diagnostic incidence of non-Hodgkin's lymphoma has risen a dramatic 80 percent over the last 20 years, making it the second most rapidly rising cancer by rate of incidence in the United States. Furthermore, lymphoma is the second leading cause of cancer-related deaths. An astonishing 60 percent of all childhood malignancies are lymphomas, or their cousin, leukemia. According to the National Cancer Institute (NCI), lymphoma represents the third most frequent type of cancer in the under 20-age group. Within these statistics, Mr. Chairman, is an urgent human cry for leadership and focus.

Since receiving my diagnosis three years ago, I have been struck by the almost academic pace of lymphoma research. The scientists and researchers involved in developing diagnostic and treatment approaches have excellent skills. The federal budget for cancer research has been increasing, but progress has been too slow, and there is a notable lack of urgency. To address this situation, Mr. Chairman, the Lymphoma Research Foundation of America supports the campaign of doubling the budget of the National Institutes of Health (NIH) by the year 2003.

The National Cancer Institute (NCI) is in the process of completing a Progress Review Group, or PRG, on lymphoma, leukemia, and myeloma. One purpose of the PRG is to identify the overlaps in research and where gaps exist. As a participant in the PRG Roundtable meeting consisting of scientists, clinicians, industry, patient advocates and federal agencies, it was obvious that cross-disciplinary and multi-institutional research collaboration is needed. This would enable researchers to better communicate research results and to share resources, reagents, and patients. Ultimately, it would result in quickening the pace of the research itself. The PRG report produced by this process is designed to create a national prioritized research agenda for lymphoma and other hematological cancers. But we believe that the recommendations alone will not bring about needed change rapidly enough. Therefore, we request that a budget plan accompany the report.

In addition, because of the link between lymphoma and environmental, bacterial, and viral factors, we request the National Institute on Environmental Health Sciences (NIEHS) to report to Congress on the current state of its research portfolio on lymphoma and hematological cancers. For fiscal year 2002, we request the Centers for Disease Control and Prevention (CDC) to expand its support in investigating the possible environmental causes of lymphoma and increase its data collection on lymphoma to provide accurate statistics on the disease. Both NIEHS and CDC must also be encouraged to collaborate with NCI and the NIH to avoid overlap in their research.

Lymphoma is one of the most difficult cancers to diagnose. Indeed, too many people are already in advanced stages of the disease when they receive a diagnosis. Many people are also misdiagnosed, like I was, as to the type of lymphoma they have. As a result of the highly complex nature of the disease and the many different types of lymphoma, we request an outreach campaign by the CDC to educate clinicians and the general public on the symptoms associated with lymphoma and methods to better diagnose this complicated cancer. As you are well aware, early detection and early treatment of cancer increase one's chance of survival.

I do not believe that the situation for those of us living with lymphoma has to be bleak. As evidenced by exciting discoveries resulting from the human genome

project, advances in science and technology have brought us to the brink of an explosion in our understanding of the basic science of human malignancies. We have also entered into one of the most exciting periods in lymphoma research as more targeted, nontoxic therapies that attempt to modify the immunologic and genetic abnormalities of lymphomas are developed, such as vaccines, antisense compounds and gene therapy. Newer technologies will eventually allow physicians to predict more reliably a patient's response to treatment and to customize treatment strategies.

I am a beneficiary of this progress. I am currently participating in a clinical trial at the NCI that involves treatment with a vaccine made from my own cancer cells. But I am one of only 20 participants, and even if successful, this treatment will take many, many years to reach the thousands who need it.

Many scientists believe that lymphoma, because of its cellular biology and metastatic presentation, is the perfect malignancy in which to explore new avenues of treatment. Exciting discoveries resulting from lymphoma research, such as monoclonal antibodies, have the potential to benefit many other cancers, including those of the breast, prostate, colon and lung. But the technologies and novel therapies I described above are still early in their development and have to surmount considerable obstacles before they become available to treat patients. There is still a critical need for more innovative research and collaborative efforts before our goal of more effective, safer treatments, and ultimately, cures for lymphoma and other cancers can be achieved. And that is why I am asking you today to continue to increase your support of lymphoma research and to further the extraordinary research opportunities and momentum created by this moment.

Lymphoma is the only cancer with an increasing mortality rate, in contrast to the decreasing mortality rates of many other cancers. I do not believe that we should consider this statistic as something beyond our control, and therefore, tragic but acceptable. In 1998, LRFA founder, Ellen Glesby Cohen, testified before this subcommittee. At that time, approximately 800 people per week died of lymphoma. This year, about 1,000 people per week will die. It is my hope that this subcommittee will provide the leadership and means to reverse these trends.

Thank you for the opportunity to present written testimony and share my story with you.

PREPARED STATEMENT OF THE MEDICARE PAYMENT ADVISORY COMMISSION

The Medicare Payment Advisory Commission (MedPAC) requests a budget appropriation of $8,250,000 for fiscal year 2002: the same amount as fiscal year 2001, plus $250,000 to cover the costs of an anticipated mandatory office relocation. This level of funding will enable the Commission to complete the range of reports assigned to it by the Congress under recent legislation, as well as to provide technical support on Medicare policies to congressional committees and staff. This testimony will discuss MedPAC's statutory mandate, our work in fulfillment of that mandate during fiscal years 2000 and 2001, the work we have planned in fiscal year 2002, and the resources we will need to pursue that work.

LEGISLATIVE MANDATE

The Congress established MedPAC in the Balance Budget Act of 1997 (BBA) as an independent legislative agency to provide analysis of and recommendations on policies affecting the Medicare program. The Commission consists of 17 Commissioners appointed to three-year terms by the Comptroller General. By law, Commissioners are appointed to represent diverse points of view, including those of health care providers, payers, consumers, and employers, and to bring expertise in health economics and biomedical and health services research. (See Table 1 for a listing of the Commission's members and their affiliations).

The Commission is assisted in its work by an executive director and professional research and administrative staff. Our professional staff have expertise in health economics, statistics, public policy, public health, hospital administration, medicine, and law. When specialized data or expertise are needed, the Commission also contracts with government agencies, trade associations, and private research firms.

Within its broad mandate, MedPAC is directed by law to consider specific issues relating to the Medicare program. We are charged with considering:

—Medicare payment, risk adjustment, risk selection, quality of care, access to care, and other major issues relating to the implementation and development of the Medicare + Choice program;

—methods to determine and update payments for different types of health services under the traditional fee-for-service Medicare program;

—the impact of payment policies on access to and quality of care for beneficiaries in the traditional program;
—the effect of Medicare payment policies on the broader health care system; and
—the effect of developments outside the program on Medicare.

The law directs the Commission to make recommendations to the Congress on Medicare's payment policies by March 1 of each year. MedPAC also must submit a report to the Congress addressing other issues relating to the Medicare program by June 15 of each year. In addition, the Commission is required to comment on reports submitted by the Secretary of Health and Human Services to the Congress. Finally, MedPAC must submit additional reports on specific topics of interest at the direction of the Congress. Eighteen reports were assigned to the Commission under the Balanced Budget Refinement Act of 1999 (BBRA), and an additional 11 under the Medicare, Medicaid, and the SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).

The Commission meets about eight times a year to review analyses presented by staff and to develop and discuss its recommendations. These meetings are open to the public, with time routinely provided for public comment.

ACCOMPLISHMENTS DURING FISCAL YEARS 2000 AND 2001

MedPAC fulfills its mandate to assist the Congress in improving Medicare policy in a number of ways:
—reports to the Congress required by our authorizing legislation or by other laws,
—formal testimony before the authorizing Committees of the House and the Senate,
—formal comments to the Secretary of Health and Human Services on proposed regulations, and
—technical analyses and briefings by Commission staff for congressional staff.

Statutorily required reports

The Commission submitted its March 2001 report to the Congress on time. This report contained the Commission's recommendations concerning Medicare payment policy issues and presented supporting analyses and reasoning behind the Commission's views. The report addressed the following areas:
—evaluating Medicare's payment policies,
—updating payments for physician services and for care provided in hospital outpatient departments,
—accounting for new technology in hospital prospective payment systems (PPS),
—developing input-price indexes for all health care settings,
—financial performance and inpatient payment issues for PPS hospitals,
—prospective payment for post-acute care,
—reconciling Medicare + Choice payments and fee-for-service spending,
—end-stage renal disease payment policies in traditional Medicare,
—reducing beneficiary coinsurance under the hospital outpatient prospective payment system, and
—treatment of the initial residency period in Medicare's direct graduate medical education payments.

The Commission will submit its second mandated report for the year on June 15, 2001. This report focuses on the Commission's examination of issues affecting the Medicare program in rural areas. The June report will include the following topics:
—overview of rural markets and Medicare,
—rural beneficiaries' access to care,
—prospective payment for hospitals in rural areas,
—home health payment issues,
—prospective payment systems for outpatient hospital services,
—Medicare + Choice in rural areas, and
—quality of care issues for rural beneficiaries.

This report will address several issues MedPAC was directed to study under the BBRA, including:
—the appropriateness of prospective payment for home health agencies in rural areas,
—the adequacy of Medicare's payment provisions for rural providers,
—the appropriateness of prospective payment for rural psychiatric hospitals, and
—the appropriateness of applying the prospective payment system for hospital outpatient departments to certain rural hospitals.

The June report will also include MedPAC's review of the sustainable growth rate and conversion factor for physician services, as required by the Congress.

The BBRA required that MedPAC review several policies in Medicare + Choice and on Medicare payment for post-surgical recovery care centers. In November

2000, MedPAC fulfilled these requirements by submitting three reports to the Congress: "Medical Savings Accounts and the Medicare Program, Improving Risk-adjustment in Medicare, and Medicare Payment for Post-surgical Recovery Care Centers." In May 2001, the Commission will submit reports as required under the BBRA on Medicare payment for clinical training of non-physician health professionals in hospitals and on payment for skilled nursing facilities in Alaska and Hawaii.

During the next fiscal year, Commission staff will continue to prepare and distribute other reports containing information from its analyses and research requested by the Congress or initiated on its own. Some of these reports will result from analyses undertaken by the Commission staff; others will contain findings from research and analyses conducted under external research contracts.

Testimony

During fiscal years 2000 and 2001, the chair of the Commission testified before the House Committee on Ways and Means, Subcommittee on Health and the House Committee on Commerce. Her testimony before the Ways and Means Subcommittee focused on the impact of the BBA on patients, providers and Medicare + Choice plans and her testimony before the Commerce Committee addressed the impact of the BBA on patients and providers. During this period, the executive director testified before the House Committee on Commerce and the Senate Committee on Finance. The executive director's testimony before the Commerce Committee addressed accounting for new technology in the hospital prospective payment system. Before the Finance Committee he addressed issues surrounding the Medicare + Choice program.

In addition, the Commission expects to provide further testimony on subjects related to its expertise during fiscal year 2002. Members of the Commission and staff will continue to provide briefings, technical advice, and other support to members of the Congress and their staff. The Commission also works with the Health Care Financing Administration (HCFA) and a number of private sector groups concerning Medicare payment for facility and physician's services and Medicare + Choice, as well as broader changes in health care financing and delivery.

Comments on proposed regulations

Since enactment of the BBA, the Commission has closely monitored implementation of the law by the Secretary and has commented on proposed rules and interim final regulations. Although MedPAC is not required by law to comment on proposed regulations, we do so in cases where we feel that the Congress benefits from having an independent assessment. Further, making comments as the regulations are developed provides the Congress (and the Secretary) with more timely advice than we can provide in our March or June reports. In fiscal year 2000, MedPAC submitted formal comments on the Secretary's proposal for the prospective payment system for home health services.

FUTURE WORK

Our priorities for the upcoming fiscal year include working on our two mandated reports, focusing on access and quality of care, continuing our work on Medicare in rural areas, and examining the regulatory complexity of the Medicare program. We also will continue to monitor the impact of changes in payment for ambulatory care services including hospital outpatient department and physicians, evaluate payment policies for post-acute care, and examine issues in Medicare + Choice.

Other topics the Commission will pursue were defined by the Congress under the BBRA and the BIPA. These include payments to Medicare + Choice plans, appropriate quality standards, skilled nursing facility payment, use of and payment for physician services, examining the use of consumer coalitions in marketing of Medicare + Choice plans, access to and use of the hospice benefit, Medicare coverage of services provided by certain allied health providers, the shortage of geriatricians, and the implications of the hospital-specific cap on residents in Medicare's graduate medical education payments. The Commission further anticipates that the Congress will continue to seek its advice and analytic help in monitoring implementation of the Medicare provisions of the BBA, the BBRA, and the BIPA, and the Congress continues work on legislation affecting the Medicare program.

MedPAC's staff is beginning to develop research projects on these and other topics. Commissioners will meet in July to discuss which projects should be given emphasis and we will discuss our analytic agenda at our public meetings.

APPROPRIATIONS REQUEST

As noted above, MedPAC is requesting $8,250,000 for fiscal year 2002, the same amount as fiscal year 2001, plus $250,000 to cover the costs of an anticipated mandatory office relocation. We propose to allocate a large portion of the requested funds to external research contracts to support the numerous reports request by the Congress (see Table 2).

We also plan to target funding towards salaries and benefits in an effort to achieve the staff size needed to fulfill our responsibilities and to provide the maximum support to Congress. Although, the Commission continued to experience staff turnover during fiscal year 2001 through aggressive recruiting we have attracted several highly qualified individuals. Despite a tight labor market for health policy analysts—particularly senior people with extensive knowledge of the Medicare program—we hope to be fully staffed at the beginning of fiscal 2002 to allow us to fully respond to the many responsibilities given to us by the Congress.

TABLE 1.—MEMBERS OF THE MEDICARE PAYMENT ADVISORY COMMISSION AND THEIR AFFILIATIONS

Member	Affiliation
Gail R. Wilensky, Ph.D., Chair, Bethesda, MD	Project HOPE, Center for Health Affairs
Joseph P. Newhouse, Ph.D., Vice Chair, Boston, MA	Harvard University
Beatrice Braun, M.D., Spring Hill, FL	American Association of Retired Persons
Autry O.V. ''Pete'' DeBusk, Powell, TN	DeRoyal
Glenn M. Hackbarth, J.D., Bend, OR	Independent consultant
Spencer Johnson, Lansing, MI	Michigan Health and Hospital Association
Floyd D. Loop, M.D., Cleveland, OH	The Cleveland Clinic Foundation
Alan R. Nelson, M.D., Washington, DC	American College of Physicians—American Society of Internal Medicine
Janet G. Newport, Santa Ana, CA	PacifiCare Health Systems
Carol Raphael, New York, NY	Visiting Nurse Service of New York
Robert D. Reischauer, Ph.D., Washington, DC	The Urban Institute
Alice Rosenblatt, F.S.A., M.A.A.A., Thousand Oaks, CA	Wellpoint Health Networks
John W. Rowe, M.D., Hartford, CT	Aetna US Healthcare
David A. Smith, Washington, DC	AFL–CIO
Ray E. Stowers, D.O., Tulsa, OK	Oklahoma State University—College of Osteopathic Medicine
Mary K. Wakefield, Ph.D., Fairfax, VA	George Mason University

TABLE 2.—BUDGET AUTHORITY, MEDICARE PAYMENT ADVISORY COMMISSION

[In thousands of dollars]

Object classification	Fiscal year		Change	Fiscal year 2002 request
	2002 actual	2001 plan		
Salaries:.				
Full-time staff	$2,439	$2,911	.....	$2,911
Commissioners	152	182	.....	182
Subtotal	2,591	3,093	.....	3,093
Benefits	631	760	.....	760
Travel:.				
Staff	37	31	.....	31
Commissioners	77	100	.....	100
Subtotal	109	131	.....	131

TABLE 2.—BUDGET AUTHORITY, MEDICARE PAYMENT ADVISORY COMMISSION—Continued

[In thousands of dollars]

Object classification	Fiscal year		Change	Fiscal year 2002 request
	2002 actual	2001 plan		
Standard level user charges	349	355	.....	355
Mainframe computer	941	755	.....	755
Telephone	56	50	.....	50
Postage	53	90	.....	90
Subtotal	1,050	895	.....	895
Printing and reproduction	160	250	−$32	218
Computer programming	870	900	.....	900
Research contracts	590	1,230	−30	1,200
Commercial contracts	222	230	+250	480
Government contracts	1	1	0	1
GSA support	60	66	+2	68
Subtotal	1,743	2,427	+222	2,649
Supplies	38	38	.....	38
Publications	34	33	.....	33
Subtotal	72	71	.....	71
Equipment and furnishings	23	18	+60	78
Lapsing	230	.....	.....	.....
Total	7,015	8,000	+250	8,250

Note.—Numbers may not add to totals because of rounding.

PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

INTRODUCTION

Mr. Chairman, thank you for the opportunity to submit testimony on behalf of the Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) regarding the fiscal year 2002 budget for the National Library of Medicine (NLM). I am Marianne Comegys, associate professor of medical library science at the Louisiana State University Health Sciences Library in Shreveport, La.

MLA is a professional organization, headquartered in Chicago, representing over 4,000 individuals and 1,200 institutions involved in the management and dissemination of biomedical information to support patient care, education and research. In 1998, the organization celebrated its 100th anniversary.

AAHSL, is comprised of the directors of libraries of 142 accredited United States and Canadian medical schools belonging to the Association of American Medical Colleges. Together, MLA and AAHSL address health information issues and legislative matters of importance to the medical library community through a joint legislative task force.

Mr. Chairman, the National Library of Medicine, on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The Library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences. The collections stand at 5.8 million items—books, journals, technical reports, manuscripts, microfilms, photographs and images. Housed within the Library is one of the world's finest medical history collections of old and rare med-

ical works. The Library's collection may be accessed in the reading room or requested on interlibrary loan. NLM is a national resource for all U.S. health science libraries through a National Network of Libraries of Medicine.

On behalf of the medical library community, I would like to thank the subcommittee for its leadership in securing a 15 percent increase for NLM in fiscal year 2001. With respect to the Library's budget for the coming fiscal year, I would like to touch briefly on four issues; (1) NLM's basic services, (2) NLM's outreach and telemedicine activities, (3) NLM's PubMed Central and clinical trials databases, (4) and NLM's facilities needs.

THE GROWING DEMAND FOR NLM SERVICES

Mr. Chairman, it is a tribute to NLM that the demand for its services continues to steadily increase each year. An average of 250 million Internet searches (30 percent from the general public) are performed annually on NLM's MEDLINE database, which provides access to the world's most up to date health care information. Moreover; medical libraries, academic health centers, hospitals, community health centers, veterans health care facilities, and private physicians rely heavily on NLM and its National Network of Libraries of Medicine to deliver quality health care everyday.

NLM also plays a critical role in maintaining the integrity of the world's largest collection of medical books and journals. Increasingly, this information is in digital form, and NLM, as a national library responsible for preserving the scholarly record of biomedicine, is developing a strategy for selecting, organizing, and ensuring permanent access to digital information. Regardless of the format in which the materials are received, ensuring their availability for future generations remains the highest priority of the Library.

Mr. Chairman, simply stated, NLM is a national treasure. I can tell you that without NLM our nation's medical libraries would be unable to provide the type of information services that our nation's health care providers, educators, researchers and patients have come to expect.

Recognizing the invaluable role that NLM plays in our health care delivery system, the Medical Library Association and the Association of Academic Health Sciences Libraries join with the Ad Hoc Group for Medical Research Funding in recommending a 16.5 percent increase for NLM and NIH overall in fiscal year 2002.

NLM'S OUTREACH AND TELEMEDICINE ACTIVITIES

Outreach and Education

NLM's outreach programs are of particular interest to both MLA and AAHSL. These activities, designed to educate medical librarians, health care professionals and the general public about NLM's services, are an essential part of the Library's mission.

The need for enhanced outreach activities has grown significantly in recent years following NLM's decision to make its MEDLINE database available for free over the World Wide Web. The Library has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. We were pleased that the Committee again last year recognized the need for NLM to coordinate its outreach activities with the medical library community.

Mr. Chairman, we applaud the success of NLM's outreach initiatives and look forward to continuing our work with the Library again in fiscal year 2002 on these important programs.

Telemedicine

Mr. Chairman, telemedicine continues to hold great promise for dramatically increasing the delivery of health care to underserved communities across the country and throughout the world. NLM has sponsored over 50 telemedicine related projects in recent years, including 21 multi-year projects located in various rural and urban medically underserved communities. These sites serve as models for:

—Evaluating the impact of telemedicine on cost, quality, and access to health care;

—Assessing various approaches to ensuring the confidentiality of health data transmitted via electronic networks;

—Testing emerging health data standards.

Mr. Chairman, it is clear that telemedicine will play a major role in the delivery of health care in the 21st Century. Medical librarians and health information specialists have an important role to play in supporting this revolutionary approach to

health care and we encourage Congress and NLM to continue their strong support of telemedicine in our nation's medically underserved areas.

PUBMED CENTRAL /CLINICAL TRIALS DATABASE

The medical library community applauds NLM for its leadership in establishing PubMed Central, an online repository for life science articles introduced in early 2000. PubMed Central evolved from an electronic publishing concept proposed by former NIH Director Dr. Harold Varmus. The site houses articles from the Proceedings of the National Academy of Sciences, the American Society for Cell Biology's journal Molecular Biology of the Cell, and other publications.

This new online resource will significantly increase access to biomedical information by health care professionals, students, researchers and the general public. The medical library community believes that health sciences librarians have a key role to play in the further development of PubMed Central. Because of the high level of expertise health information specialists have in the organization, collection, and dissemination of medical literature, we believe our community can assist NLM in issues related to copyright, fair use, and information classification on the PubMed Central site. We look forward to collaborating with the Library as this exciting new project continues to unfold this year.

Mr. Chairman, I also want to comment on another relatively new service offered by NLM—its clinical trails database (Clinicaltrials.gov). This listing of some 5,200 federal and privately funded trials for serious or life-threatening diseases was launched in February of 2000. This free service is currently logging more than 2 million page hits a month and is an invaluable resource to patients and families interested in participating in cutting edge treatments for serious illnesses. The medical library community congratulates NLM for its leadership in creating

ClinicalTrials.gov and looks forward to assisting the Library in anyway possible to advance this important initiative. This database is a nice compliment to NLM's extremely successful consumer web-site MEDLINEplus, which now covers over 450 health topics.

NLM'S FACILITIES NEEDS

Mr. Chairman, over the past two decades NLM has assumed several major new responsibilities particularly in the areas of biotechnology, health services research, high performance computing, and consumer health. As a result, the Library has had tremendous growth in its basic functions related to the acquisition, organization, and preservation of an ever-expanding body of biomedical literature.

This increase in the volume of biomedical information as well as Library personnel (NLM currently houses over 1,100 people in building built to accommodate 650) has resulted in a serious shortage of space at the Library. In addition, the National Center for Biotechnology Information at NLM builds sophisticated data management tools for processing and analyzing enormous amounts of genetic information critical to advancing the Human Genome Project.

In order for NLM to continue its mission as the world's premier biomedical library, a new facility is urgently needed. The NLM Board of Regents has assigned the highest priority to supporting the acquisition of a new facility. The medical library community is pleased that Congress last year appropriated the necessary architectural and engineering funds for facility expansion at NLM. We encourage the subcommittee to continue to provide the resources necessary to acquire a new facility and to support the Library's health information programs.

Mr. Chairman, thank you once again for the opportunity to present the views of the medical library community.

PREPARED STATEMENT OF THE MENDED HEARTS, INC.

I am Robert H. Gelenter, the legal representative for the Mended Hearts Inc, a national heart disease patient support group of 25,000 members across the country. We visit patients in about 450 hospitals throughout the United States. I have been appointed by the group to assist in this lobbying effort—a volunteer position.

More than 25 years ago, I was diagnosed with a rare heart disease. After having severe chest pains and trouble breathing for more than two years, I was diagnosed with hypertrophic cardiomyopathy, a disease in which the heart enlarges. The heart muscle eventually thickens so much that it can't pump blood effectively and does not grow in the normal parallel patterns. More than 35 percent of young athletes who die suddenly die from this disease. But, it affects men and women of all ages. It is sudden and one of the things known about this disease is sudden cardiac death.

There is no cure for this disease. Medication may work and there is surgery that may or may not alleviate the pain. If that doesn't work a patient may need a heart transplant, yet spare organs are scarce. The doctor who made my diagnosis was trained at the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Initially, I received several medications which allowed me to engage in most activities. But, some activities, such as walking up hills, gave me problems like shortness of breath and severe chest pains. But, generally I could function normally. However, after about 10 years, the discomfort was increasing, and it became apparent that I was in serious trouble. I could not walk sixty feet without having to stop to catch my breath. Sometimes the pain was so great that I would almost double over in the middle of the street. My wife told me that my face would become gray. The perspiration would pour off by body. If I was lucky I could find a chair to sit on. The quality of my life had deteriorated so drastically that I knew I needed some treatment.

Finally in 1988, I went to Georgetown University Medical Center for an angiogram—the gold standard for diagnosing heart problems. The cardiologist who performed the angiogram told me that he had bad news and worse news. The bad news was that I had a 95 percent blockage in my left anterior descending heart artery—the so-called "widow makers spot." The worse news was that I had a major chance of having a major heart attack with a less than a 5 percent chance of surviving that heart attack because of the hypertrophic cardiomyopathy. At this point, my wife was quietly crying and I was perspiring profusely. Since Georgetown University Medical Center did not have the expertise to operate on me, they called the NIH to see if they would accept me as a patient. I was sent home pending notice from the NIH.

My parents begged me to go to New York or San Francisco for second opinions. But, I knew that I had run out of alternatives. No matter what the result, I needed treatment and I needed it immediately.

I was accepted by the NIH. After entering the National Heart, Lung, and Blood Institute on February 6th, I was operated on February 11th, 1988. No matter how trite the expression—that was the first day of the rest of my life. The surgery, considered drastic and rare, is still considered the gold standard throughout the world for the treatment of hypertrophic cardiomyopathy. The Murrow Procedure, in honor of the creator, was developed and improved at the NIH.

Although this surgery is no longer performed at the National Heart, Lung, and Blood Institute, there is another experimental ongoing protocol in which the same effect is being attempted by using alcohol to deaden the excessive heart tissue.

Now, I am on medication for the rest of my life. My condition is progressive. Five years ago, I was fitted with a pacemaker to insure that my heart beats at the correct rate. I am 100 percent dependent on this pacemaker. Without the pacemaker, there are times when my normal heart beat is so slow that I would die.

I am eternally grateful to the physicians funded by the National Heart, Lung, and Blood Institute, particularly to Dr. MacIntosh and his staff, for the gift of life. Because of this marvelous research supported by the NHLBI, I have lived 13 years pain free. I have seen two children graduate from college and three grandchildren born, I have shared these years with a wonderful wife. I have been able to work at my profession—an attorney at law.

I have had the gift of life restored to me. So to express my gratitude for that gift, I visit patients recovering from heart episodes at two hospitals, Washington Hospital Center and Washington Adventist Hospital.

I ask for a doubling of the fiscal year 1998 National Heart, Lung, and Blood Institute budget by fiscal year 2003. As the fourth increment toward reaching that goal, I advocate a fiscal year 2002 appropriation of $2.679 billion for the NHLBI, including $1.650 billion for its heart disease and stroke-related budget.

My experience is the proof that the research supported by the Institute benefits not just the patients at the NIH Clinical Center, but throughout the United States. The benefits go worldwide as well.

Heart attack, stroke and other cardiovascular diseases remain the No. 1 killer and major cause of disability of men and women in the United States. Nearly 41 percent of people who die in the United States die from cardiovascular diseases. This year, nearly 950,000 Americans will die from cardiovascular diseases, including more than 150,000 under the age of 65.

PREPARED STATEMENT OF MIAMI CHILDREN'S HOSPITAL

In recognition of the indispensable role that independent children's hospitals, like Miami Children's Hospital, play in children's health, I urge you to continue the commitment to the Children's Hospital Graduate Medical Education ("GME") program by calling for and supporting full funding this year.

As President and Chief Executive Officer of Miami Children's Hospital, I am very concerned about the cut in funding the Administration is proposing for the GME program this year. The Children's Hospital Graduate Medical Education program provides funding to about 60 independent children's hospitals that were left out of a GME financing system that depends on Medicare. Children's hospitals do not qualify for Medicare GME support which leaves a gap of $285 million annually. As you know, Congress passed legislation in 1999 to address this inequity. The $235 million authorized last year takes a big step in the right direction to reaching the $285 million goal. Achieving an appropriation of $285 million this fiscal year will make an essential investment in the children's hospitals' missions as centers of education and research, and regional centers of excellence.

Instead of moving towards that goal, the Administration has announced that the President's budget will propose a 15 percent cut, an equivalent of $35 million, for GME payments to children's hospitals. Independent children's hospitals make up only one percent of all hospitals, train thirty percent of pediatricians, fifty percent of specialists, and a larger portion of pediatric researchers. Despite these significant contributions, the survival of these institutions is contingent upon reaching the $285 million goal and thus closing the gap.

I look forward to your continued support for GME funding.

Miami Children's Hospital (MCH) hereby submits for the record, testimony regarding the need to develop a significant Ambulatory Care Center at Miami Children's Hospital.

Miami Children's Hospital is a private, non-profit entity that offers a full range of services from birth to age 21 with primary care pediatrics as the cornerstone. Also, MCH is the largest provider of Pediatric Orthopedics in Miami Dade County. By percentage of net revenue, Miami Children's Hospital is the largest Medicaid provider for children in the state of Florida. The services include preventive medicine, the only children's hospital in Florida with such a department, and the most sophisticated medical and surgical tertiary care.

Miami Children's Hospital is South Florida's only independent, free-standing licensed specialty hospital exclusively for children. Our mission to provide excellent family centered health care has helped us pave the way to our continuing success. Some of the success along our path include: being the only children's hospital in Florida to successfully separate conjoined twins; it is the leading child neurological facility in the region. Furthermore, MCH houses the only pediatric cardiac intensive care unit in the Southeastern United States. It is one of only 10 centers nationwide selected to participate in the clinical trial of CardioSEAL, a revolutionary closure device to be used in treating children with atrial septal defects. It was successfully completed in its first clinical trial.

The Hospital is also very pleased to have been ranked first in Florida, second in Southeast and tied 14th in the country as top hospital by Child Magazine. This recognition highlights our dedication to pediatric excellence and focuses on the outstanding work taking place in South Florida. For example, MCH is the first hospital in the state of Florida to have pediatric Extra Corporeal Membrane Oxygenation (ECMO) available. This procedure allows children born with certain system failures, such as renal or cardio-pulmonary, to have an effective oxygenation of blood while recovering. In addition, Miami Children's Hospital has been the first in the United States and in the international arena in spearheading many procedures. For instance, it was the first in the United States to perform a tracheal transplant. It was first in the Southeastern United States to perform a tracheal transplant. It was first in the Southeastern United States in performing reconstructive surgery for brachial plexus injuries as well as in repairing Pectus Excavatus (sunken chest). MCH also performed the world's first extracardiac Fontan operation that did not require cardiopulmonary bypass, i.e., the need of heart lung machine, and the world's first endoscopic ventricular thrombectomy, i.e., removal of cardiac clot without surgery. It also led the world's first conference on minimally invasive surgery for congenital heart disease and hosted the first Youth Leadership Conference on Health. MCH is also credited with developing the first international medical teleconference in pediatrics. It was first in the United States and the Americas to use the Helex Septal Occluder to treat atrial septal device (ASD), a common heart defect.

Miami Children's Hospital is dedicated to the development of technology that will be less invasive to children. Always at the forefront of cutting-edge technology, most

recently, MCH created a pediatric brain tumor center. The cornerstone of the new center will be a powerful new tool for treating brain cancer: an interoperative magnetic resonance imaging (MRI) unit that can be rolled into the operating room to provide surgeons with real-time scans of the child's brain. The resulting accuracy will bring new levels of confidence to parents and doctors that all of the tumor has been removed.

The demand for pediatric care services has grown enormously, especially in Miami Dade County, since MCH is the only hospital exclusively for children in the region and indeed in South Florida. To meet these growing needs, we are presently engaged in the construction of a new Ambulatory Care Center that will serve to meet the needs of a growing population of our patients. The three story Ambulatory Care Building would provide patient services for the following pediatric specialties: Orthopedics, Rheumatology, Urology, Nephrology, Urodynamic Laboratory, Enuresis Center, Dermatology, Neurosciences, Behavioral Health, and Pediatric Dentistry. Our goal to meet the growing demand for children's services helped create the Miami Children's Hospital Dan Marino Center in South Florida. An extension of MCH, it is an integrated neuro developmental center specializing in the diagnosis and treatment of children at risk for developmental and psychological problems.

Even with such innovative technologies and procedures, MCH still finds itself unable to meet the growing needs of children. Miami Children's Hospital treats more than 185,000 children each year. The Hospital is faced with severe waiting list challenges, for certain services (i.e. child neurological services) the wait can be up to six weeks or more. The Hospital has for two decades made investments through its own services, as well as through community-based contributions.

A major component of Miami Children's Hospital is its mission and commitment to early intervention and preventive medicine. Miami Children's Hospital's mission is on track to become a leading pediatric preventive medicine institute in the United States. For example, Miami Children's Hospital has established mobile pediatric health vans called the "Health-on-Wheels" program to reach underserved and disadvantaged areas. Since September 1995, two 40-foot, mobile Health-on-Wheels vehicles carrying state-of-the-art medical and dental facilities, in the hands of board-certified pediatricians, pediatric nurse practitioners, nurse assistants and paramedics, have served over 22,000 children in Dade and Monroe counties. As of 1998, the Program has administered 13,510 immunizations, 4,129 tuberculosis screens and 8,721 hearing and vision tests. Of the 14,000 children evaluated, 11 percent were diagnosed with an acute medical condition.

The Hospital has a state-of-the-art critical care transport service for patients in need of specialty care using ground ambulance, helicopter or fixed-wing aircraft called "LifeFlight". The helicopter is one-of-a-kind in that it can transport two patients, travel up to a 200 mile radius and is configured with state-of-the art medical technology. LifeFlight is used in conjunction with other transportation to bring patients from Florida, as well as world-wide to the Hospital.

Miami Children's Hospital has excellent clinical services, medical research and a comprehensive teaching program for doctors, nurses and medical specialists. The Hospital has eliminated the need to send Florida's children elsewhere to get the medical attention they so desperately need. Additionally, Miami Children's Hospital offers array of services that draw children world-wide to the Hospital. Programs that have been established at Miami Children's Hospital can be used in other parts of the United States.

Moreover, area hospitals are sending their patients to Miami Children's Hospital because of its focus on early intervention and treatment, especially given their specialization in developmental disabilities, as well as the use of the Hospital's expansive imaging equipment. There is no need to send Florida's children elsewhere to get the medical attention they so desperately need.

As you know, funding to improve health care services and access to health care facilities for children has been a priority for Congress. Therefore, we would appreciate any assistance you may be able to render to ensure that children in need of special care receive the quality care they deserve, by including $4 million for the Miami Children's Hospital Ambulatory Care Center in the fiscal year 2002 Labor, Health and Human Services, and Education Appropriations Bill.

The estimated cost of construction for the entire Ambulatory Care Center is $13.2 million. We are requesting that approximately $4 million dollars of this cost be funded by the federal government, possibly through the Health Resources and Services Administration's Facilities account. The balance of the funding for the project will be supported as follows: one-third through philanthropic contributions via the Miami Children's Hospital Foundation and one-third through operating money generated by the hospital.

Miami Children's Hospital wishes to express its deep appreciation to this Committee for permitting us to submit this presentation on Miami Children's Hospital's Ambulatory Care Center. Your positive response for Miami Children's Hospital's request for support will have a positive impact on the health and well-being of our children in need.

Thank you.

PREPARED STATEMENT OF THE MISSISSIPPI DEPARTMENT OF REHABILITATION SERVICES

Thank you for the opportunity to present testimony for the record on an issue vital to Americans with disabilities—the need for adequate funding for every state's vocational rehabilitation program.

Established in 1920, the Public Vocational Rehabilitation Program (VR) is the cornerstone of our nation's commitment to people with disabilities toward becoming economically independent. Last year, the vocational rehabilitation program assisted 235,000 Americans with disabilities to go to work. The combined income of these 235,000 individuals during their first year of employment was a staggering $3.1 billion. Vocational Rehabilitation works!

However, the current federal funding formula threatens to slam shut the door of opportunity for a vast number of these citizens. While a mandatory cost-of-living adjustment applies to the entire program, a different formula prescribed in the Rehabilitation Act (as amended by the Workforce Investment Act of 1998) applies to how funds are allocated to the states. For example, while the national program has received annual two to three percent cost-of-living (COLA) increases from Congress during the past eight years, many states have gotten less than the COLA during each of those years. Specifically, in Federal fiscal year 2000, 22 states (including Mississippi) received less than the 1.24 percent COLA increase, and six actually received fewer dollars during Federal fiscal year 2000 than in Federal fiscal year 1999. A majority of states—29 in all—received less than the Federal fiscal year 2001 COLA of 2.6 percent provided in the Congressional appropriation. Unless the formula is fixed, more will follow.

Compounding this problem is the fiscal pressure exerted on the vocational rehabilitation program. For example:

—The success of the Individuals with Disabilities Education Act (IDEA) means that more young adults than ever before are entering the vocational rehabilitation program for post-secondary training leading to employment.

—Post-secondary tuition has skyrocketed to 200–300 percent above any COLA increase.

—Medical costs are inflating at an alarming rate and will continue to do so.

—The use of assistive technology (such as computerized wheelchairs) in the rehabilitation of Americans with disabilities involves significant expense.

—Because of Welfare-to-Work, the Ticket to Work/Workforce Incentives Improvement Act and the Workforce Investment Act, a large pool of previously unemployed adults is now entering the workforce.

Americans with disabilities have high expectations for the future. They're becoming better educated and eagerly expect to work in competitive, skilled jobs. As a nation, we have an obligation to ensure that every citizen is able to attain the dignity that comes with employment and self-reliance.

With the projected Consumer Price Index (CPI) for Federal fiscal year 2002 at 3.4 percent, and without some language to hold states harmless from the application formula, more than 20 states will fall short of this CPI and thousands of Americans with disabilities won't receive the services they need to go to work.

It was never the intent of Congress that any state should receive less than a COLA increase. On behalf of Americans with disabilities, I respectfully request that:

—the attached "Amendment for Appropriations for Vocational Rehabilitation" language be adopted;

—every state receive "hold harmless" protection at the actual percentage of the cost-of-living increase so that no state loses federal dollars, as happened during fiscal year 2000;

—an additional appropriation of $19.1 million be made to the vocational rehabilitation program to remedy the COLA problem; and

—each state receive a 5 percent increase in new federal funds (above the COLA) to meet the increasing demands upon its vocational rehabilitation program.

The very future of Americans with disabilities is at stake. Thank you for this opportunity to express my concerns and solutions.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE TO END HOMELESSNESS

The National Alliance to End Homelessness is a national membership organization with nearly 2,000 members around the country. Most are local nonprofit community-based and faith-based organizations that are doing the hands-on work to end homelessness for families and individuals. As our name implies, our primary focus is ending homelessness, not simply making it easier to manage. There is nothing inevitable about homelessness in the United States. We know more about homelessness and how to address it than we ever have before. We know what program models are effective for what kinds of people. It remains only to bring these solutions to a scale commensurate with the problem, and to focus them on bringing homelessness to an end.

It is our contention that an end to homelessness is a goal that we can achieve by the end of the decade. To do so we need to pursue four lines of attack simultaneously. We must:

—Plan for outcomes
—Close the front door in to homelessness
—Open the back door out of homelessness and in to housing
—Build the infrastructure.

PLANNING FOR OUTCOMES

We have an extensive system for dealing with homelessness. Too often, however, this system focuses only on managing the problem and not on a permanent solution. To change this focus we need to be sure we have accurate information on who homeless people are, how they become homeless, and what works to allow them to secure and stay in housing. Most homeless people have some contact with mainstream social services programs; indeed, a 1996 study funded by the Interagency Council on the Homeless found that 62 percent of currently homeless people in families, and 22 percent of those single, were receiving some type of income-based government assistance.

Recommendation: Encourage all programs to collect information about housing status among those the program serves.—Over the past few years this subcommittee has encouraged agencies that oversee large "mainstream" (i.e. not homeless-targeted) programs to pay attention to the amount of homelessness among the populations they serve. This has led to important work by the agencies involved, to examine ways to make these programs more conscious of housing stability as an end to be achieved. More remains to be done, and the subcommittee should continue its diligence in this regard. State agencies administering TANF, and recipients of substance abuse and mental health block grants should, at a minimum, be required to monitor and report on clients' housing status, as the success of their programs depends greatly on housing stability.

Recommendation: Encourage TANF, Foster Care and Substance Abuse and Mental Health block grant reporting agencies to include a description of preventing and ending homelessness in their annual State plans.—Many homeless people come from these systems of care. The homeless assistance system, while it provides temporary housing services for people while they are homeless, can not stop the flow of people entering its doors. Rather, the mainstream programs should be aware of the integral role they play in preventing and ending homelessness.

Recommendation: Require recipients of PATH, GBHI, and Healthcare for the Homeless program funds to implement and participate in homeless management information systems.—Many communities are implementing "homeless management information systems", and some have integrated data collection across systems of service (i.e. shelters, criminal justice, psychiatric facilities). Recipients of HUD targeted homeless funds are required to collect data on homelessness in order to prevent duplicate counting of homeless persons, and to analyze their patterns of use of assistance. PATH, GBHI and Healthcare for the Homeless grantees should also be collecting the data necessary to properly serve the homeless population, and therefore more effectively expend limited resources.

CLOSING THE FRONT DOOR IN TO HOMELESSNESS

We need to hold government-funded systems accountable for, at the very least, ensuring that the Americans they serve do not become homeless. We must treat homelessness among people with mental illness as sign that the mental health system needs improvement; homelessness among former foster children as a similar sign for the child protection system; homelessness among people with addiction disorders for the substance abuse treatment system.

Recommendation: No tolerance for discharge into homelessness from residentially-based programs in HHS.—No system of care should be discharging people into homelessness. The homeless assistance system is not large, or well-funded, enough to accommodate people being shifted out of other systems of care, nor should it be. We need to make mainstream systems more accountable in order to close the front door into homelessness. Some localities—after recognizing the cost shifting occurring between various publicly-funded institutions—have started to implement discharge planning as requisite and/or part of performance goals. Every locality should be required to follow suit.

OPENING THE BACK DOOR OUT OF HOMELESSNESS AND INTO HOUSING

Most people who become homeless find housing on their own in relatively short order. We need to speed up that process, and prevent disruptions during the period of homelessness. A minority, however, remains homeless for a long time. Among this group, disabilities are prevalent, including mental illness, substance addiction, and HIV/AIDS. Most of the chronically homeless, therefore, are already being served by, or are eligible for, services funded by the Department of Health and Human Services.

This subcommittee's work can have a huge impact on efforts to rehouse people who are chronically homeless and chronically ill. Besides housing, they need treatment and services:

—Outreach, particularly to long-term homeless people with mental health and substance abuse problems, to ensure that they make use of the services that are available.
—Short-term treatment in a residential setting aimed at stabilizing these individuals and transitioning them into permanent housing.
—Treatment and long-term aftercare linked with permanent housing, creating permanent supportive housing, a powerful model that improves the lives of long-term homeless people while saving public money that would otherwise be spent on hospital emergency rooms, emergency detoxification, acute mental health care, shelters and jails.
—Help with employment, as soon as homeless people are stabilized in a residential setting.
—Case management to ensure that all services are available.
—Preparing people with few skills for success, once their housing situation has been stabilized.
—Assistance, particularly with children, to avoid disruption of family life during times of homelessness.

These services are especially urgent given the Department of Housing and Urban Development's emphasis on funding the housing, not the services, associated with homeless assistance programs. 30 percent of the funds in the HUD homeless programs is reserved for permanent housing. This is a unique opportunity to build infrastructure in communities to move the most disabled and chronically homeless people out of homelessness. But these same housing projects need services in order to be successful.

Recommendation: Appropriate $100 million for the Grants for the Benefit of Homeless Individuals program.—This program, first authorized in 1992, has the potential to fill the most gaping hole in the system of supports for chronically homeless people—the lack of effective substance abuse treatment services. The program would provide competitive grants from the Substance Abuse and Mental Health Services Administration to local agencies, to provide specific services for homeless people with addictive disorders and/or mental illnesses. Last year the Committee appropriated $10 million for substance abuse treatment for homeless people. An expansion of this program would supplement the funds committed for housing by HUD, and greatly increase program success.

Recommendation: Appropriate $75 million for Projects for Assistance in Transition from Homelessness.—PATH provides formula grants to each state for outreach, case management and treatment for homeless people with severe mental illnesses, including those with a dual diagnosis of mental illness and drug or alcohol addiction. PATH is ideal for funding outreach and case management, allowing people with severe mental illness to be brought into the system of care, their treatment stabilized, and services to continue once they are permanently housed.

Recommendation: Provide $172 million for Health Care for the Homeless (through a $2 billion appropriation for Consolidated Health Centers).—Health Care for the Homeless is part of the Consolidated Health Centers line item in the budget for the Health Resource Services Administration. The program funds clinics that specialize in the unique treatment challenges presented by people who are homeless, often for

long periods of time. Clinics provide primary care, as well as diagnostic, preventive, emergency medical, pharmaceutical, addiction, and mental health services. They also conduct intensive outreach and case management, linking patients to housing, income and transportation. HCH projects are ideal to provide outreach and to stabilize the worst-off homeless people.

Recommendation: Appropriate $120 million for the Runaway and Homeless Youth Programs.—The Administration for Children and Families within HHS operates coordinated competitive grant programs addressing the problems of homeless and runaway youth. Runaway and Homeless Youth programs support cost-effective, community-based services that protect youth from the harms of life on the streets and either reunify them safely with family or find alternative placements. RHYP ends homelessness by engaging in outreach, and quickly rehouses as many homeless youth as possible. For others, it provides services that will prepare them to enter adulthood housed.

BUILD THE INFRASTRUCTURE

In addition to initiatives that focus on homelessness, bringing homelessness to an end will require larger systemic reforms to improve the incomes of the poorest Americans, to make housing more affordable, and to make services widely available to those who need them. This subcommittee's efforts in areas such as child care, education and employment are critical in this regard.

Recommendation: Appropriate $1.4 billion for the Low-Income Home Energy Assistance Program.—Inability to pay for utilities is second only to inability to pay rent as an economic cause of homelessness. LIHEAP has for many years proven an effective program with bipartisan support, designed to help low-income people afford these charges and avoid homelessness. We encourage Congress to provide adequate funding for this important program.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH AND THE FOUNDATION FIGHTING BLINDNESS

The National Alliance for Eye and Vision Research (NAEVR) and the Foundation Fighting Blindness are pleased to have the opportunity to submit their views to the Subcommittee. NAEVR is a nonprofit advocacy coalition of 37 eye research organizations dedicated to expanding our national capacity to address eye and vision research opportunities. The Foundation Fighting Blindness is a non-profit research foundation dedicated to finding treatments and cures for retinal degenerative diseases such as retinitis pigmentosa, macular degeneration and Usher syndrome. These blinding eye diseases affect over 6 million Americans of every age and ethnicity. The Foundation Fighting Blindness supports 17 interdisciplinary research centers and over 150 targeted grant programs around the country.

We would like to begin by thanking the Subcommittee for your continuing commitment to biomedical research supported by the National Institutes of Health (NIH) and the National Eye Institute (NEI). Congress has been tremendously supportive of pushing the frontiers of medical research through support of the NIH. We know that you have many difficult decisions with regard to funding priorities in your Appropriations Bill and we appreciate the strong support that you have provided NIH. With this funding, NEI supported researchers have developed several promising experimental treatments with the potential to halt vision loss and restore sight for millions of Americans. We are now at a turning point. Clinical trials testing a number of new treatments are within our grasp. To advance these promising treatments to clinical trials requires even greater financial commitment from organizations like The Foundation Fighting Blindness and the federal government. Currently, only a fraction of the research needed to make treatments and cures a reality is funded.

FISCAL YEAR 2002 FUNDING REQUEST

We urge your continued commitment to the congressional campaign to double the NIH budget by fiscal year 2003. We strongly support the recommendation of the Ad Hoc Group for Biomedical Research Funding calling for a $3.4 billion, or 16.5 percent, increase for NIH in fiscal year 2002. This request represents the necessary funding level to maintain the course towards the NIH doubling effort.

Within the context of the NIH budget, the National Alliance for Eye and Vision Research and the Foundation Fighting Blindness request your support for a budget of $620 million for the NEI in fiscal year 2002. This funding level represents a $109.4 million, or 21 percent, increase above the current year budget. This level of

funding for eye and vision research is called for as a result of previous disparities, which have disadvantaged NEI in the NIH priority setting and funding allocation process. Historically, the NEI ranks among the lowest Institutes relative to the percentage increase in funding provided by the Congress.

A fiscal year 2002 budget of $620 million also reflects the professional judgment of the vision research community as the funding necessary to continue ongoing research initiatives and pursue new scientific opportunities that have resulted from the nation's investment in eye and vision research. We would like to discuss some of the exciting research opportunities that will be pursued with this level of investment to assure you that an investment in eye and vision research will be a wise and cost-effective investment.

Genetics and Gene Therapy.—Ongoing genetic studies are revealing the normal function of genes and how those functions are impaired when genes mutate which in turn will provide essential insight into many types of vision dysfunction. Gene therapy holds great potential as a therapeutic strategy to halt the progression of many forms of blinding eye diseases, including macular degeneration, retinitis pigmentosa, and glaucoma. Gene therapy has already proven to be successful in preventing vision loss and restoring sight in rodent models of retinitis pigmentosa.

Tissue and Cell Transplantation.—NEI-sponsored scientists are determining whether transplanting healthy cells into the retina might lead to new treatments for people with blinding eye diseases, such as diabetic retinopathy, glaucoma and age-related macular degeneration—the leading cause of blindness in the United States.

Drug Therapy.—A new therapeutic drug developed may be important in treating blindness in human caused by diabetic retinopathy or macular degeneration. Vessels that grow abnormally in the eyes can leak fluid or blood, causing rapid and severe vision loss. This new drug, PKC 412, blocks new abnormal vessel growth and has no apparent adverse effects on normal vessels. More tests are needed to determine whether the drug is a viable, effective alternative in the treatment of diabetic retinopathy.

Neurodegeneration Research.—Research on neurodegeneration and the rescue and regeneration of neural cells is an area of tremendous opportunity with application to many neurological diseases and conditions, and to cases of traumatic injury, including:

—Rescue of Photoreceptors in Retinal Degenerative Diseases: A number of research advances now support the development of strategies for preventing or slowing down photoreceptor degeneration in retinal degenerative diseases. There are numerous opportunities for basic research in this area, as well as opportunities for translating these research advances to patient care. A number of approaches show promise, including the use of growth factors, transplantation, and molecular and genetic technologies.

—Survival of Retinal Ganglion Cells: Retinal ganglion cells (RGCs) can be studied in culture conditions, providing a special opportunity for investigating signaling mechanisms that normally promote survival and how these mechanisms are altered by injury.

Protection of Nerve Cells in Glaucoma—Researchers have found elevated levels of nitric oxide synthase in the optic nerve heads from human eyes with glaucoma and animal models of glaucoma. By pharmacologically inhibiting the production of nitric oxide in these animals, scientists found that axons of the optic nerve were protected from neurodegeneration. NEI-supported scientists are also conducting research to improve the understanding of the nature and course of glaucoma, incorporating studies of co-morbidity, natural history, and genetics with special emphasis on Hispanic, Native American, and African-American populations.

Resources for Research on the Visual System.—In order to better understand the molecular and genetic basis for diseases of the eye and disorders of vision, it is essential that research be conducted to identify and sequence genes that are expressed in the visual system. There are a number of projects which could be pursued much more aggressively with additional NEI funding. This genetic information will be collected from ocular tissues that are qualitatively and quantitatively representative of the genes expressed in the visual system and optimized to detect rare or unique sequences. It is anticipated that this catalogue of genes expressed in the visual system will be publicly available in an easily accessible and retrievable format to facilitate research on eye diseases with the goal of improving treatment or preventing their occurrence.

Control of Angiogenesis.—Diseases that affect the retinal blood vessels are among the major causes of visual disability and blindness in this country. These include diabetic retinopathy, retinopathy of prematurity, neovascular glaucoma, and age-related macular degeneration in which the proliferation of abnormal new blood vessels

can result in the rapid and irreversible loss of vision. Scientists have discovered that inhibitors of certain growth factors and enzymes are ideal candidates for the treatment of these diseases.

Bioengineering and Advanced Instrumentation.—NEI is pursuing the development of advanced assistive devices for the visually impaired, adaptive optics and other imaging techniques to improve non-invasive examination of ocular tissues for both research and disease diagnosis, instruments to analyze the biomechanics of the eye, and instruments to analyze visual performance. NEI is continuing research on the further development of laser-targeted dye delivery systems which could revolutionize the visualization of blood vessels in the retina and the treatment of eye disorders; and optical coherence tomography and confocal scanning laser polarimetry for quantitative measurements of the retinal nerve fiber layer.

Clinical Research and Health Disparities.—Research in this area will enhance our understanding of glaucoma, diabetic retinopathy, and myopia incorporating studies of comorbidity, natural history, and genetics with special emphasis on populations at increased risk. For example, rates of blindness from glaucoma are six times higher in African-Americans than in Caucasians, however age-related macular degeneration is rare for African-Americans as compared to Caucasians.

Low Vision.—A related area of concern is low vision, or vision impairment which is not correctable by glasses or contact lenses. As many as 12 million Americans suffer from visual impairments which affect their ability to read, drive, work, and perform many everyday activities we all take for granted. The most common eye diseases which cause visual impairment in adults are AMD, cataract, glaucoma, diabetic retinopathy, and optic nerve atrophy. Even more serious are the eye diseases which cause visual impairment in children. These include retinopathy of prematurity, cortical visual impairment, and coloboma. Low vision in children often affects their development and results in the need for special education, vocational training, and social services throughout their lives. The cost of these impairments is more than $22 billion each year.

Under the auspices of the National Eye Health Education Program (NEHEP), NEI has developed and is initiating a program directed at low vision in order to increase public awareness about visual impairment and the impact it has on everyday life. The Low Vision Traveling Exhibit will be displayed in shopping malls around the country during the next five years and was recently launched in Birmingham. Alabama. The program provides information about low vision services and the devices which are currently available to assist those with visual impairments. This effort is directed at those suffering from visual impairments and also to medical professionals, eye care specialists, managed care organizations, and family members. NAEVR supports this public education partnership and urges the Committee to support it as well.

By the year 2030, the NEI estimates that the elderly population in the United States will double and more than 66 million Americans will be at risk for blinding eye diseases. If we do not make significant investments in vision research, we will have both an economic and health care crisis in this country, given our nation's demographics. With increased support for the NEI, we can make treatments for many vision diseases and disorders happen within our lifetime.

Conclusion.—Mr. Chairman, the members of the National Alliance for Eye and Vision Research and the Foundation Fighting Blindness are supportive of an increased research focus on eye and vision disorders that improves the quality of life for all Americans by allowing individuals to remain independent and lead productive, fulfilling lives. We urge the Subcommittee to provide a total NEI budget of $620 million, or a 21 percent increase in fiscal year 2002. In this new millennium we must ensure that we are doing our best to find ways to prevent and treat eye and vision disorders, and are providing quality eye care services and devices for those who are already suffering from visual impairment.

Thank you for allowing the National Alliance for Eye and Vision Research and the Foundation Fighting Blindness to present their views.

PREPARED STATEMENT OF THE NATIONAL ALOPECIA AREATA FOUNDATION

Chairman Specter and Members of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, I am Vicki Kalabokes, Chief Executive Officer of the National Alopecia Areata Foundation (NAAF) for the past fourteen years. Before I begin my testimony, I would first like to express to you my deep gratitude for the Congress' on-going bipartisan support of research at the National Institutes of Health (NIH), and most particularly for their recent support of increased funding, via passage of the Children's Public

Health Act of 2000, for autoimmune disease research-research that might not otherwise have been funded.

As a non-profit voluntary health agency, the National Alopecia Areata Foundation is the largest organization in the nation dedicated to supporting research and finding a cure or acceptable treatment for alopecia areata, a common but mysterious and unpredictable autoimmune skin disease resulting in hair loss. The Foundation also provides emotional support for those with the disease through a publication program, an annual conference, and support groups. The support groups provide information and direction to thousands of people with alopecia areata. As a lay organization and the nationwide center for those affected by alopecia areata, the Foundation is often the first place, outside of the medical community, that a person turns to for help and information. Frequently people call who are scared, misinformed, and afraid. The support groups provide a forum to reach out to others, solve common problems and grow.

The National Alopecia Areata Foundation receives no federal grants or subgrants, nor do we receive federal contracts or subcontracts. The Foundation is also a member of, and the past headquarters for, the Coalition of Patient Advocates for Skin Disease Research (CPA–SDR). The Coalition, which operates as a voluntary organization and as such receives no public or private money, provides an umbrella to over 25 "lay" skin groups. These groups represent millions of people who suffer from a wide range of skin diseases. We work together for two reasons. First, to provide information to others about why research is needed. And secondly, so that we may push for a wide ranging research agenda. Recent research has demonstrated that diseases such as alopecia areata, lupus, vitiligo and others are the result of a malfunctioning immune system. When the key is found to one of our diseases, then it is very likely that many of the other diseases represented in the Coalition will be cured. By working together we can and will make a difference.

Alopecia areata is an autoimmune skin disease that strikes over 4.5 million Americans. It results in the loss of hair. For the fortunate few it is a quarter-size patch that can be easily covered, for many others it is the loss of every hair follicle on their entire body. For over half of the people with alopecia areata, it starts between the ages of 5 and 9. It strikes members of all ages and ethnic groups; males and females are equally affected. The loss of hair has several types of impacts. Hair provides significant protection for the body. The loss of eyelashes or nasal hairs means that even the simple acts of opening and closing one's eyes, or breathing in or out, cannot keep dust or foreign particles away. These natural physical acts become a very difficult process.

However, alopecia is not simply a physical problem, it has surprisingly serious psychological consequences. For many people, when they first discover their hair falling out they are devastated. They think that they are the only ones in the world with the disease. Frequently when they go to their doctors they discover that even their physicians have little idea of what is happening, why it is happening, or even if others suffer from it. For some, treatment options stop at that point, while for others, they begin the long process of finding someone who knows something about the condition.

Unfortunately in our society the lack of information is not the only problem. Frequently people with alopecia arata believe that they are vulnerable to the stares and grimaces of those around them. People have lost their jobs. A noted news anchor lost his on-air job because he was suddenly perceived as being unappealing. This lack of being appealing (either real or perceived) causes many people to lose confidence in themselves and they begin to withdraw from society.

Recently, the Foundation received a call from a young woman who was denied the ability to take her GRE (Graduate Record Examination) simply because she arrived to take the test wearing a head covering. She was sternly reprimanded and, without prior notification, was informed that absolutely no hats or head coverings were allowed to be worn while taking the exam. Her choice was either to remove her scarf and suddenly expose her completely bald scalp, or to leave the room immediately and forfeit taking the test. And in Washington D.C., a young child was deprived of taking a school field trip simply because others feared his hair loss was contagious. In the recent past, two parents called about their children. These two girls, one 12 and the other 14 at the time, were in the process of losing their hair. They stayed inside their homes, fearing that going outside would lead to harassment, cruel stares, and not-being accepted as normal. Sadly in this image-conscious society, this is so often the case. It seems to be hardest on the children, who are routinely teased and even shunted into special education classes.

Fortunately, there are people who can help, and in many of our support groups people learn how they can help themselves both cosmetically and psychologically. They learn that they are not alone and that they can do something about their

sense of vulnerability and isolation. But the real solution will be when we find a cure for alopecia areata.

Over the past fifteen years the Foundation has raised and provided nearly $2.5 million for research studies. Our privately funded research grants have been studying the mechanisms of hair biology; the genetics and functioning of the immune system; the etiology, genetics, clinical presentation and therapies of alopecia areata, and the development of non-human research studies looking for the cause of and treatments for alopecia areata. One of NAAF's recent grant awards resulted in the scientific demonstration that alopecia areata is indeed an autoimmune disease. In addition, an association exists between alopecia areata and numerous other autoimmune diseases such as vitiligo, thyroiditis, Addison's Disease, Type I diabetes, and others. Obviously the potential benefit from cross-over research is enormous.

Part of our research program is to continue to work with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to create a research agenda. In September 2000, NIAMS announced the awarding of a disease registry on alopecia areata, a watershed event in the history of alopecia areata research. This award of more than $2.7 Million over five years will establish a research registry consisting of five sites across the United States. This commitment by NIAMS to the advancement of alopecia areata research creates an enormous opportunity to further basic, clinical, and translational studies in alopecia areata. It will provide an essential resource for all investigators interested in studying alopecia areata and will stimulate opportunities for additional research support from federal and private sources. The monies from this grant will not go to NAAF, but directly to the institutions of the investigators overseeing the research at these five centers.

In 1990, 1994, and 1998, NIAMS and NAAF conducted three international research workshops on what is known about alopecia areata. One of the many results from these joint programs was that NIAMS funded a significant study on the structure of the disease. Another result was the discovery of animals with alopecia-thus NAAF was able to support the first non-human host of the disease. Recent genetic studies have revealed unique markers (HLA or histocompatibility leukocyte antigens) on the surface of white blood cells in those with alopecia areata, strongly suggesting the existence of both susceptibility as well as severity genes. These findings are very similar to what has been noted in HLA marker groups of those with other autoimmune diseases.

We are now planning the Fourth International Research Workshop on Alopecia Areata in 2002 in conjunction with NIAMS. This symposium, as with the earlier meetings, will bring researchers, clinicians, and patients together from around the world to study what progress has been made and how new studies should be structured. The convening authority of NIAMS is critical for this sharing of knowledge.

Working together in this unique private-public partnership is a significant step towards finding a cure. We hope to continue this relationship with NIAMS providing limited funds for critical studies, while we continue to work to support the research effort as well. With this partnership we have been able to sharpen the research agenda so that we are looking at questions that are building on a wider and more informed base of knowledge.

The National Alopecia Areata Foundation asks that you continue to support NIAMS by increasing the overall budget of the National Institutes of Health (NIH). The NAAF believes that we must sustain the current level of increased commitment to the NIH. The NAAF joins the Ad Hoc Group for Medical Research Funding, the NIAMS Coalition, and the Coalition of Patient Advocates for Skin Disease Research in asking Congress to support a 16.5 percent ($3.4 Billion) increase in the budget of the NIH for fiscal year 2002. This increase would allow us to get back on track to continue the bipartisan effort to double the NIH budget by fiscal year 2003—a sentiment shared by the President, the Congress and the American people.

Funding biomedical research through the NIH is today's investment in America's future. The economic burden in the United States for musculoskeletal and skin diseases is staggering. The annual cost for medical care and lost wages resulting from skin diseases alone is estimated to be $22.3 Billion, affecting over 65 million Americans. The research for these diseases falls under the umbrella of NIAMS and today's technology, like never before, has enabled us to understand, treat and ultimately cure many of these devastating, chronic skin diseases. Support for the NIH, and therefore NIAMS, is particularly instrumental in unlocking the genetic mysteries of autoimmune skin diseases such as alopecia areata.

Again, we are asking for an increase of 16.5 percent or $3.4 Billion. This increase would allow NIAMS to increase its ability to continue to fund more research projects and support more programs that will help these 65 million Americans who are impacted by skin diseases. We also believe that work done in any of the disease areas represented by the Coalition of Patient Advocates for Skin Disease Research, will

have a profound impact on the lives of the millions of those who suffer from one or more of the diseases that NIAMS is charged with investigating. We also believe that when a cure is found for any of these diseases that there is a good chance that it will help in finding a cure for many of the other skin diseases.

Again, thank you for your past support of medical research funding. Thank you so very much for your time and concern.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS

When a young woman starves to death in the midst of plenty; when a young woman despairs of hope in trying to cope with a deadly illness at age 32 after struggling to survive for 17 years; and when thousands of people all across America strive to live, but are victims of insurance discrimination, assistance and guidance are desperately needed. All of these are recent documented cases of eating disorders. eating disorders is the major illness in our nation which receives totally inadequate support or funding.

Eating disorders are rampant in our society and have reached epidemic levels. All segments of society, young and old, rich and poor, both sexes and all races are impacted by eating disorders. These illnesses, which include anorexia nervosa, bulimia and binge eating disorders, ravage the lives of more than 8 million people in the United States including seven million women and young girls. An estimated 6 percent of the individuals with severe eating disorders will die; a higher mortality rate than for any other mental illness. For those who remain ill the constant thoughts of food, weight, body and behaviors distort body image and their thought processes to the degree that their lives are centered in a kind of hell rather than in living.

Although eating disorders are so prevalent in society, neither the federal government nor most states in the nation have adequate programs or services to combat anorexia nervosa, bulimia or binge eating. There are few programs to prevent or educate children and youths about eating disorders in schools and colleges. Resources that public health agencies and schools devote to the prevention of eating disorders are negligible in comparison to the resources and attention that they give to the prevention of other serious health problems such as drug and alcohol abuse. At all levels, federal, state and local, a significant commitment must be made to the prevention of these life-destroying illnesses.

Children and adolescents are a critical target of these prevention programs as eighty-six percent of individuals with eating disorders report the age of onset by 20 years. Of these 43 percent were between 16–20 years; 33 percent between 11–15 years; 10 percent 10 years and younger. Shockingly eating disorders have been found in children as young as 5 years of age. Something must be done to save these children.

We request that a minimum of $10,000,000 be appropriated for the development and implementation of comprehensive education and prevention programs that promote healthy notions about emotional development of self, nutrition, body development and growth through educational wellness for all of America's school-aged children and early identification of those at risk for eating disorders. The need for the request is substantial as ANAD estimates that twelve percent of high school students and ten to twenty percent of college students suffer from an eating disorder.

Founded in Illinois in 1976, ANAD is the first national health organization of its kind. Dedicated to education, awareness, prevention and alleviating the effects of eating disorders, ANAD helps victims and their families by providing hotline counseling, support groups, referrals to health care professionals, information packets and newsletters, along with education/prevention programs. The services are offered free of charge and the programs developed are low cost. ANAD also undertakes and encourages research, fights insurance discrimination and dangerous advertising, and organizes advocacy campaigns to protect potential victims of eating disorders. Prevention and education about eating disorders are pivotal to ANAD's mission. Each year our outreach programs touch the lives of tens of thousands of people.

The causes of eating disorders are varied and have not been thoroughly delineated, however issues of identity and self-esteem and other psychological problems often underlie eating disorders. Societal and cultural influences emphasize thinness and work simultaneously with media and advertising campaigns to continually reinforce the message to be thin. Unrealistic self-images often result. Individuals feel vulnerable and powerless in relationship to the world at large and eating disorders provide the illusion of being in charge of one aspect of their lives, food.

Education and prevention programs which teach children the skills needed to cope with the emotional complexities of life in a positive and life and self affirming way

are crucial. ANAD's theme of "Accept Yourself, Accept Others" encourages people to make healthy choices, build self-esteem and lead to healthier living practices. Teaching proper nutrition alone is not enough as evidenced by a statement a dietitian with an eating disorder once made. "Through my training, I can teach anyone the right diet for any condition . . . as to myself none of that applies to me."

Prevention programs and support services need not be expensive to be effective as proven by ANAD's many successful programs and services. Implementation of these programs will ultimately lead to an enormous financial savings as it will reduce the number of victims who will need expensive and lengthy medical and psychiatric care required to treat serious eating disorders. In monetary terms the cost savings will be enormous and in human costs, the savings will be immeasurable.

We also request the Senate to increase current funding by an additional $10,000,000 for research into the causes and treatment of eating disorders, and research evaluating the effectiveness of different prevention, treatment and self-help support strategies. By elucidating the causes of eating disorders the specific at-risk population can be identified and helped prior to the life-destroying effects of the illnesses taking hold on their lives. Deciphering the role of genetics in determining who is at-risk for these disorders would also be valuable in prevention and treatment of eating disorders. This funding is essential to the development of truly effective prevention programs and treatment strategies.

Furthermore, improving patients' access to quality, affordable treatment through insurance reform and parity bills is vital. High quality treatment is available, however many victims of eating disorders are unable to access this treatment due to restrictions placed on them by insurance companies. Concurrent medical and psychological services are often necessary when treating people suffering from eating disorders. Often, because eating disorders are treated solely as a mental illness, patients are both denied the medical treatment that they require and are subjected to the extremely low caps on benefits for treatment of mental illness.

Action must be taken to change the uphill battle that victims of eating disorders face when confronting insurance needs. On the legislative front, proposals for insurance reform and health care reform must ensure that patients with eating disorders can receive reimbursement for both medical and mental health care. Government funded mental health centers should be encouraged to develop multidisciplinary approaches to the treatment of eating disorders.

We ask the Senate to help safeguard the rights of people with eating disorders through reforms of the health care and insurance systems. We also ask the members of this subcommittee and the Senate to enact legislation that provides funding aimed at preventing another generation of youth from developing eating disorders. This legislation would also fund research into the causes of eating disorders which would in turn strengthen the effectiveness of eating disorder treatment protocols.

Thank you.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS

Mr. Chairman and Members of the Subcommittee, my name is Dr. Robert Felter, and I am the Chairman of Pediatrics and Medical Director at Tod Children's Hospital in Youngstown, Ohio.

I submit this testimony on behalf of the National Association of Children's Hospitals in Alexandria, VA, in support of the Children's Hospitals' Graduate Medical Education (GME) program in the Health Resources and Services Administration. On behalf of the nation's nearly 60 independent children's teaching hospitals, I urge you to continue to provide adequate funding for Children's Hospitals' GME so that these institutions will have the resources to continue to train and educate the nation's pediatric workforce.

BACKGROUND

The National Association of Children's Hospitals or "N.A.C.H." is a not-for-profit trade association, representing more than 100 children's hospitals across the country. Its members include independent acute care children's hospitals such as Tod Children's Hospital, as well as children's hospitals in Akron, Cincinnati, Cleveland, Columbus and Dayton; acute care children's hospitals organized within larger medical centers, such as Kosair Children's Hospital in Louisville, KY; and children's specialty and rehabilitation hospitals, such as the Hospital for Sick Children in Washington, DC.

N.A.C.H. seeks to serve its member hospitals' ability to fulfill their four-fold missions of clinical care, education, research, and advocacy devoted to the health and well-being of children. Children's hospitals are regional and national centers of ex-

cellence for children with serious and complex conditions. They are centers of biomedical and health services research for children, and they serve as the major training grounds for future pediatric researchers, as well as a significant number of our children's doctors. These institutions are advocates for the public health of children, and they are essential to the health care safety net for children of low-income families.

While they account for less than 1 percent of all hospitals, the independent children's hospitals train nearly 30 percent of all pediatricians and nearly half of all pediatric specialists, and they are the major producers of future pediatric researchers.

Independent children's teaching hospitals are experiencing very serious financial challenges that affect their ability to sustain their missions. In addition to the challenges of covering the costs of their academic programs, they include challenges in covering the higher costs of sicker patients in a price competitive marketplace, meeting the costs of uncovered services such as child protection services and poison control centers, and assuming the costs of devoting a large portion of their patient care to children from low-income families.

On average, independent acute care children's hospitals devote nearly half of their patient care to children who are assisted by Medicaid or are uninsured. They devote more than 75 percent of their care for children with one or more chronic or congenital conditions. For children with rare and complex conditions, independent children's hospitals often provide the majority of care in their region or even nationwide.

Left unresolved, children's hospitals' financial challenges will seriously affect not only their academic programs of education and research but also their clinical care missions as safety net providers and centers of excellence. In fact, their roles as safety net providers and centers of excellence are made possible in part by their having strong academic programs.

ISSUE OF CONCERN

The issue of concern to NACH, which brings me here today, is that independent children's hospitals have faced serious financial burdens and competitive disadvantages in recent years, because they receive virtually no GME support through Medicare—the only source of significant and stable GME support available to teaching hospitals. Because children's hospitals do not care for the elderly, they have few (if any) Medicare patients and thus receive less than 0.5 percent or 1/200th of the federal Medicare GME support provided to other teaching hospitals.

In recent years, while the Medicare program was spending about $7 billion annually on GME programs at over 1,000 teaching hospitals across the nation, children's hospitals received less than $2 million in federal support for their continuing education programs. The Lewin Group, an independent health policy analysis firm, calculated in 1998 that independent children's teaching hospitals should receive approximately $285 million in federal GME support for nearly 60 institutions to achieve parity with the financial compensation provided through Medicare for GME support to other teaching hospitals.

In the absence of any movement towards broader GME financing reform, Congress enacted the Children's Hospitals' GME discretionary grant program to address the existing inequity and ensure that these institutions could receive equitable federal support to sustain their teaching programs. The pediatric community, including the American Academy of Pediatrics, Association of Medical School Pediatric Department Chairs, and others, recognize the critical importance of the GME programs of the independent children's teaching hospitals, not only to the future of the individuals hospitals and their essential services but also to the future of the nation's pediatric workforce and pediatric research overall.

In fact, after three years of work assessing the needs of pediatric education in the next decades, the leadership of the pediatric education community last year issued 34 recommendations, including a recommendation for equitable GME support for independent children's teaching hospitals. The Future of Pediatric II (FOPE II) Task Force said: "Pediatric residents and fellows at freestanding children's hospitals should receive the same level of federal support as those trained elsewhere."

CONGRESSIONAL RESPONSE

The 106th Congress recognized the pressing need to provide independent children's teaching hospitals with the same federal support for their teaching programs that they provide to all other teaching hospitals through Medicare by taking action on two fronts:

First, Congress has both authorized and reauthorized the program. In November 1999, with broad bipartisan support, Congress authorized $285 million for the Children's Hospitals' GME Program in fiscal year 2001 as part of the "Healthcare Research and Quality Act of 1999." In September 2000, Congress reauthorized the program through fiscal year 2005 at "such sums as necessary" as part of the "Children's Health Act of 2000." Congress passed both the authorization and reauthorization bills by unanimous consent.

Second, and more importantly, Congress appropriated $235 million for Children's Hospitals' GME in the Fiscal 2001 Labor/HHS/Education Appropriations bill as a specific line-item within the Health Resources and Services Administration (HRSA) account. Last year's funding was a significant increase over the fiscal year 2000 funding of $40 million—an initial funding level provided for the program before it was authorized.

The $40 million appropriated in Fiscal 2000 was distributed through HRSA to 57 children's hospitals according to a formula based on the number and type of full-time equivalent (FTE) residents trained, as well as the complexity of care and intensity of teaching the hospitals provide. HRSA will soon be finalizing the process of distributing $235 million in Fiscal 2001 funding to children's hospitals to cover a higher percentage of the costs associated with their GME programs.

IMPACT ON TOD CHILDREN'S HOSPITAL

Tod Children's Hospital, which is part of Forum Health, is a 97 bed-facility that serves as a regional referral center, delivering care to children in northeastern Ohio and western Pennsylvania, with more than 30 subspecialties and a number of specialized programs, such as a children's emergency center and a pediatric inpatient cancer unit. We serve all children, devoting more than 60 percent of our care to children who are assisted by Medicaid or uninsured.

Tod Children's Hospital also is a teaching hospital, training 27 resident FTEs, including 24 in pediatrics and three in medicine and pediatrics. Despite the small size of our training program, it has an enormous impact on the availability and quality of health care for children in the Youngstown area. The majority of our residents go on to practice in Ohio, and in the last six years, more than 40 percent went on to practice in Youngstown. Today, 50 percent of pediatricians practicing in Youngstown were trained at our hospital.

Youngstown is an economically depressed community, which makes it hard to attract strong, clinical talent to come to and stay in our area. Without our training program, the pediatric workforce of Youngstown would be seriously affected. And without our training program, our ability to maintain a children's hospital and its substantial contribution to the quality of care for all of the children of our region would also be seriously challenged.

Clinical care and residency training go hand in hand. A strong training program contributes to a strong clinical program, and a strong clinical program contributes to a strong training program. Our hospital spends more than $2 million to cover the direct costs of our GME program, which represents a major expense for our institution. As a consequence, every year our hospital faces difficult financial tradeoffs as we struggle to balance our commitments to training and clinical care. Even with the GME funding our hospital received as a result of the fiscal year 2000 appropriation, Tod Children's could not sustain is residency training program without cutting our family-based HIV clinic serving infected children and their mothers and scaling back our child-life program. These kinds of financial decisions are not easy to make. However, with equitable GME support from the federal government—comparable to what other teaching hospitals receive—our hospitals will be able to cover the added costs that result from their teaching missions while being able to provide other important programs and services that affect the health and well being of the children of our region.

The significant increase in funding we project to receive from the fiscal year 2001 appropriation is absolutely vital to our residency training program, our hospital, and our community. Without it, the future of our training program will be in jeopardy, and that in turn will put in jeopardy the long-term future of our children's hospital and the health of the children of our community.

With such a major impact on a small institution like Tod Children's and our community, you can imagine the magnitude of the impact that Children's Hospitals' GME funding will have on much larger institutions and their regions—Children's Hospital Boston with 238 resident FTEs, Children's Hospital of Michigan with 160 resident FTEs in Detroit, or Children's Hospital Medical Center in Cincinnati with 153 resident FTEs.

FISCAL 2002 NEED

I am here to impress upon you that adequate funding for Children's Hospitals' GME is an ongoing need. Our institutions continue to train new pediatric residents and researchers every year. While we have appreciated very much the Congressional support—particularly with the funding provided in Fiscal 2001—we have received, the teaching mission carried out by children's hospitals will not end this year. Now, we seek to achieve full parity with other teaching hospitals for federal GME support, which will require the full authorization of $285 million for Fiscal 2002.

In order to make children's health a top priority for our country, Congress should appropriate the fully authorized funding level of $285 million for Children's Hospitals' GME in Fiscal 2002. These funds will ensure that independent children's hospitals receive the resources necessary to continue to train and educate the nation's pediatric workforce and sustain their core missions, including clinical care and research.

Support for a strong investment in GME at independent children's teaching hospitals is consistent with the repeated concern the Subcommittee has expressed for the health and well being of our nation's children—through education, health, and social welfare programs. It also is consistent with the Subcommittee's repeated emphasis on the importance of enhanced investment in the National Institutes of Health (NIH) overall, and in NIH support for pediatric research in particular, for which we are very grateful.

Finally, support for this program is a strong investment in cost effective health care. Please remember that prevention is the core of pediatrics. We train every pediatrician to specialize first in primary and preventive health care, which maximizes children's long-term health and reduces the long-term cost of their care, not only as children but also as adults. As a result, it's an investment in the future health of everyone. The children we care for today may be only 25 percent of our population; but tomorrow, they will be 100 percent of all adults.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF DEVELOPMENTAL DISABILITIES COUNCILS

The National Association of Developmental Disabilities Councils is a national organization representing Developmental Disabilities Councils in thirty-nine states and territories. Combined with the Councils represented by the Consortium of Developmental Disabilities Councils, there are a total of 55 Councils—one in each State, the District of Columbia, and the territories of American Samoa, the Commonwealth of the Northern Marianas Islands, Guam and Puerto Rico. NADDC provides leadership to member Councils to support their work for change on behalf of individuals with developmental disabilities and their families. On the national level we support policies that enhance the quality of life for all people with developmental disabilities—individuals who experience a severe, chronic disability which occurs before the age of 22 and results in substantial functional limitation in three or more areas of major life activity (self-care; receptive and expressive language; learning; mobility; self-direction; capacity for independent living; and economic self-sufficiency).

Council activities are authorized through the Developmental Disabilities Assistance and Bill of Rights Act (Public Law 106–402). The "DD Act" was originally enacted in 1963 as the Mental Retardation Facilities and Construction Act in response to the need for alternatives to large institutions. It has been expanded to meet the growing needs for community supports with each subsequent reauthorization. In addition to the State Councils on Developmental Disabilities (Part B of the Act), the Act also provides authority for funding in each State and territory for a statewide Protection and Advocacy System and a University Center for Excellence in Developmental Disabilities Education, Research and Service (formerly the University Affiliated Programs).

The Governor in each State and territory appoints members of State Councils. Sixty percent of the Council membership must be people with significant disabilities and their family members. The rest are state agency administrators, private providers, and members of the community. Together this group develops and implements a statewide plan which lays out activities to enhance the lives of people with developmental disabilities through a variety of systemic change, capacity building and advocacy activities. The Councils' plans promote a comprehensive system of services and supports designed to increase the independence, productivity, inclusion, integration and self-determination of individuals with developmental disabilities.

Federal funding for these activities is administered by an agency also designated by the Governor.

Flexible systems based on individual empowerment and self-determination that require partnerships between the professional and the consumers have proven to be the key ingredients for the successful promotion of the goals expressed in the DD Act. Unfortunately, systems change is difficult and state systems for developmental disabilities were designed years ago to "treat" rather than partner with the individual receiving the service. The Councils have a key role to play in bringing changes about in ways that can positively impact individuals with developmental disabilities.

To assist States, the Act lists a number of "areas of emphasis" for Council activities. Councils can choose to work on issues related to quality assurance, childcare, housing, transportation, recreation, education, employment, health, and formal and informal community supports. They are required to strengthen, support and expand opportunities for individuals with developmental disabilities to receive and provide leadership training and to work in coalitions. They are also free to establish priorities outside of those prescribed in the Act to meet the unique needs of individuals with developmental disabilities in their own State or territory.

While Councils are not service providers, one of the ways that we are able to advance change is through direct support of best practice activities. One of the more recognized activities of the State Councils are grants to public and private agencies that support system change projects, demonstrating at the local level that there is a better way to provide services to individuals with disabilities. Because there are too few quality community services for people with developmental disabilities, the Councils have taken on the responsibility of assisting grantees seek new State, local, and private sector funds to support these activities. Preliminary data for fiscal year 2000 indicates that in this way Councils helped leverage far more in state, local and private funds for services and supports than the taxpayer invested in the four DD programs combined at the Federal level.

DD Council work goes far beyond service system improvement into new areas of community development that improve the lives of everyone—including people who do not have disabilities. Realizing that people are best protected and included in their communities if their lives are intertwined with families, neighbors, friends and co-workers, DD Councils also work on community and economic development so that all citizens share in the resources communities have to offer. It is clear that if we want people with disabilities to have competitive jobs and life-long careers, we must invest in the economic vitality of our communities: poverty-stricken communities result in poverty for people with disabilities. If we want people with disabilities to live safe and healthy lives, we must invest in affordable housing initiatives for them and their neighbors: slums and homelessness are bad for everyone. If we want children with disabilities to attend school with their non-disabled peers and become productive, civic-minded adults, there must be quality education for all children. If we want people with disabilities to be included in our communities, we must have communities that appreciate and believe in the equality of all people.

For all of these reasons, Councils are viewed as invaluable change agents in the States and have made a significant difference in the lives of individuals and their families across the nation. Best practices promoted by Councils have resulted in, among other accomplishments, strong early childhood programs; improvements in school services; access to real, inclusive jobs through supported employment; small business ownership; training and empowerment of self-advocates; means to address the crisis in the shortage of qualified direct care professionals; home ownership; accessible transportation systems; appropriate community activities for individuals with developmental disabilities as they become older; and tremendously important supports for families so they can remain healthy and intact. In keeping with changing times, Councils across the country are now called on to address burgeoning community waiting lists; to plan for the huge demands that will be placed on services by the aging baby boom generation—including the loss of a large percentage of the service provider population as they reach retirement; and to face the challenges of abuse and neglect in a wide range of settings.

A sampling of activities across the country should be helpful in understanding the importance of the Developmental Disabilities Councils in each State. To give the big picture would take volumes, but the following provides a glimpse into some of the State Councils list of achievements.

—The DD Council in Ohio developed a self-determination initiative that has proven so successful that it has been adopted by the State Department and has spread to 30 out of the 88 counties. This effort continues to grow through the State, resulting in more control for individuals with developmental disabilities over their own lives.

—Through a grant with Very Special Arts of Idaho (VSAI) the Idaho Council is assessing the accessibility of arts, leisure, and recreational facilities and programs across the state.
—In Iowa the DD Council working in coalition with other like-valued groups was successful securing all of the state's Tobacco Settlement Fund ($55 million) for purposes related to health care and the needs of children, adults and families, with a strong focus on special needs.
—One hundred and sixty individuals with developmental disabilities in Mississippi became employed in their communities as a result of the DD Council's activities in that state. One hundred and fifty eight businesses employment people with developmental disabilities, and 630 people were trained in the Person Centered Planning process.
—Housing shortage issues are tackled head-on by a number of Councils. One initiative in New York uses a low income housing tax credit designed to encourage private sector investment in the production of low-income housing. The program allows the owner/developer of a qualified property a dollar-for-dollar credit claimed over an extended period of time to equal an established share of the property's construction costs.
—The Maryland Council has led a statewide, cross-disability initiative to expand homeownership opportunities to low-income people with significant disabilities. This work has resulted in the state's commitment of $8.2 million in mortgage funds. The program received a HUD "Best Practice" award in 1999.
—In North Dakota public transit services, when available, are not fully accessible. Thanks to start-up funding provided by the DD Council, the cities of Mandan and Bismarck have been able to address transportation needs for people with disabilities in these cities by combining formerly fragmented and autonomous transit programs into a consolidated, accessible community-wide public transportation system. Without access to this system riders with disabilities would not be able to realize employment ambitions, shop for necessities, achieve independence or experience general community involvement and participation.
—The South Carolina DD Council is active in developing and monitoring a universal newborn hearing screening program required on all newborns in the State. The program is designed to detect hearing impairments in infants. With early detection and intervention children are more likely to experience normal language development.
—The Community Self-Employment Program in Arkansas resulted in a number of new entrepreneurs in the state—business owners who experience a disability. The project was designed to provide loans to assist and support individuals in ownership and operation of their own business. Businesses included include Web-site designing, a concession business, a recycle shop for computers and business machines, legal abstracting, Web marketing, and a pizza store.
—The DD Council has a long history of leading systems change efforts in Hawaii. Among its accomplishments are the closure of Waimano Training School and Hospital, the state institution for people with mental retardation, and the successful integration of those residents into the community. The Council also played a key role in the development of state legislation that created the nation's first statute codifying self-determination for persons with developmental disabilities (Act 133, 1998).
—With an initial start-up grant in 1996 of $124,000.00 for the Home of Your Own Program, the Nevada DD Council has leveraged more than $3 million in non-HOYO funding to provide first time home ownership to 51 Nevadans with disabilities. Through a partnership with Accessible Space, Inc. and the Office of Community Based Services, the Council with initial funding of $250,000.00 has leveraged over $24 million in HUD funding to build 4 affordable, accessible assisted living apartment buildings for Nevadans with severe disabilities and has HUD funding approved to build 2 more such apartments.
—The New Hampshire Council has done significant work in voter access, giving rise to national attention to voter access issues through work with state and national election officials. The Council published and widely disseminated a voter manual. The Council in New Hampshire has also taken the lead in work incentives activities in their state. They have facilitated a statewide effort to coordinate the integration of three federal grants to implement the Workforce Investment Act and other employment initiatives with the Governor's Task Force on Employment and Economic Opportunities.

Every Council has to set priorities identified at the State level and hard choices have to be made. Unfortunately, there are many more critically needed infrastructure activities than DD Councils alone can generate funds to address. In our public

testimony last year we listed some of these needs. Regrettably, they have not changed.

—Direct Care Staff—The need for additional direct care staff continues to be at a crisis level in most of our communities. We cannot train front line personnel rapidly enough. We know that properly trained staff on the day-to-day firing line can spot abuse and neglect and take immediate action to stop such incidents and prevent any repetition. High turnover rates and poor compensation are significant challenges to our services system. If these issues are not addressed, we will see individuals with developmental disabilities lose their newfound independence.

—Inclusive Child Care—There is a well-documented shortage of quality childcare for working parents. This is an even more serious problem for parents of children with disabilities who do not want their children segregated from their nondisabled peers—for parents who want their children in childcare settings that welcome all children.

—Transportation System Redesign—One of the major blockades for individuals with disabilities who wish to work but who require special transportation accommodations is the lack of such accommodations. The lack of affordable, accessible transportation is often identified as the single most constant problem faced by individuals with developmental disabilities in achieving employment and community life.

These are examples of some of the issues that remain largely untouched by Council advocacy due to the lack of funding. This list will grow as the Councils take on the new activities Congress included for the DD Councils in the Act last year. The law now includes a role for the Councils in addressing issues of: (1) aging parents of adult sons and daughters with developmental disabilities; (2) waiting lists; (3) abuse and neglect; (4) inappropriate restraints; (5) development of person-centered quality assurance systems; and (6) increased emphasis on self-advocacy.

There are high expectations of Councils in every State, and DD Councils have demonstrated that they get results and are a bargain for the federal tax dollar. DD Councils are taking a significant next step to build communities that work for everyone, including people with developmental disabilities, in addition to their work to improve the service system. Because they do not provide services and can act independently of the service system, the voice of the DD Council has proven to be critical in each State and territory to the lives of people with developmental disabilities and their families.

Unfortunately, the current reach of the State Councils is far smaller than it could be, given adequate funding. The two tables appended to this statement reflect a seven-year funding history for the DD Councils. It is notable that funding was cut by 8 percent in fiscal year 1995 and has yet to return to the fiscal year 1995 level. Councils are not able to keep pace with the growing needs in every State. With the fiscal year 2001 Federal investment in Council activities of $67.8 million, the smallest 14 states receive $420,000 and the average allocation is less than $1 million, far less than needed keep pace with the cost of living, let alone to fulfill the promises of the DD Act, including the requirements added in the recent reauthorization. The lack of adequate funding has made it difficult to advance the independence and inclusion of individuals with significant disabilities in every State.

To remedy this shortfall, the National Association of Developmental Disabilities Councils (NADDC) urgently recommends an appropriation of $85 million for DD Councils. This represents a restoration of the fiscal year 1995 cut, CBO cost of living percentage increases for the past 5 years, and an additional $3 million for new requirements. Our sister programs, Protection and Advocacy Systems and University Affiliated Programs have also languished since 1995 with insufficient funding and NADDC recommends $35 million for P&As and $28.5 for UAPs. For Projects of National Significance, the only national research and development program targeted especially to individuals with developmental disabilities, including the Family Support Program, we recommend $16 million. This totals $164.5 million the DD Act programs need to keep up the momentum and to launch the necessary changes in the new century.

PREPARED STATEMENT OF THE NATIONAL AHEC ORGANIZATION

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the National AHEC Organization.

I am Project Director at the Northeastern Ohio AHEC, located in Rootstown, and a member of the National AHEC organization. We are a professional organization representing the Area Health Education Centers (AHECs) and Health Education

and Training Centers (HETCs). Together, we seek to further the AHEC mission; to enhance access to quality health care, particularly primary care and preventative care, by improving the supply and distribution of health care professionals through community and academic/educational partnerships. Health Education and Training Centers (HETCs) have a similar mission to AHECs, but are unique in their focus on public health matters associated with areas found along our nation's border with Mexico, the State of Florida, and other extremely underserved areas within our country.

WHAT AHECS DO

Since our inception almost thirty years ago, AHECs, in partnership with local/state/federal initiatives and educational institutions, have provided clinical training opportunities to health professions and nursing students in underserved communities and have extended the resources of academic health centers to these locations. Currently, there are 40 AHEC programs and more than 160 AHEC centers.

AHEC programs concentrate on four areas:

—Developing health care recruitment/preparation programs in underserved areas for underrepresented and disadvantaged students. These efforts provide hands on science and math instruction and exposure to local health professionals. Not only is this an educational opportunity, but an encouragement for young people to enter health professions careers.

—Oversee the community based training of primary care health professions students and residents in health professions shortage areas. AHECs are pioneers in the effort to train residents in a community based setting. The contribution of this type of training is immense to the healthcare workforce. It allows for individuals to complete their education in the locale they will serve. In 1998, AHECs provided community based training to approximately 15,000 health professions students in underserved areas.

—Provide information, support, and technical assistance to health care professionals to ensure an opportunity for continuing education. In 1999, AHECs provided Continuing Education Programs for 174,425 participants.

—Promote healthy lifestyles in a manner which is appropriate to specific community and population needs.

AHEC's play a vital role in integrating community needs, educational resources, and health professionals. An example of this effort is the Canton Area Regional Health Education Network, an AHEC Center, which operates a primary care project in partnership with the Kent State College of Nursing. Primary health care nurse practitioners, medical students, and allied health students provide a broad range of care; screening for disease, education, and follow-up care, to migrant workers. Initially, this was limited to adults, but has since expanded to include immunizations and primary care for children, as well as women's health services.

THE ROLE OF HEALTH EDUCATION AND TRAINING CENTERS (HETCS)

The HETC programs are a subset of the National AHEC program, created with the purpose of improving the number and placement of health professionals along the border between the United States and Mexico, the State of Florida, and other areas of extraordinary need. Like AHECs, the cooperation between faculty, students, and communities serve as the base for HETC development.

In the state of Kentucky, in one year, over 6,000 disadvantaged students were involved in programs focusing on healthy lifestyles, violence prevention, and dental health. This was achieved through partnerships among local schools, community centers, Boy's and Girl's Clubs, and HETCs.

JUSTIFICATION FOR FUNDING RECOMMENDATIONS

Mr. Chairman, I respectfully ask the Subcommittee to support our recommendations of increasing the funding for the health professions and nursing education programs under Title VII and Title VIII of the Public Health Service Act to at least $440 million. This is consistent with the funding level recommended by the Health Professions/Nursing Education Coalition.

A 20 percent increase for the AHEC and HETC programs is needed for fiscal year 2002. Last year, no new AHEC programs were started. To enable AHEC programs to expand service to states that currently have no program and strive towards completing a 50 state network, additional funding is crucial. AHEC programs have a multitude of responsibilities, from recruitment of minority and disadvantaged students into health professions careers, to enhancing the quality of the health care workforce through telecommunications training, telemedicine, distance learning, and providing health career experience to K–16 students.

HETCs provide training experiences for health professions students and local providers at sites of severe underservice to improve access to health care, diversity and cultural competence of the healthcare workforce. One out of five U.S. citizens live in a border HETC county. Within these areas, only 62 primary care physicians per 100,000 reside in border counties compared to 105 per 100,000 nationally. To help alleviate this situation, each HETC project supports at least one training and education program for physicians and one for nurses so that a portion of the clinical training for students is in the service area.

Mr. Chairman, thank you for the opportunity to present the views of the National AHEC Organization. We look forward to working with you and your staff. I would be happy to answer any questions that you or your colleagues may have.

PREPARED STATEMENT OF THE NATIONAL CENTER FOR VICTIMS OF CRIME

The National Center for Victims of Crime is the nation's leading nonprofit advocacy and resource organization serving victims of all crime. Since its founding in 1985, the National Center has worked with nearly 10,000 public and private nonprofit organizations and agencies across the country, and has provided information, support, and technical assistance to hundreds of thousands of victims, victim service providers, allied professionals, and advocates.

One of the highlights of the Violence Against Women Act of 2000 (VAWA II) was the increased resources to support rape prevention and education. This money funds the rape crisis centers nationwide that provide support, counseling, community outreach, and education activities that are the nation's best hope for making inroads against this terrible crime.

While advocates cheered to see the increase as part of VAWA II, the President's fiscal year 2002 Budget proposes retaining the previous funding levels. Rather than the $80 million authorized, the Administration proposes funding this important program at $45 million. We call on this Subcommittee to fully fund this important program.

THE IMPORTANCE OF RAPE EDUCATION

The incidence of sexual assault in this country remains high; despite an overall drop in crime rates, there was a 20 percent increase in rapes, and a 33.3 percent increase in sexual assaults in 1999.[1] Rape prevention and education efforts are key to ending sexual violence, by changing attitudes about rape and ending the isolation of victims.

In the National Center's 1992 landmark study, "Rape in America: A Report to the Nation," sexual assault victims were asked about the extent to which they were concerned about issues specific to their personal rape experiences. Rape victims reported that they were concerned about:

—her family knowing about the assault (71 percent);

—people outside her family knowing she had been sexually assaulted (68 percent); and

—people thinking it was her fault or that she was responsible (69 percent).[2]

This combination of concerns may explain why so few rape victims report their assaults. The Rape Prevention and Education Grants represent the best opportunity for change.

Rape education changes attitudes; it is a direct response to the problem of victim blaming which allows sexual violence to fester. Victims blame themselves: "If only I hadn't . . ." Their friends and family often judge them: "Why didn't she . . .?" It is only by education that victims will stop blaming themselves and society will stop blaming the victims. It is only through education that blame can be shifted back where it belongs: to the offender.

When that happens, victims will be more willing to reach out to the services they need. Indeed, rape crisis centers around the country report that following public awareness and education activities, more victims come forward to seek help. This serves as a concrete indication of the importance of such education and outreach efforts.

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[1] Rennison, Callie M. (August 2000). Criminal Victimization 1999: Changes 1998–99 with Trends 1993–99. Washington, D.C.: Bureau of Justice Statistics, U.S. Department of Justice, Table 1.

[2] National Victim Center & Crime Victims Research and Treatment Center. (1992). Rape in America: A Report to the Nation. Arlington, VA: National Victim Center. P. 4.

THE CONNECTION BETWEEN EDUCATION AND PREVENTION

Education about rape can prevent rape. As young people become aware of the frequency of acquaintance rape, they broaden their efforts to protect themselves from merely locking doors against strangers to taking precautions with those they know. Education is also key to reducing drug-facilitated sexual assault. As detection and prosecution remains difficult, the best means to reduce such crimes is prevention through education. Through education and public awareness efforts, young people can learn to reduce their risk, and understand the warning signs that they or a friend may have ingested Rohypnol, GHB, or other drugs commonly used to facilitate sexual assault.

As noted above, education also fosters requests for assistance. This, in turn, leads to prevention of future assaults by reducing repeat victimization. In 1998, the Canada Solicitor General found that sexual assault victims are thirty-five times more likely to be re-assaulted than individuals who were never assaulted.[3] As education prompts victims to seek services, they will get the support to reduce their likelihood of revictimization. As one rape crisis director recently stated, "We have the opportunity in rape crisis agencies to explain to [victims] their risks and offer support to help them decrease their vulnerability in a blameless manner." Thus, there is a direct connection between rape education and rape prevention.

PURPOSES OF FUNDING

As newly expanded under the Violence Against Women Act of 2000,[4] rape prevention and education money can be used for:

—educational seminars;
—operation of hotlines;
—training programs for professionals;
—preparation of informational material;
—education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;
—education and training to increase awareness about drug-facilitated sexual assault; and
—other efforts to increase awareness about, or to help prevent, sexual assault, including efforts to increase awareness in underserved communities and awareness among individuals with disabilities.

These are important efforts, that deserve to be fully funded. The lack of such full funding directly impacts the ability of state and local organizations to reduce rape in America.

From its conversations with sexual assault coalitions nationwide, the National Center has learned of the dire need that exists for these prevention and education funds. As examples:

—Approximately one out of six sexual assault programs in the National Center's referral database does not have a 24-hour toll-free hotline. In some states, there is no hotline, and for centers that cover large geographic areas, calling the center may cost the victim and be reflected on the victim's phone bill, violating her confidentiality.
—In Alabama, less than half of the 15 rape crisis centers have a full-time outreach staff member. None of the programs have translated materials, and only two have a bilingual staff member.
—Arkansas has no statewide sexual assault hotline, and no translated materials or translators in sexual assault programs.
—In California, of 92 rape crisis centers, only 25 have translated materials.
—Of Georgia's 21 rape crisis centers, only four have translated materials and 4 have a bilingual staff member. Furthermore, while the state has a law mandating sexual assault education in the schools, 50 counties have no rape crisis program to provide this education, and the programs that do exist consistently turn away requests for presentations due to lack of staff.
—Mississippi has nine rape crisis centers, but because of a lack of funds, two-thirds have no community outreach program. The state coalition has received requests to provide training regarding drug-facilitated sexual assault, but has not had the money to develop such training.
—Ohio estimates that of its 40 rape crisis centers, only four have translated materials, and only six have a bi-lingual staff member.

[3] Canada Solicitor Genera. (1998). Multiple victimization (Canadian Urban Victimization Survey Bulletin No. 10). Ottawa: Ministry of the Solicitor General.
[4] Part of the Victims of Trafficking and Violence Protection Act of 2000 (H.R. 3244).

—The Pennsylvania Coalition Against Rape reports that 25 counties do not have access to a full-time rape crisis education staff member. Moreover, in the last year, rape crisis centers have turned down over 7,000 requests for programs/presentations, largely due to a lack of staff and volunteers. As a result between 129,000 and 206,000 persons were not served.

—Of the 10 rape crisis centers in Utah, only one has translated materials. None have bilingual staff. Only half have 24-hour hotlines. Three of the programs have no full-time education staff member. The Utah Coalition Against Sexual Assault reports they are only reaching 50 percent of the junior high and high school students in the state through their education efforts.

—In Wisconsin, only three of the state's 38 rape crisis centers have a full-time community educator. Between one-half and two-thirds of the centers have only one staff member.

When Congress increased the authorization for the Rape Prevention and Education Grants as part of VAWA II, it recognized the importance of this program in reducing sexual victimization. The National Center calls on Congress to honor its commitment to women by providing full funding for the Rape Prevention and Education Grant Program for fiscal year 2002.

For more information, contact Susan Howley, public policy director, National Center for Victims of Crime, at (703) 276–2880.

PREPARED STATEMENT OF THE NATIONAL COALITION FOR HEART AND STROKE RESEARCH

My name is Jack Owen Wood. I solicit your support for more aggressive federal funding for research into prevention and treatment of the sister diseases, stroke and heart disease. Strokes and heart attacks are occurring at an alarming rate.

I am representing the National Coalition for Heart and Stroke Research. The coalition consists of 14 organizations representing more than 5 million volunteers and members united in support for increased funding for heart and stroke research. Members of the Coalition include: American Academy of Neurology; American Academy of Physical Medicine and Rehabilitation; American Association of Neurological Surgeons; American College of Cardiology; American Heart Association; Americans for Medical Progress Congress of Neurological Surgeons; American Neurological Association; Association of Black Cardiologists; Citizens for Public Action on Blood Pressure and Cholesterol, Inc.; Mended Hearts, Inc.; North American Society of Pacing and Electrophysiology; Stroke Connection, Inc.; and the National Stroke Association.

I will deal primarily with one man's personal experience with stroke and its functional and financial costs—my own. I have only the use of my right arm.

I was born in 1937, raised in Vicksburg, Mississippi, earned an engineering degree at Mississippi State University and currently reside in Port Orchard, Washington.

I worked for the Boeing Company in Seattle, am a former Director of the Washington State Energy Office, served as Director of Cost and Revenue Analysis and as the Forcasting Manager for a major Northwest Area Natural Gas Utility until May 1, 1995.

On May 1, 1995, at the age of 57, I was stricken and severely disabled by my stroke. Two years later I experienced a triple bypass heart operation. You might say I've "been there and done that" for both major cardiovascular diseases. So you see, I am an expert.

Last year I was offered an exciting and rewarding volunteer opportunity. I was asked to lead the "JACK WOOD STROKE VICTOR TOUR" for the American Heart Association.

The JACK WOOD STROKE VICTOR TOUR was a 5-state lobbying tour. Through it I tried to meet personally with every Northwest Congressional representative on his or her home turf (in Alaska, Idaho, Montana, Oregon and Washington). In each meeting I was joined by local people, stroke survivors and their families and medical professionals. I told my story and asked them to join the Congressional Heart and Stroke Coalition and to support increased federal heart and stroke research funding.

I am proud to say I traveled to 18 communities and meet personally with 28 members of our delegation or their staff. Nearly half of our congressional delegation is now members of the Congressional Heart and Stroke Coalition.

One of the most powerful memories for me was the frequency in which Members of Congress or staff members related their personal experience with stroke. One member I spoke to lost both parents to stroke. I suspect many of you have stories too.

I realize your interest is greater than the physical impact of my stroke. Your concern must include the financial impact, not only on me, but on our country from increased health care costs and lost productivity and its many implications.

I have confronted the difficult and painful task of calculating that cost to me. Besides being a man whose stroke took his ability to pick up and play with his grandchildren, his livelihood, and marriage, I remain a statistician at heart. I couldn't resist calculating and telling that part of my story. But please remember my story is not dissimilar to that of many of the 4.5 million stroke survivors in the United States. Many of whom were stricken in their prime earning years. Who in a matter of moments, seemingly without warning, are transformed from a contributor and provider to a receiver and patient.

My full analysis is on the final page of my written testimony. Allow me to highlight three figures that I feel sum up my data and should be important to you. I estimate that my stroke at age 57:

—Reduced my earnings before retirement age 65 by over $600,000.

—Subsequently, the cost to the federal government in lost income and other taxes, early Medicare payments and Social Security disability payments is over $320,000.

—My HMO spent approximately $150,000 to respond to and treat my stroke.

—One man, over one million dollars.

About 600,000 Americans will suffer a stroke this year costing this nation an estimated $45 billion in medical expenses and lost productivity.

Earlier I described a stroke as occurring seemingly without warning. All too often as in my case, people either don't know or ignore the signs of a stroke, even one in progress. When my stroke hit I denied it. It took me two days after my stroke to acknowledge it and seek help. Because of research into new treatments, we now have t-PA, which if administered within 3 hours of the onset of stroke symptoms, can dramatically reduce the damage of certain kinds of strokes. Had I recognized and acknowledged my stroke, gone to a hospital with a neurologist on staff and had there been tPA, the impact of my stroke most certainly would have been lessened.

What is even more painful to me is that my impending stroke could have been detected. Unfortunately, we need to create easier and less expensive diagnostic techniques so that effective diagnostics can be given routinely as part of regular health exams. And they must be covered through insurance.

I am not asking for your sympathy. Instead, please think of me as two of the ghosts in the famous Dickens' story. Please don't misunderstand, I'm not casting you as Scrooge. See me as both the ghosts of things past and things yet to be. I too am here to tell you, the future, which I represent, needs not be. It is largely up to you.

I hope my story and estimate of the cost of my stroke convinces you that taking on stroke and heart disease through increased research, leading to better prevention, diagnosis and treatment is fiscally responsible. The human and financial costs are astronomical.

Thank you for your past support of research and recent decision to eliminate (at least for now) restrictions on reimbursement for rehabilitation services, essential to those who have experienced a stroke. Please continue and broaden that support.

PREPARED STATEMENT OF THE NATIONAL FUEL FUNDS NETWORK

INTRODUCTION

The National Fuel Funds Network thanks the members of the Subcommittee for the opportunity to submit this testimony. We thank the Chairman and other subcommittee members for your efforts in securing $1.86 billion in sorely needed energy assistance funding for fiscal year 2000.

The National Fuel Funds Network (NFFN) supports funding for the Low-Income Home Energy Assistance Program (LIHEAP) in the amount of $2 billion in regular funds plus $300 million in emergency funds, the maximum amount authorized for fiscal year 2002. NFFN also supports advance funding in the amount of $2 billion for fiscal year 2003. The Network also supports the Bingamin amendment to the bankruptcy reform bill, which authorizes $3.4 billion for LIHEAP.

The NFFN is a membership organization comprised of over 200 dues-paying representatives of private fuel and energy assistance funds, community action agencies, social service organizations, utility companies, local and Tribal governments, trade associations and private citizens. Our member organizations are located in 44 states and the District of Columbia.

The NFFN members raise private contributions in their local communities or states to assist people with low incomes to pay home energy bills. Fuel funds range

from small church organizations that distribute hundreds of dollars in a single neighborhood to large independent organizations that distribute millions of dollars across a state. Fuel funds may be a division of a large social service agency, or a local utility or energy company may operate them. Some Indian tribes maintain fuel funds to supplement LIHEAP programs. Since our first steering committee meeting in 1984, the NFFN and its member organizations have put into action a commitment to help people of limited means, due to chronic poverty and temporary misfortune or illness, meet their basic energy needs.

Whatever their form, all fuel funds raise and distribute private sector monies, and they all, inevitably, discover that the resources they manage and the resources provided by LIHEAP are inadequate. Therefore, fuel funds are becoming increasingly involved in attempting to locate or direct even more financial resources to help the poor meet their energy needs.

Nationally, fuel funds assist almost 1.8 million households to make heating and cooling bill assistance payments of over $102 million this year. These payments, while vitally needed, are quite small in comparison to the $1.86 billion in fiscal year 2000 LIHEAP funding.

During the 1990's there was a consistent demand for energy assistance funding despite the fact it was one of the warmest winter decades on record. The households assisted during this period were among the poorest of the poor with average household incomes of less than $8,000 per year in most states for a family size of 2.6.

A 1999 NFFN survey revealed that many fuel fund managers reported an increase in their energy assistance caseloads due in part to the 1996 Welfare to Work legislation.

Fuel Funds have worked vigorously to raise private non-federal funds to assist needy households during the last decade, raising $74 million in 1994, $88 million in 1998 and an estimated $100 million this winter.

Despite these valiant efforts, the amount of funds raised by fuel funds is very small compared to federal LIHEAP funds of $1.86 billion for his winter.

The current 2000/2001 winter has highlighted the need for not only continued but increased LIHEAP funding.

IMPACT OF RISING ENERGY PRICES

The increases in energy costs this winter, especially natural gas has greatly increased the energy burden i.e. the ratio of energy costs to household income borne by poor households. As you know, natural gas prices this winter have averaged, at times, three to four times the prices paid last year. In addition, the weather across most of the country this winter was not only considerably colder than last winter, but colder than normal, with records set in some areas.

The combination of colder weather and dramatically higher energy costs have imposed an unbearable energy burden on the poor.

A December 2000 study by Economic Opportunities Studies estimated the energy burden for poor households this winter would be 19 percent for households with incomes of 125 percent of poverty and 14 percent for households at 60 percent of the average of the states' median incomes compared to 3.2 percent for middle-income households not eligible for assistance.

The above energy burdens were based on a projected natural gas price increase of 40 percent above the 1999–2000 winter. Current estimates indicate natural gas prices will average 60 percent more above last winter, thus imposing an even greater burden on the poor.

Moreover, by the time the heating season and cut off moratoria ended, millions of households faced utility cutoffs because of arrearages amassed during the winter. Indeed, a recent National Energy Assistance Directors Association study tallies 3.6 million households in only eighteen states.

FUEL FUNDS RESPONSE TO CRISIS

Fuel Funds, in response to the above escalations in energy costs and colder weather have aggressively stepped up their fundraising and service delivery efforts.

For example, the Victorine Q. Adams Fuel fund in Baltimore City anticipates servicing 50 percent more households this winter compared to last winter or 3,000 vs. 2,000 respectively.

The Dollar-Help program in St. Louis has increased its fundraising from about $550,000 two years ago to an estimated $800,000 this winter and will serve about 2,500 households this winter as compared to 2,000 in 1999.

KeySpan Energy recently announced a $3 million in grants to fuel funds serving New York City, Long Island and New England. Entergy—New Orleans donated $1 million to two fuel funds in that city.

NFFN estimates contributions to fuel funds are up at least $12 million this year for a total of $100 million vs. $88 million raised in 1998–99.

Local and state governments have also increased their funding of energy assistance in their jurisdictions.

In Ohio Governor Taft committed $2.5 million in state funds for energy assistance and challenged the state's utilities to match the state's commitment. In response, Columbia Gas of Ohio formed the Columbia Energy Assistance Fund with $3.5 million, Dominion East Ohio Gas expanded the People Helping People Fund with a $1 million contribution and Cinergy expanded its Heatshare program from $100,000 to $500,000.

Some cities have used a portion of their increased Gross Receipts tax revenues to fund energy assistance efforts through Community Action Agencies and fuel funds.

In the city of St. Louis, the Board of Aldermen and the Mayor appropriated $1.13 million for energy assistance. In western Missouri, several cities either reduced their Gross Receipts taxes or donated a portion for energy assistance.

The above efforts, while worthy of praise are small when compared to the LIHEAP funding for this winter of $1.86 billion. Therefore, it is clear that the most ambitious private efforts cannot replace LIHEAP. These private efforts, when used in partnership with LIHEAP serve as a very helpful safety net supplement to the very needy.

Most states have experienced dramatic increases in applications for assistance this winter as a result of the severe weather and energy cost increases. Many of the agencies responsible for delivering assistance are experiencing large backlogs due to a shortage of modern computers and electronic capability such as e-mail.

Approximately half way through the 2000–2001 heating season in Colorado, more than 49,585 households have been approved for energy assistance through the LIHEAP program. This number exceeds the caseload of 48,417 households served during the entire 6 month heating season in 1999–2000. Applications for assistance set records exceeding the number of applications ever to have been accepted by the state administered federally and privately funded LIHEAP program.

Privately funded non-profits, charities and faith-based organizations have also seen caseloads up by more than 50 percent from last year serving in excess of an additional 10,000 households not currently served by LIHEAP.

Call volumes to my agency, Colorado Energy Assistance Foundation show astronomical increases rising from approximately 25 calls a day in January and February to recorded levels of 543 calls per day. Averages are running in the neighborhood of 270 calls per day.

To ease the problem of backlogs and to avoid the non-delivery of sorely needed help, NFFN recommends the use of a portion of LIHEAP appropriation for the purchase of new sorely needed delivery equipment.

The summer of 1995, with its oppressive heat and loss of lives taught us that energy assistance is a year around issue and the need for LIHEAP funding is almost constant.

As evidenced by this winter, the volatility in energy prices experienced this winter, as well as cold weather can wreak havoc on the lives of the poor.

In St. Louis, for example some lenders are offering to refinance mortgages for people to pay increased heating bills.

CONCLUSION

In conclusion, NFFN strongly supports and urges the approval of a fiscal year 2002 LIHEAP appropriation of $2.3 billion, $2 billion in regular funding and $300 million in emergency funds. We also urge the Subcommittee to provide advance appropriations for fiscal year 2003 at the same level. State and Tribal agencies need advance funding to insure stability and continuity. This holds especially true in a time of volatile home energy prices.

Fuel Funds will continue their efforts to serve as a helpful safety net supplement to LIHEAP but cannot in any way replace the vital role LIHEAP plays in the lives of the poorest of our neighbors.

NFFN is grateful for this opportunity to submit testimony the Subcommittee.

PREPARED STATEMENT OF THE NATIONAL INDIAN CHILD WELFARE ASSOCIATION

The National Indian Child Welfare Association appreciates the opportunity to submit testimony regarding fiscal year 2002 funding child welfare and mental health programs that serve our most precious resource—our children. Our comments will focus on the need for mental health services for Indian children and for

research and services related to abuse and neglect of Indian children. Specifically, we need increased resources and/improved access to the following DHHS programs:

(1) Substance Abuse and Mental Health Services Administration (SAMHSA) programs:

—Knowledge, Development and Application category—Circles of Care tribal children's mental health grant program

—Comprehensive Community Mental Health Services for Children and their Families grant program—funding for tribal children's mental health service sites.

(2) Administration for Children and Families (ACF) Office of Child Abuse and Neglect under the Child Abuse Prevention and Treatment Act (CAPTA) programs:

—National Clearinghouse for Child Abuse and Neglect Information and

—Child Abuse Research and Demonstration.

(3) There are barriers to funding services for Indian children, especially in the Foster Care and Adoption Assistance programs, the Mental Health Block Grant, and the Child Abuse Prevention and Treatment Act state grants.

The National Indian Child Welfare Association (NICWA).—NICWA, headquartered in Portland, Oregon, provides a broad range of services to tribes, Indian organizations, and state and federal agencies that serve Indian children and families throughout the United States. These services are not direct client services such as counseling or case management. Rather, they are services that strengthen the programs that serve Indian children and families. Our services include: (1) professional training for tribal and urban Indian child welfare and mental health professionals; (2) technical assistance to improve child welfare and mental health programs that serve Indian children; and, (3) activities to promote improved public policy for Indian children and families. In addition to maintaining a strong network in Indian country by working closely with the National Congress of American Indians and tribal governments across the nation, we have established mutually beneficial partnerships with organizations including the Federation of Families for Children's Mental Health, the Child Welfare League of America, and Casey Family Programs.

Program.—Circles of Care tribal grantees under the budget category of Knowledge, Development and Application (last year for this 3-year grant program is fiscal year 2001).

Fiscal year 2001 Enacted.—$2.4 million (approximately $0.7 million was reserved for the Circles of Care grant program).

DHHS Division.—Substance Abuse and Mental Health Services Administration.

Recommendation.—$3 million, with $1.1 million for the Circles of Care projects

Justification.—The Circles of Care projects utilize the most current and innovate thinking in delivering Indian children's mental health services. The current nine Indian community grantees, which base their efforts in "a system of care" model, are engaging local communities in partnerships and capacity building for children's mental health services. Within the field of children's mental health, a system of care is a formal collaboration of the family and community members, professional and other organizations committed to enhancing the lives of emotionally disturbed children and their families.

All of the Circle of Care Indian projects are subject to rigorous external evaluation which helps determine the feasibility of project designs and also the potential for successful replication in other communities.

Historically, American Indians/Alaska Natives have had little access to mental health services, and funding from Indian Health Service for this purpose has been minimal. Funding planning efforts is critical to the successful building of systems of care for American Indian/Alaska Native children with severe emotional disturbances. We ask Congress to provide additional planning grants so that other tribes and urban Indian organizations can enter into partnerships with Indian and non-Indian agencies to develop community-based mental health programs.

The Circles of Care programs are demonstrating that careful planning combined with community partnerships can make a positive difference in helping children with severe emotional disturbances and their families.

Program.—Comprehensive Community Mental Health Services for Children and their Families grant program (tribal service site funding).

Fiscal year 2001 Enacted.—Approximately $91.7 million.

DHHS Division.—Substance Abuse and Mental Health Services Administration.

Recommendation.—Recommend (1) reserve 10 percent of the total allocation to this program for tribal applicants and (2) exempt Indian tribes and organizations from population limits used to allocate these grant funds.

Justification.—Developing systems of care for Indian children with, or at risk of, emotional and behavioral disorders has been initiated through the Children's Men-

tal Health Services tribal service grantees. To date, seven tribal sites have received grant awards. Information and descriptions of the most "promising practices" of the full range of the mental health services are being documented in the Promising Practices monograph series. The monograph devoted to the Native American grantees was released in June 2000. This monograph poignantly illustrates the success of community-based systems of care when American Indian communities are afforded the advantages of designing systems tailored to their specific needs.

Focusing on cultural and family strengths, parent and community involvement, and ongoing service evaluation, the service sites yield rich information useful to Indian and non-Indian providers. Substantive data gathering is an integral part of tracking the success and challenges of implementing new systems of care in Indian country. The verbal reports of parents and children enrolled in some of the project's systems of care suggest a high rate of success and demonstrate high consumer satisfaction by parents and children. A 10 percent allocation would enable funding of additional sites that are in desperate need for children-specific mental health services.

The formula for funding grantees only allows a specified number people to be served within a given state. If a state becomes a grantee it would almost automatically exclude any American Indian/Alaska Native tribes from being awarded a grant in that same state even though they would be serving different populations and using a different service delivery system. Many states have numerous tribes in rural areas with small populations. We believe that the program should fund tribes in a way that honors the government-to-government relationships. An allocation of dollars to these Native populations that is unrestricted by state populations addresses the inordinately high index of need for mental health services of American Indian/Alaska Native children.

Program.—National Clearinghouse for Child Abuse and Neglect Information, Child Abuse Research and Demonstration.

Fiscal year 2001 Enacted.—$33 million (no portion of these funds are reserved for a Tribal grant program, but Tribes receive services from the clearinghouse as well as a few discretionary grants).

DHHS Division.—Office of Child Abuse and Neglect.

Recommendation.—Recommend an allocation of at least $2 million to support research, information services and demonstration projects in American Indian communities.

Justification.—Beginning with the passage of the Indian Child Welfare Act in 1978, tribes began in earnest to reclaim their responsibility for the protection of tribal children (Canby, 1998). Today almost every tribe in the nation provides some form of child welfare services to their children, and approximately two-thirds are directly involved in the investigation of cases of child abuse and/or neglect (Earle, 2000). Efforts to address the problems of abuse/neglect of Indian children living on tribal lands are hampered by the fact that no one knows how widespread the abuse/neglect of Native children really is. Although there are various sources of data for the rates of abuse/neglect of Indian children, the accuracy of these data is suspect not only due to problems of definition and limited scope but to the inability to collect accurate data on the known cases of child abuse/neglect.

U.S. Bureau of Justice statistics for 1995 reported a per capita rate of one substantiated report of a child victim of abuse or neglect for every 30 American Indian children aged 14 or younger. This compares to one report for every 58 children of any race, approximately half the rate for Native children. It was the highest rate of abuse or neglect reported for any ethnic group. In addition, American Indians and Asians were the only racial/ethnic groups to experience increases in the rate of abuse or neglect of children under age 15 from 1992 to 1995 (Dept. of Justice, 1999). Data from the National Child Abuse and Neglect Data System (NCANDS) show that, for child maltreatment victimization rates by race and ethnicity in 1998 (40 states reporting), the rate for Native children was 19.8 cases per 1000 children. This compares to a rate of 3.8 for Asians/Pacific Islanders, 8.5 for Whites, and 10.6 for Hispanics (U.S. Dept. of Health and Human Services, Children's Bureau, 2000). Tribes and policy makers desperately need research on the extent of the problem and information about how to combat child about in their communities.

STATUTORY AND REGULATORY BARRIERS TO FUNDING SERVICES FOR INDIAN CHILDREN

While we recognize this Committee does not have the authority to amend language in the authorizing statutes, we feel it is important that the Committee be aware of the disparity in access to federal funding that exists for Indian children. Therefore, we are providing information on key programs that have the potential to fund services for Indian children under tribal jurisdiction, but contain significant

barriers. The appropriations for these programs, however, do fall under the purview of this Subcommittee.

Program.—Foster Care and Adoption Assistance (Title IV–E of the Social Security Act).

Fiscal year 2001 ENACTED.—Entitlement funding $5 billion (foster care) and $1.2 billion (adoption assistance).

DHHS Division.—Children's Bureau under the ACF.

Recommendation.—Support legislation (to be introduced in the Senate in March) to include tribal governments as eligible for direct reimbursement for Title IV–E services they provide to eligible Indian children under their jurisdiction and care. We point out that the American Public Human Services Association, the organization of state social service agencies, has recently formally endorsed the provision of direct funding to tribes under the IV–E statute.

Justification.—While Congress intended for the Title IV–E program to serve all eligible children in the United States, Indian children under the jurisdiction of a tribal government and living on tribal lands do not have an entitlement to this important program afforded other children. The statute provides services only for income-eligible children placed by states and public agencies with which states have agreements. While approximately 70 tribes have been able to forge agreements with a state to access Title IV–E funds, the vast majority of tribes have no access. In those states where agreements exist, tribes often receive only a portion of the funding available overall to support foster care and adoption related services. With no stable source of foster care and adoption assistance funding, tribes have struggled to provide the same level of protection and permanency that other children are guaranteed under this federal program. By enacting the soon to be introduced legislation in the Senate that would add tribes to Title IV–E, the federal government can provide a higher level of security and permanence for Indian children than would be found in any other federal funding source.

Program.—Mental Health Performance Partnership Block Grant.

Fiscal year 2001 Enacted.—$420 million.

DHHS Division.—Substance Abuse and Mental Health Services Administration

Recommendation.—We recommend the authorizing statute be amended to provide tribal governments direct access to the Mental Health Block Grant. We recommend that 3 percent of the overall appropriation be reserved for direct allocation to tribal governments. To fund this recommendation without impacting state allocations, we also recommend increasing the overall level of appropriation by 3 percent. The specific allocation for individual tribes could be based on a formula that would be similar to the one used for the allocation of tribal funds from the Child Care and Developmental Block Grant. This formula provides a base amount of funding for every tribe, in addition to a per capita amount based on the tribe's population.

Justification.—Tribal governments do not have access to the Mental Health Performance Partnerships Block Grant and therefore miss out on funding opportunities to support mental health services for both Indian adults and children. These monies are distributed by formula to state and territorial governments, but not to tribal governments. Additionally, tribes and tribal organizations are eligible applicants for only some of the discretionary mental health grants under the Substance Abuse and Mental Health Administration. Mental health block grants not only can address immediate mental health needs, but also support long-term capacity building for tribes and the communities they represent.

Program.—Promoting Safe and Stable Families Act (Title IV–B , Subpart 2 of the Social Security Act).

Fiscal year 2001 Enacted.—$305 million capped entitlement.

DHHS Division.—Children's Bureau under ACF.

Recommendation.—Amend the authorizing legislation to increase the amount of reserved funds for tribal governments from 1 percent to 3 percent of the overall appropriation. Current levels of funding and the statutory language only allow 66 tribal grantees to be eligible to receive funding under this program.

Justification.—This program is part of an overall federal system of child welfare funding designed to support a more comprehensive array of program services in child welfare. Title IV–B, Subpart 2 helps promote services to prevent the removal of children from their homes, reunify them with their families after removal when possible and provide services to support adoption when return to the home is not possible. As an indicator of need, Indian children in the United States are placed in substitute care at a much higher rate than is the average for all other children in the nation. 12.5 out of every 1,000 Indian children are placed in substitute care, compared to 6.9 out of every 1,000 children from all races (Child Welfare League of America, 1996, with 34 states reporting substitute care data). This funding has been a good fit for tribes who have been eligible to receive grants. However, with

only a small portion of the total number of federally recognized tribes eligible, the program has had little impact on the overall need for these services in tribal communities across the United States. One of the primary purposes of the program was to stimulate systems change, a goal that is definitely needed in child welfare, but again, the small amount of funding and restricted eligibility has made it very difficult to create and sustain any meaningful change for tribal governments.

Program.—State grants under the Child Abuse Prevention and Treatment Act (CAPTA).

Fiscal year 2001 Enacted.—$21 million.

DHHS Division.—Office of Child Abuse and Neglect.

Recommendation.—We recommend that the authorizing statute be amended to provide tribal governments direct grants for child abuse prevention and treatment programs. Tribes receive no funding under the state grants.

Justification.—Given sharply increasing reports of maltreatment, (Greenfeld and Smith, 1999) prevention programming must be expanded in American Indian communities. While Indian people have a heritage for child protection, we also have a growing problem with child abuse and neglect. If we are to survive as nations, we must turn this around. It is essential that Tribes build the capacity to conduct comprehensive child abuse and neglect prevention and treatment programs. National attention on this topic is needed. It is our belief that direct tribal grants under CAPTA will be helpful in shaping future of our children.

PREPARED STATEMENT OF THE NATIONAL LATEX ALLERGY NETWORK

On behalf of the National Latex Allergy Network (formerly ELASTIC Inc.), a nonprofit voluntary health organization, and the 2.3 million Americans estimated to be sensitized to natural rubber latex. I would like to thank Senator Specter, Ranking Member Senator Harkin, and Members of the Subcommittee for the opportunity to provide written testimony.

We are respectfully requesting that the Senate subcommittee allocate federal funds to facilitate and advance research in the area of latex allergy. Scientists from all over the country are working very hard to help the growing number of people who are becoming sensitized to latex. There is a critical need for financial support in all areas of research, including pathophysiology, existing and unknown causative factors, occupational asthma, diagnostics, immunotherapy, product and environmental safety standards, treatment standards and prevention strategies.

Increased use of latex, most notably, latex gloves, to prevent infectious diseases has been followed by an increase in the number of people affected by latex allergy. In 1991, the FDA issued a medical alert in response to growing reports of allergic reactions by patients to latex-containing medical devices. At this same time the CDC was investigating clusters of anaphylactic reactions among young patients undergoing treatment at various children's hospitals across the country.

The explosion of anaphylaxis and serious allergic reactions to latex gloves and other medical equipment shocked physicians, researchers and regulatory government agencies because, quite simply, prior to the mid-1980's, latex allergy was virtually unheard of.

Latex, or more accurately, natural rubber latex, is harvested from the Brazilian rubber tree found in Africa and Southeast Asia. The culprits are certain allergenic proteins retained in varying amounts in finished products such as gloves, medical equipment, balloons, condoms and toys. With the exception of medical gloves and other medical devices, there are no regulations for content labeling or warnings.

How a product is made determines the amount of latex allergens retained in the finished item. Currently, there are no federal regulations that limit the amount of allergenic proteins in finished products. The FDA Center for Medical Devices and Radiological Health is in the process of finalizing recommendations for maximum levels of extractable protein and powder per glove for medical exam and surgeon's gloves. This has been a lengthy effort and applies only to the medical gloves regulated by this agency.

A joint statement of the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology published in 1997 defines latex allergy as an IgE-mediated latex allergy that results from cumulative exposure of susceptible individuals to natural latex rubber proteins (allergens) and identify medical gloves and equipment as the largest single source of exposure to these potent allergens. Exposure to bio-available latex allergens is by direct contact with an offending device or by inhalation of allergens carried by cornstarch powder with which most powdered gloves are coated. The clinical manifestations of latex allergy range from mild contact urticaria to fatal anaphylaxis.

Latex allergy, an IgE-mediated reaction to proteins retained in finished natural rubber latex products, has emerged in the 1990s as one of the most pervasive problems in medicine, affecting both patients and health care providers. "Latex allergy has resulted in death, progressive asthma, severe food allergy from cross-reactivity, and disability of health care professionals with the accompanied loss of self-esteem and income as a result of their inability to work in their chosen profession." (Kelly KJ, Walsh-Kelly CM—Latex allergy: A patient and health care system emergency. J Emerg Nursing Dec 1998 24;6:539–545)

While similar to peanut, stinging insects and drug allergies in the risk for life-threatening anaphylaxis, latex allergy is unique in that the latex gloves and other medical products used in emergency situations to save a life could cause a fatal anaphylactic reaction.

Since the early 1990s, the FDA has received over 2,000 adverse event reports describing allergic reactions to medical gloves containing natural rubber latex. These reports relate both to patients and users of natural rubber latex products. These reports include 16 deaths, 5 caused by latex gloves.

While working as a general dentist, I had never heard of latex allergy, let alone had any inkling of the enormous burden it would impose on my family, the dilemma it would pose for my health care providers and the debilitating effect it would have on my health. That is, not before the summer of 1994 when I was diagnosed with latex allergy and asthma caused by the latex gloves I wore everyday and the "second-hand latex" from the latex-laden powdered gloves everyone in the office used.

Nor did I think that something so innocuous that I would lose my practice and become so chronically ill those even day-to-day activities would be nearly if not totally impossible. Who would have thought the very products we used everyday as health care providers would end my career in dentistry and impose an enormous physical, emotional and financial burden on my family?

Latex glove use has spilled over to non-medical settings, so much so that a Philadelphia nurse and latex allergy prevention advocate has developed a new spin on an old nursery rhyme. "Butcher, baker, beautician, thief, mechanic, chef, fire chief . . . the common denominator here is routine latex glove use! The list of occupations also wearing gloves for barrier protection includes; farmers, produce pickers, factory workers, restaurant and food service workers, day care workers, dog groomers, landscapers, painters, toll collectors, auto factory workers as well as florists, housekeeping and janitorial service workers, students for science, art and shop classes.

Latex allergy develops primarily because of repeat exposure to significant levels of allergenic proteins retained in finished products made from natural rubber latex (NRL), in particular latex gloves and other medical equipment that contact mucosal tissues.

The transfer of allergenic latex proteins from glove surfaces to food products has been scientifically documented resulting in an often hidden source of latex exposure for consumers. Disposable latex gloves, commonly utilized by food handlers, are a source of indirect food additives violating Section 402(a)(1) of the FDA Food Regulations which state: "A food is illegal (adulterated) if it bears or contains an added poisonous or deleterious (harmful) substance which may render it injurious to health."

Health risks to consumers and workers associated with latex glove use in all aspects of food service—from farm to table. As stated in the 1999 Food Code Annex 3 3–3–4.15; 3–304.15—Gloves, Use Limitation—"Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2 for this section)." The FDA is currently evaluating safety issues associated with latex glove use in the food industry.

Avoidance of latex allergens is presently the only method to prevent reactions, latex-related asthma and latex sensitization. Commonplace use of medical and non-medical latex gloves as well as hundreds of other products encountered in daily life makes this task extremely difficult. Ironically, the prevalence of latex in gloves and other life-saving equipment used by first responders, emergency medical service providers, emergency rooms and hospitals, has resulted in a critical public health crisis—access to safe emergency and routine health care for the growing number of latex allergic patients.

Mr. Chairman, I thank you again for the opportunity to provide the Committee with information about this newly emerged disease, latex allergy. Government agencies are working hard to provide product and environmental standards and guidelines. Federal funding for medical research would provide the thousands of families affected by latex allergy a source of hope for universal access to safe health care, safe school and work environments and especially hope for a cure. Please help us

advance and expedite treatment and a cure for latex allergy by providing funding for research.

PREPARED STATEMENT OF THE NATIONAL DOWN SYNDROME SOCIETY

Chairman Stevens, Members of the Committee: The National Down Syndrome Society is pleased to submit written testimony in support of improved health care for individuals with mental retardation, including people with Down syndrome.

NATIONAL DOWN SYNDROME SOCIETY (NDSS)

The National Down Syndrome Society represents more than 350,000 individuals with Down syndrome who live in the United States, their families, friends and professionals who serve them. The National Down Syndrome Society was established in 1979 to ensure that all people with Down syndrome have the opportunity to achieve their full potential in community life. Since that time, NDSS has become the largest non-governmental supporter of Down syndrome research in the United States. Today, NDSS continues to increase public awareness about Down syndrome and discover its underlying causes through research.

Under the leadership of a Board of Directors, Scientific Advisory Board, Clinical Advisory Board, Affiliate Advisory Board and Self-Advocate Advisory Board, NDSS distributes timely and informative materials, supports activities of local parent support groups, sponsors conferences and scientific symposia and undertakes major advocacy efforts—all to help improve lives of people with Down syndrome.

More than 125 parent support groups and related member organizations comprise the NDSS Affiliate Program. The NDSS affiliate members form the grassroots structure of the organization and represent thousands of individuals with Down syndrome and their families from around the country.

DOWN SYNDROME

Down syndrome is the most commonly occurring chromosomal abnormality, occurring in approximately one in every 800 to 1,000 live births. There are approximately 6,000 people born with Down syndrome in the United States each year and thousands more impacted by this genetic condition. Most people with Down syndrome have some degree of mental retardation, usually in the mild to moderate range.

Children with Down syndrome are at increased risk for certain health problems. Congenital heart defects (50 percent), endocrine problems (10 percent), neurological conditions (10–20 percent), increased susceptibility to infection, respiratory problems, obstructed digestive tracts and childhood leukemia occur with greater frequency among children who have Down syndrome. Adults with Down syndrome are at a significantly increased risk for Alzheimer's disease (25 percent), dental problems, thyroid concerns, musculoskeletal problems and depression. These, of course, do not include the many other kinds of health care problems that everyone in the population is susceptible to.

Today, the average life expectancy of individuals with Down syndrome is approximately 55 years, with many living even longer. As this population ages, the need for access to adequate health care and for well-trained professionals to address these needs, becomes even more critical.

HEALTH CARE PROBLEMS FOR PEOPLE WITH DOWN SYNDROME

While advances in medicine have rendered most of these health problems treatable, some people with Down syndrome do not have access to necessary care. NDSS has identified the following major health care issues, based on speaking to many of our constituents:

—Physicians and health care professionals not adequately trained to meet the medical and health care needs specific to individuals with Down syndrome.

—Access to health care and surgical procedures being denied to individuals with Down syndrome based on discrimination and attitudes, rather than medical necessity.

—People being denied health insurance on the basis of Down syndrome being considered a "preexisting condition."

These problems with the current systems as they relate to individuals with Down syndrome represent just some of the issues we hear.

THE CHALLENGE

Throughout the years, NDSS has heard hundreds of stories from parents about insensitive attitudes on the part of health care professionals, whether in presenting

a diagnosis of Down syndrome or in treatment, as well as professionals being inadequately prepared with the necessary information and resources to work with their child. NDSS has also been contacted by numerous physicians, nurses, social workers, genetic counselors and others seeking information and resources that will help them to better care for their patients who have Down syndrome. There is very limited training available for health care professionals on how to address the specific needs of people with Down syndrome.

There are many resources available, such as the Down Syndrome Health Care Guidelines, which are critical in helping to ensure that adequate attention is paid to particular health care concerns. The challenge has been getting these resources into the hands of those who need it the most. NDSS works closely with the Down Syndrome Medical Interest Group, comprised of more than 150 physicians and clinicians worldwide who have an interest in working with this population, to share information and develop resources that will improve the quality of life for individuals with Down syndrome.

Attached is a summary of Down Syndrome Health Care Guidelines, based on Health Care Guidelines for Individuals with Down Syndrome: 1999 Revision (Down Syndrome Preventive Medical Check List), published in Down Syndrome Quarterly (Volume 4, Number 3, September, 1999, pp. 1–16).

CONCLUSION

The opportunities today for individuals with Down syndrome and mental retardation have never been greater, thanks to the commitment and dedication of many legislators, organizations, families and agencies. In the past 25 years alone, groundbreaking legislation has lead to de-institutionalization, inclusion in schools and a no-tolerance attitude towards discrimination against people with disabilities. Now that the laws are in place and the opportunities to succeed available, we owe it to people with mental retardation to ensure they are healthy enough to take advantage of all that is available.

We appreciate your taking the time to read our testimony, and applaud you for your interest in helping to improve health care for people with mental retardation. Please do not hesitate to contact us if we may be of any assistance to you in your efforts.

ATTACHMENT I—ADDRESSING THE HEALTH CARE NEEDS OF PEOPLE WITH DOWN SYNDROME

The National Down Syndrome has been dedicated to improving health care for individuals with Down syndrome since its inception in 1979. Under the direction of a Science Advisory Board and Clinical Advisory Board comprised of distinguished, world-renowned experts on Down syndrome-related issues, NDSS has developed programs and resources to address these needs.

Science Scholar Award Program.—Each year NDSS awards research grants to promising postdoctoral scientists who have demonstrated extraordinary skill and achievement in seeking a better understanding of Down syndrome. Since 1983, more than twenty researchers have received this prestigious salary grant.

Research Partnership.—NDSS, the National Institute of Child Health and Human Development and the National Institute of Neurological Disorders and Stroke are engaged in a $3.9 million partnership to further Down syndrome research. The funding goes to organizations and individual researchers studying Down syndrome-specific cognition, behavior and related therapies. The $3.9 million partnership represents the most funding ever earmarked for Down syndrome research.

International Down Syndrome Research Conference.—In an effort to increase communication among the world's most distinguished scientists working in fields related to Down syndrome, NDSS hosts international scientific conferences on relevant research topics. The proceedings of these conferences are published and distributed worldwide.

Educational Services.—The NDSS Information and Referral Center responds to over 25,000 requests annually via E-mail and toll-free hotline. A large percentage of these requests are related to health care issues. NDSS has developed and disseminated a Clinical Care Booklet series to educate parents and professionals about some of the most commonly occurring health care problems, including the Heart, the Endocrine System, Neurology, Alternative Therapies, Speech and Language, and others.

Changing Lives: Down Syndrome & the Health Care Professional Program.—This new program, still in the pilot phase, is being developed to support health care professionals in the delivery of appropriate care and to help children with Down syndrome get the healthy start they deserve. The program aims to educate health care

professionals in the community about Down syndrome and how best to treat and diagnose these patients; educate health care professionals on the medical and developmental needs a baby with Down syndrome may have and the best care practices to address these needs; provide health care professionals with materials and resources to share with new and expectant parents of children with Down syndrome; and raise the awareness of health care professionals of how attitudes and beliefs affect the experience of raising a child with Down syndrome.

ATTACHMENT II—NDSS SCIENCE ADVISORY BOARD AND CLINICAL ADVISORY BOARD

SCIENCE ADVISORY BOARD

David Patterson, Ph.D., Chair, Eleanor Roosevelt Cancer Research Institute, CO; Terry J. Hassold, Ph.D., Department of Genetics, Case Western Reserve University, OH; Julie R. Korenberg, Ph.D., M.D., Department of Pediatrics, Cedars-Sinai Medical Center, CA; Ira T. Lott, M.D., Department of Pediatrics, Irvine Medical Center, CA; and Lynn Nadel, Ph.D., Department of Psychology, University of Arizona, AZ.

CLINICAL ADVISORY BOARD

William I. Cohen, M.D., Chair, Down Syndrome Center of Western PA, Children's Hospital of Pittsburgh, PA; Joan E. Guthrie Medlen, R.D., Disability Solutions, OR; Jon F. Miller, Ph.D., Waisman Mental Retardation Center, University of Wisconsin-Madison, WI; Bonnie Patterson, M.D., Cincinnati Center for Developmental Disorders, University of Cincinnati, OH; Richard A. Villa, Ed.D., Bayridge Consortium, Inc., CA; Leslie Walker-Hirsch, M.Ed., Moonstone Group, NY; and Patricia C. Winders, PT, Down Syndrome Clinic, Kennedy Krieger Institute, MD.

ATTACHMENT III—SUMMARY OF DOWN SYNDROME HEALTH CARE GUIDELINES

(Based on Health Care Guidelines for Individuals with Down Syndrome: 1999 Revision, Down Syndrome Preventive Medical Check List, published in Down Syndrome Quarterly, Volume 4, Number 3, September, 1999, pp. 1–16)

DOWN SYNDROME—NEONATAL (BIRTH–1 MONTH)

Review parental concerns. Chromosomal karyotype; genetic counseling, if necessary.

If vomiting or absence of stools, check for gastrointestinal tract blockage (duodenal web or atresia, or Hirschsprung disease).

Evaluation by a pediatric cardiologist including echocardiogram. Subacute bacterial endocarditis prophylaxis—SBE, in susceptible children with cardiac disease.

Exam for plethora, thrombocytopenia.

Review feeding history to ensure adequate caloric intake.

Thyroid function test—check on results of state-mandated screening at birth.

Auditory brainstem response (ABR) or otoacoustic emission (OAE) test to assess congenital sensorineural hearing (at birth or 3 months).

Pediatric ophthalmological evaluation (by 6 months) for screening purposes.

Discuss Early Intervention (infant stimulation) and refer for enrollment in local program.

Refer to local DS parent group for family support and resources, as indicated. Refer to NDSS.

DOWN SYNDROME—INFANT (1–12 MONTHS)

General neurological, neuromotor, and musculoskeletal examination.

TSH and T4—Thyroid Function Test (at 6 & 12 months).

Evaluation by a pediatric cardiologist including echocardiogram, if not done at birth.

Consider progressive pulmonary hypertension in patients with a VSD or atrioventricular septal defect who are having little or no symptoms of heart failure.

Subacute bacterial endocarditis prophylaxis—SBE (as indicated).

Well Child Care—immunizations.

Feeding consult, especially if constipated. Consider Hirschsprung disease.

Auditory brainstem response (ABR) or otoacoustic emission (OAE) test to assess congenital sensorineural hearing (by 3 months if not performed previously or if results are suspicious).

Ear, nose and throat exam (as needed), especially if suspicious of otitis media.

Vision exam (by 6 months & annually), earlier if nystagmus, strabismus or poor vision.

Discuss early intervention and refer for enrollment in local program (if not done yet).

Application for SSI, depending on family income; consider estate planning/custody arrangements; continue family support.

DOWN SYNDROME—CHILDHOOD (1–12 YEARS)

TSH and T4—Thyroid Function Test (annually).

Echocardiogram by a pediatric cardiologist if not done previously.

Behavioral Auditory Testing (every 6 months until age 3, annually thereafter).

Lateral cervical spine x-rays (neutral view, flexion, extension) to rule out atlanto-axial instability. Radiologist to measure atlanto-dens distance and neural canal width (at 3–5 years, then as needed).

General pediatric and neurological exam including evaluation for signs of spinal cord compression: deep tendon reflexes, gait, Babinski sign.

Use Down syndrome growth charts and head circumference charts, as well as growth charts for typically developing children.

Eye examination (annually, or more often as indicated).

Screen for celiac disease IgA antiendomysium antibodies and total IgA (between 2–3 years).

Question about obstructive sleep apnea; ear, nose and throat exam (ENT) (as needed).

Dental Exam (2 years; follow up exams every 6 months after). Twice daily teeth brushing.

Reinforce need for subacute bacterial endocarditis prophylaxis (SBE) for cardiac problems (as indicated).

Brief vulvar exam for girls.

Well Child Care—immunizations; administer pneumococcal vaccine (2 years).

Well balanced, high fiber diet. Regular exercise program.

Evaluation by a speech and language pathologist to maximize language development and verbal communication.

Review parental concerns; current level of functioning; monitor for behavior problems.

Complete educational assessment annually, as part of Individualized Family Service Plan (IFSP) for child from birth to 3 years of age, or Individualized Educational Plan (IEP) from age 4 until the end of formal schooling.

Continue speech therapy and physical therapy (as needed).

DOWN SYNDROME—ADOLESCENCE (12–18 YEARS)

TSH and T4—Thyroid Function Test (annually).

Auditory Testing (annually).

Cervical spine x-ray, if required by Special Olympics.

Monitor for obstructive airway disease and sleep apnea.

General physical and neurological examination (check for atlanto-axial dislocation).

Eye examination (annually).

Dental Exams (every 6 months). Twice daily teeth brushing.

Monitor for obesity by plotting height for weight on the growth charts for typical children.

Clinical evaluation of the heart to rule out mitral/aortic valve problems. Echocardiogram (ECHO) as indicated by clinical findings.

Reinforce the need for subacute bacterial endocarditis prophylaxis (SBE) in susceptible adolescents.

Adolescent medicine consult for puberty/sexuality issues; health, abuse prevention and sexuality education. Pelvic exam (only if sexually active).

Low calorie, high fiber diet; regular exercise program.

Smoking, drug and alcohol education.

Psychoeducational evaluations (every two years), for Individualized Educational Plan (IEP).

Begin functional transition planning (age 16 years).

Consider enrollment for SSI depending on family income; monitor independent functioning.

Update estate planning and custody arrangements; discuss plans for alternative long-term living arrangements such as community living arrangements.

DOWN SYNDROME—ADULTHOOD (OVER 18 YEARS)

TSH and T4—Thyroid Function Test (annually).

Auditory testing (every 2 years).

Cervical spine x-rays as needed for Special Olympics participation (or as indicated).

Opthalmologic examination, looking especially for keratoconus and cataracts (every 2 years).

Dental Exam (every 6 months). Twice daily teeth brushing.

Clinical evaluation of the heart to rule out mitral/aortic valve problems. Echocardiogram (ECHO) as indicated by clinical exam.

Reinforce need for subacute bacterial endocarditis prophylaxis (SBE) in susceptible adults with cardiac disease.

Baseline Mammography at 40 years. Follow up every other year until 50 years, then annually.

Pap smear and pelvic exam (every 1–3 years following the age of first intercourse). If not sexually active, single-finger bimanual examination with finger-directed cytology exam. If unable to perform, screen pelvic ultrasound (every 2–3 years). Breast exam (annually).

General physical/neurological exam (atlanto-axial dislocation); routine adult health care.

Clinical evaluation for sleep apnea.

Low calorie, high fiber diet. Regular exercise. Monitor for obesity.

Health, abuse prevention & sexuality education.

Smoking, drug and alcohol education.

Clinical evaluation of functional abilities (consider accelerated aging); monitor loss of independent living skills.

Neurological referral for early symptoms of dementia (decline in function, memory loss, ataxia, seizures and incontinence of urine and/or stool).

Monitor for behavioral/emotional changes, mental health. Psych Referral (as needed).

Continue speech and language therapy, as indicated.

Discuss plans for programming/vocational opportunities at age 21 or end of formal schooling.

Discuss alternative long-term living arrangements; estate planning/custody arrangements.

PREPARED STATEMENT OF THE NATIONAL MARFAN FOUNDATION

Chairman Specter and members of the Committee, the members of the National Marfan Foundation (NMF) thank you for the opportunity to provide written testimony in support of the budget of the National Institutes of Health (NIH) and the National Institute of Arthritis, Musculosketetal and Skin Diseases (NIAMS). This is the first year that the NMF is submitting written testimony on its own. We have been previously included in the written and spoken testimony of the Coalition for Heritable Disorders of Connective Tissue (CHDCT). We would first like to express our gratitude of the Committee's ongoing support of NIH research, and most particularly their support for increased funding for research on rare and genetic disorders—research that might not otherwise have been funded.

The NMF believes that we must sustain the current level of commitment to the NIH. The NMF joins the Ad Hoc Group for Medical Research Funding, the Coalition of Heritable Disorders of Connective Tissue, the NIAMS Coalition, and the Coalition of Patient Advocates for Skin Disease Research in asking that Congress support a 16.5 percent increase in the budget of the NIH for fiscal year 2002. This increase would allow us to get back on track the bipartisan effort to double the NIH budget by fiscal year 2003—a sentiment shared by the President, the Congress and the American people.

The Marfan syndrome is a potentially fatal, relatively rare genetic disorder of the connective tissue. The NMF requests the establishment and support of Scientific Research Centers for Marfan Syndrome and Related Disorders which will allow these centers to gather significant numbers of Marfan affected people to investigate clinical therapies, which in the case of a rare and multi-system disorder, are the only way to compile enough individuals to establish well-controlled clinical studies. This can bring about a comprehensive understanding of the clinical burden of this syndrome and help to predict manifestations of the disease before they occur. In addition, the recruitment of geneticists, molecular and cell biologists who can contribute their expertise to a common problem, serve to coordinate basic research and enable these studies to be translated rapidly into advances in patient care. The goal of establishing Scientific Research Centers for the Marfan Syndrome and Related Disorders can only be accomplished through the available mechanisms of the National Institutes of Health.

The NMF represents people affected with the Marfan syndrome. Voluntary health organizations such as ours consistently hear the frustrations, confusion and despair of people who deal with the daily medical issues associated with genetic disorders. In multi-systemic disorders such as Marfan syndrome, numerous physicians in specialties such as cardiology and cardiovascular surgery, orthopedics, ophthalmology, respiratory/pulmonary, neurology, and genetics must be consulted to manage the manifestations of this syndrome. The families are distraught from the overwhelming emotional turmoil of dealing with so many doctors and the fear of losing 2 their life at an early age, not to mention the tremendous monetary burden. These circumstances are multiplied many times over since this genetic disorder can affect more than one family member and more than one generation.

It is estimated that a quarter of a million people in the United States are affected by the Marfan syndrome and relate disorders. The Marfan syndrome is a potentially fatal, genetic disorder of the connective tissue. The Marfan syndrome is a multi-system disorder because the connective tissue is essentially the glue and the scaffolding of the body, and manifests itself in the heart, eyes, skeleton and blood vessels. Individuals with the Marfan syndrome are uncharacteristically tall, with arms, legs, toes and fingers that are disproportionately long and thin. Typically, patients also have poorly developed muscles and abnormally curved spines.

The life-threatening aspect of this disorder is the weakening of the aorta, the largest artery that supplies blood to the heart. In the Marfan syndrome, the abnormalities in the connective tissue place a great deal of stress on the aortic artery and significantly weaken the walls of this most important blood vessel. Tears form in the walls of the aorta and death can only be prevented by surgical intervention. There is no simple diagnosis for the Marfan syndrome. Many patients who present in emergency rooms fail to receive life-saving treatments. For example Jonathon Larson, the Tony awardwinning playwright of the hit Broadway musical "Rent", died at the age of 35 after being misdiagnosed by two different hospital emergency rooms. In addition, communities across this country often are faced with the premature death of a future basketball star or athlete, because parents, coaches, and physicians failed to realize that their height, a tremendous asset on the basketball court or other athletic arena was in reality a sign of the Marfan syndrome. This was unfortunately the case for Flo Hyman, the captain of the 1984 U.S. Olympic Women's Volleyball Team. She was not diagnosed with the Marfan syndrome until after her death from aortic dissection at the age of 31 on the volleyball court. Similar scenarios are noted in many cases. A woman who lost a brother, a sister and a son to the Marfan syndrome remembers how she learned about the disorder, "It was the first day of school for my three excited sons and the bus was just minutes from arriving. Suddenly my son fell to the ground in convulsions and extreme pain. It took the hospital 28 hours to determine the problema four-foot long tear in his aorta . . ." It is stories such as these that move us to advocate for this Committee's support for increased research funding. Research is the only hope for Marfan-affected individuals.

To this day ignorance still exists on how to adequately diagnose the Marfan syndrome. Many people die at a young age in the emergency room with a ruptured aorta because these people were never diagnosed. One of the main problems is that there is no simple diagnostic test for this multi-system disorder. Because most features of the Marfan syndrome progress with age, the diagnosis is often more obvious in older persons however, this can turn out to be deadly. Furthermore, those persons who are considered to be candidates of this syndrome but cannot get a precise diagnosis must also continually monitor themselves since the 3 symptoms manifest over time. Research is desperately needed in this area. Development of a rapid molecular diagnostic test could save thousand of lives.

Research into the basic mechanisms of the Marfan syndrome has borne fruit. In 1991, scientists discovered the cause of the Marfan syndrome, an alteration of the gene that encodes the protein fibrillin-1. Although this important finding did not lead us directly to a cure, it has allowed scientists to focus their research to look for answers to more specific questions. More research is needed to determine how this mutant gene actually produces the change in human biology that leads to this disease and is responsible for variability within the syndrome from mild to extremely severe cases. Additional basic research in molecular studies will also help us to fully investigate the interaction of the fibrillin-1 gene product with other molecules in the extracellular matrix to better understand pathogenesis of this disease. The use of this knowledge to develop a genetic manipulation strategy to eventually cure this disease is becoming technically feasible but is years away. In the meantime, more immediate issues need to be dealt with.

Clinical research is needed to identify strategies and therapies for reducing aortic enlargement, to determine the optimal time for surgical intervention and to predict

risk for aortic dissection. This is extremely important to save lives as noted in a recent letter to the NMF. A young woman writes "My cousin's 17 year-old daughter died with a ruptured aortic aneurysm. She knew she had Marfan syndrome and had echocardiograms every six months. Her aorta was not large enough for surgery but she must have not read the book, because she died anyway. She had an echocardiogram just six weeks before she died." It is stories such as these that alert us to the fact that much more research is needed in this most crucial area. It is imperative to determine what are the clinical features and presentations of acute aortic dissection in Marfan patients and how is this different from non-Marfan patients.

Clinical research can also offer more solutions to be used immediately to alleviate some of the pain and disabling effects such as curvature of the spine, dislocated lenses in the eye, and abnormalities in the heart valves. Clinical research of treatments for back pain due to scoliosis and more specifically for dural ectasia, the enlargement of the membrane that surrounds the brain and spinal cord, are desperately needed to reduce the amount of pain and suffering endured by Marfan-affected individuals.

Funding biomedical research through the NIH is today's investment in America's future. The technology and the science are available to understand and ultimately cure or eradicate many of these devastating genetic disorders. Support for the NIH is especially crucial to unlocking the mysteries of rare diseases, such as the Marfan syndrome. We need your support.

PREPARED STATEMENT OF THE NATIONAL MEDICAL ASSOCIATION

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to present the views of the National Medical Association (NMA). I am Dr. Rodney Hood, President of the NMA, and a practicing internist in San Diego, CA.

I am very pleased to have the opportunity to submit NMA's fiscal year 2002 appropriations priorities to this Subcommittee. Established in 1895, the National Medical Association is the Nation's largest and oldest professional, educational and scientific organization representing the interests of more than 26,000 African American physicians and their patients, as well as nearly 100 state and local societies. As such, the NMA has been committed to improving the health status and outcomes of minority and disadvantaged people for more than 105 years. And while the Association has focused primarily on health issues related to African Americans and medically underserved populations, NMA's principles, goals and initiatives benefit all people.

As the leading force for parity and justice in medicine and the elimination of disparities in health, the NMA's primary goals include improving the health status and health outcomes of minorities. In our quest to improve healthcare, we have promoted the increased representation of African Americans and other underrepresented minorities in the health professions; the integration of hospitals and universities; the protection of the rights of our patients involved in—and increased participation in—biomedical research and the promotion of increased access to health care services for all Americans.

In recent years, there have been considerable discussions about eliminating the health disparities that pervade our nation's minority populations, to the extent that there are now national initiatives to close the gap. In order to understand the critical need to provide increased federal funding for programs established to address the health status of African Americans and other medically underserved populations, it is important to know that centuries of discrimination against African Americans have left us with a complicated legacy of poor health outcomes, illness, disease and death that are widespread and pervasive. This is what authors W. Michael Byrd, M.D., M.P.H. and Linda A. Clayton, M.D., M.P.H. call the Slave Health Deficit. The programs supported by this Subcommittee are critical to the elimination of health disparities. NMA looks forward to working closely with the Subcommittee and relevant federal agencies to ensure that the tremendous advances made through biomedical research, health professions training and community based public health and disease control are equally available to all Americans, particularly those who have not fully benefited from these advances.

SUPPORT THE DEVELOPMENT OF A HEALTH POLICY AND RESEARCH INSTITUTE

Recently, NMA joined the Office of the U.S. Surgeon General and the American Public Health Association, in partnership with the nation's leading health providers and business leaders, to issue a Call to the Nation to Eliminate Racial and Ethnic Health Disparities. In response to this challenge, the National Medical Association urges Congress to provide $1 million to support the development and implementa-

tion of a Health Policy and Research Institute focused on achieving health parity for African Americans. NMA is concerned that historic and current data points to a modern-day form of "health care racial profiling" that must be addressed if we are ever going to achieve parity in health care. Recent studies are confirming what minority—particularly African American—physicians, health professionals and caregivers have known for years: there are significant disparities in the quality of healthcare provided to minority patients across this nation. In addition, there are disparities in training and professional advancement opportunities for minority medical students and professors of medicine; and in opportunities for equitable participation by minority physicians in the managed care system. NMA strongly believes that without achieving parity in the health status of African Americans, who experience disproportionate rates of disease, morbidity and mortality, the goals of the U.S. Surgeon General's Healthy People 2010 Initiative will remain unattainable.

NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES, NIH

Mr. Chairman, the disparate health status experienced by African Americans and other minorities is a serious problem that threatens to increase in complexity as the Nation, with its growing minority population, proceeds through the 21st century. The long-term prognosis for the elimination of health disparities among minorities is largely dependent upon a strong federal commitment to biomedical research and research training. However, in order to fully realize the benefits of scientific investigation, research and research training, much more needs to be done by the National Institutes of Health (NIH) and policy makers to ensure that those who are suffering disproportionately, with chronic and debilitating diseases, are able to share in these advances.

NMA is pleased that Congress supported the elevation of the Office of Research on Minority Health at NIH to Center status, during the 107th Congress. This effort is critical to the Nation's ability to effectively address the disproportionate cancer, and other disease, mortality rates that exist among minorities and the underserved. This Center will enable NIH to ensure that research targeted towards minorities is carefully and strategically coordinated across the Institutes and provide increased support for important minority focused biomedical research projects. Additionally, the Center will help NIH to address the, often systematic, oversight of minorities in clinical trials.

NMA supports fiscal year 2002 budget increase of $3.4 billion (16.5 percent above the fiscal year 2001 funding level), for the National Institutes of Health, to keep us on the path toward doubling the NIH budget by fiscal year 2003. NMA sincerely hopes that as increased funding is made available to NIH, Congress will provide adequate funding specifically targeted towards programs to improve the status of minority health. NMA recommends that the National Center for Minority Health and Health Disparities be funded at a level adequate to support the Center's expanded agenda as well as the broadened populations it serves.

Funded at an estimated $130 million, in fiscal year 2001, more than $90 million of the Center's budget is identified to support specific, longitudinal research efforts and programs. That provides very little latitude with which the Center can sufficiently support new or expanded functions, such as Research Endowments, Centers of Excellence and the Loan Repayment program.

Now that there is a greater recognition of the need to make improving the health status of minority Americans a national priority, the NMA is asking this Subcommittee to make the same commitment to minority health research.

HEALTH PROFESSIONS TRAINING THROUGH THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The NMA strongly urges the Subcommittee to substantially provide increased funding for Health Professions Training Programs at HRSA and supports the Health Professions and Nursing Education Coalition's recommendation of at least $440 million for Title VII and VIII, of the Public Health Service Act, in fiscal year 2002. Each one of the Health Professions Training Programs, including the Training for Diversity Programs, impact minorities, and other Americans, who reside in Health Professions Shortage Areas (HPSA's) where there are shortages of both primary care and specialist physicians. Funding cuts to these programs will negatively impact the ability of minorities to pursue careers in health, as well as the patients who benefit from their training.

Nearly all of the Health Professions Training Programs fund a variety of programs that are essential for students and institutions that work to improve the racial and ethnic diversity of the health professions workforce. These programs ensure that all Americans, regardless of their race or geographic location, have access to

quality health care services. Narrowing the health status gap that exists between minorities and non-minorities is a national priority. Thus, increasing the numbers of minorities in the health professions training pipeline, as well as those serving in the health professions, is absolutely critical to accomplishing this goal.

Numerous responsible studies demonstrate that, historically, African Americans and other minorities are more likely than their non-minority counterparts to serve in medically underserved areas. However, while African-Americans represent approximately 12 percent of the U.S. population, they represent only 2–3 percent of the Nation's medical professionals.

Mr. Chairman, this Subcommittee has always been a strong supporter of the Health Professions Training Programs. Your continued support is vital to ensuring that bright, capable minority students who want to pursue careers in the health professions have that opportunity, despite the looming financial burdens and matriculation challenges. We appreciate and recognize all that you have done for health professions training in the past and urge you to be even more ardent supporters in fiscal year 2002.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) RACIAL AND ETHNIC HEALTH DISPARITIES INITIATIVE

The National Medical Association strongly supports increased funding for the DHHS initiative to reduce racial and ethnic disparities in health [Racial and Ethnic Approaches to Community Health (REACH) Initiative]. Studies clearly indicate that there is a connection between race and ethnicity and the growing health disparities and disease burden among African Americans and other underserved racial and ethnic minorities. With the Nation's changing demographics, it is anticipated that minorities will comprise nearly 50 percent of the United States population during the 21st Century. Increased support of this initiative is critical to the future health of this nation and its workforce.

Currently funded at $35 million, the REACH Initiative must be funded at a level that will allow the CDC, in collaboration with OMH and other appropriate federal agencies, to intensify its efforts to eliminate health disparities by funding additional communities for Phase I planning grants, Phase II comprehensive grants, training activities under national and regional minority organizations, expanded and enhanced technical assistance, research on social and behavioral determinants, distance-based training, effective health interventions and targeted health outcomes.

Additionally, in recognition of the strengths that national/multi-geographical minority organizations can provide this program, NMA urges the Committee to request that DHHS include such organizations among the entities that are eligible to compete for funding without preventing other applicants from receiving these grants. Such organizations often have the capacity to influence communities through coalitions and collaborative relationships that have already been established and provide essential support to local organizations that may lack the infrastructure needed to implement the full scale of programmatic activities required for this important program.

The REACH Initiative is critical to enhancing efforts geared towards disease prevention, health promotion and the delivery of care to racial and ethnic minorities. Adequate support of this critical program will enable us to gain a better understanding of the relationship between race and ethnicity and health status, thereby giving us tools that will help us to eliminate health disparities. The development of close working relationships with minority communities is critical to ensuring that programmatic implementation strategies and activities, such as data collection, are culturally sensitive and appropriate.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) OFFICE OF MINORITY HEALTH (OMH)

NMA was pleased that, for fiscal year 2001, Congress provided $50 million in funding for the Office of Minority Health. However, given the additional demands the DHHS Health Disparities Initiative has placed on this office, such funding remains inadequate to meet the programmatic needs of the Office. NMA strongly supports providing adequate funding for OMH to ensure continued support for the Office's current programs as well as the expansion of its critical efforts. Significantly more support is needed to allow OMH to accomplish the goals established by the Health Disparities Initiative.

STUDY ON ETHNIC BIAS IN MEDICINE

Mr. Chairman, during fiscal year 2000, Congress commissioned an Institute of Medicine (IOM) Study on "Ethnic Bias in Medicine." This study will help provide

a clear understanding of the extent to which ethnic bias is ingrained in the practice of medicine and the education of health professions students. Such knowledge is absolutely essential to the effort to eliminate health disparities by 2010. NMA recommends the Subcommittee request that the Institute of Medicine report back to the Committee regarding the findings and recommendations of the study, upon its completion, and urges the Committee to convene a hearing to address this important study.

HEALTH CARE INITIATIVE FOR THE UNINSURED

In order to provide medical care to the estimated 46 million uninsured Americans, physicians and other health care providers, who provide this care, must often waive payment or provide care on a reduced basis to the uninsured. In fact, studies show that minority physicians provide disproportionate levels of care for the uninsured. At the same time, the number of uninsured workers has increased and changes in managed care have led to reduced Medicaid revenues. The NMA is concerned about ensuring that uninsured Americans receive health care coverage and that physicians are able to receive an equitable reimbursement for their services. Therefore, we strongly urge the Subcommittee to provide adequate support for this much-needed initiative to strengthen health services for uninsured workers. This initiative will provide grants, over five years, to strengthen the ability of public and private entities, in 100 communities, to provide comprehensive care and coordinate health care for uninsured workers.

MINORITY HIV/AIDS INITIATIVE

While new treatment therapies have led to the recent decline in HIV/AIDS death rates, African Americans continue to die from this disease at disproportionate rates. In fact, recent data from the Centers for Disease Control and Prevention shows that AIDS is the number one killer of African American men between the ages of 25 and 44 and the second leading cause of death among African American women of the same age. And, while Blacks and Hispanics accounted for 65 percent of AIDS cases, estimates indicate that by the year 2005, Blacks will account for 60 percent of all AIDS cases.

Mr. Chairman, the data paints a clear picture of the devastation HIV/AIDS has brought to minority communities. The NMA thanks the Committee for its support of the Minority HIV/AIDS initiative during the fiscal year 2001 funding cycle and recommends full funding in fiscal year 2002 funding for this critical initiative to address HIV/AIDS across the nation's racial and ethnic minority communities. The Minority AIDS initiative is in the early stages of implementation. Funding for this program needs to be increased to a level that will sustain and expand its current efforts. This program's infrastructure and capacity to address disparities in AIDS must be strengthened.

HEALTHY PEOPLE 2010

The National Medical Association views the Healthy People 2010 initiative as one of great importance. Healthy People 2010 is to be commended for making the health objectives identical for all Americans, rather than having different (generally lower) targets for minorities as was the case for the Healthy People 2000 initiative. The NMA strongly believes that all health status targets should be the same for all Americans. We urge the Subcommittee to continue to provide the necessary resources to the Department of Health and Human Services to fund this important initiative.

IN CLOSING

Mr. Chairman, thank you for the opportunity to present the views of the National Medical Association. I am pleased to respond to any questions that you have. Our Association looks forward to working with this Subcommittee to address the challenges we have outlined for you today.

PREPARED STATEMENT OF THE NATIONAL MPS SOCIETY INC.

Mr. Chairman and members of the Subcommittee: My name is Les Sheaffer, I serve on the Board of Directors of the National MPS Society and chair the Committee on Federal Legislation. My daughter Brittany is 8 years old and is suffering with MPS III. I have submitted this testimony to express the views of the National MPS Society regarding the budget of the National Institutes of Health.

I wish to offer my thanks to Chairman Specter and the members of the Subcommittee for their continued support for genetic and biomedical research through the National Institutes of Health.

The Mucopolysaccharidosis disorders are relatively rare genetically determined disorders caused by the body's inability to produce certain enzymes. The lack of production of these vital enzymes results in the interruption of the usual breakdown of specific normal molecules, which are then stored in every cell in the body. Storage causes progressive damage including respiratory system, bones, internal organs, nervous system and brain damage. The most profound effect of these disorders is the poor quality of life these children eventually endure and a drastically shortened life span. These disorders manifest themselves in children sometimes at birth and develop more rapidly with age as cells become more damaged by storage.

The MPS disorders are inherited when both parents are carriers of a recessive gene that causes enzyme deficiency in the child. The parents maintain a 1 in 4 chance of producing a MPS child with each pregnancy. The exception is MPSII in which the mother may be the carrier and normally only boys are affected. The occurrence of MPS in the general population is believed to be 1 in 25,000 births.

There are eight types of MPS disorders; Huler Syndrome MPS IH, Scheie Syndrome MPS IS, Huler/Scheie Syndrome MPS IHS, Hunter Syndrome MPS II, Sanfilippo Syndrome MPS III, Morquio Syndrome MPS IV, Maroteaux-Lamy Syndrome MPSVI, and Sly Syndrome MPS VII. All MPS disorders result in some combination of the affects listed above.

NIH funded research is a cornerstone component in the effort to develop treatments for these deadly diseases. The grants funded by NIH have resulted in a great deal of important information that is integral in the quest for viable treatments for the MPS disorders. There is no question that NIH appropriations for genetic and biomedical research are truly an investment of federal funds.

NIH supported grants relating to MPS over the past few years have included: bone marrow therapy, animal models, gene therapy, enzyme therapy, molecular studies, stem cell research and other studies. Through the support of the NIDDK, NINDS and NICHD these projects are contributing to a better understanding of MPS disorders as well as narrowing down possible viable treatment options for MPS. There is still much work to be done, with adequate funding this important work can continue.

The 14.2 percent increase for NIH in the fiscal year 2001 appropriations bill will continue to provide the essential federal funds for future advancements. I truly hope that this commitment continues to hold the highest priority.

Expanded research in MPS disorders is a goal of our organization however we understand the value of basic and clinical research leading to advances in treatments for all disease sufferers. It is also my view that legislation and funding for programs supporting pediatric research grant programs, collaborative research in NIH institutes, increased access to clinical trials, training of pediatric research professionals and multidisciplinary research and other enhancements will contribute to conquering many crippling diseases.

The National MPS Society represents hundreds of children with MPS and their families across the United States. The support of Congress for genetic and biomedical research is greatly appreciated, without this support we could not hope to find treatments for MPS and the many other disorders that plague thousands of American children.

Prepared Statement of the National Multiple Sclerosis Society

Mr. Chairman and distinguished members of the subcommittee, we appreciate the opportunity to submit written testimony on behalf of the National Multiple Sclerosis Society. The Society is the world's largest private voluntary health agency devoted to the concerns of all those affected by MS. Throughout the Society's 55-year history, our number one priority has been research to understand MS and apply this knowledge to the development of new treatments and a cure. Our current annual budget for research is nearly $30 million. This represents the largest privately funded program of basic, applied and clinical research and training related to multiple sclerosis in the world.

In this statement, we wish to emphasize the importance of NIH basic and clinical research to all people with chronic illnesses and disabilities and highlight our solid working relationship with NIH. Indeed, NIH and the National MS Society collaborate to further biomedical research and to end the devastating effects of MS. The most recent example is the first-ever collaborative research effort between the NIH and the National MS Society, supporting a multi-year research effort on gender and

sex-based differences between men and women with MS and other autoimmune diseases. This effort, focused primarily at the NIAID, serves as an outstanding model for future collaborations between the Society and NIH, which we welcome and look forward to.

MS is a progressive, degenerative and disabling disease of the central nervous system, unpredictable in its course, and devastating in its effects. It affects a third of a million Americans and their families, friends and employers. It can cause spasticity, tremor, abnormal fatigue, bladder and bowel dysfunction, cognitive problems, visual problems, mobility impairment, and in the worst cases, complete paralysis and blindness. The disease usually is diagnosed between the ages of 20 and 40—but is life long. Many people with MS live thirty years or more with constant unpredictability and progressive disability. MS affects more than twice as many women as men, can result in loss of employment and loss of a place in society and the community. Recent studies sponsored by the National MS Society show that the annual direct and indirect cost of the disease for each affected individual as a result of MS averages $44,000—and the total cost can exceed $2.6 million over an individual's lifetime. For all people with MS in the United States, the annual cost exceeds $13 billion. Ending the devastating effects of this unpredictable disease is completely dependent upon the discovery of safe and effective treatments that halt progression of the disease and reverse its symptoms.

RECENT INSTITUTE OF MEDICINE REVIEW OF CURRENT KNOWLEDGE OF MS

In April 1999, the National MS Society's Board of Directors commissioned the National Academy of Sciences/Institute of Medicine (IOM) to undertake a strategic analysis of the current state of knowledge of multiple sclerosis and to evaluate strategies for future productive basic and clinical research. The Board commissioned the $1.2 million study in the hope it would identify promising areas of research and other strategies that had not previously been exploited, not just for the National MS Society, but for all agencies and pharmaceutical companies engaged in the battle against MS around the world.

The IOM assembled a committee of 14 independent scientists and physicians from basic and clinical academic research and from industry, with expertise in many different fields of science and medicine. Over the course of 18 months, the committee reviewed the therapeutic frontiers and quality of life issues, and sought comments from 45 outside consultants. A draft report was prepared, and was reviewed by experts from outside the MS Society.

While underscoring the quality of current MS research worldwide and the progress that has been made, the committee made 18 recommendations that fall into three categories: research on the cause, course and treatment of MS; disease adaptation and management; and building and supporting the MS research "enterprise" (the training and infrastructure to attract and keep the best minds focused on the problem of MS). Many are strategies already being employed through existing research programs at the National MS Society as well as through research programs related to MS supported by government agencies, including NIH, and other MS societies around the world.

Recommendations for Research on Causes, Course, and Treatments:

—Research the pathological changes underlying the natural course of MS.

—Investigate how nerve cells are damaged, how that damage can be prevented, and role of glial cells (such as oligodendrocytes and astrocytes) in damage and repair.

—Identify the genes that make people susceptible to developing MS.

—Search for a possible pathogen or pathogens that trigger MS.

—Exploit the power of neuroimaging technology (such as MRI and related technologies).

—Continue to investigate the immune system events that lead to MS.

—Develop animal models that better reflect the features of MS.

—Find strategies to protect and repair neurons and oligodendrocytes, including research into stem cells.

—Investigate more effective ways to manage troubling symptoms of MS.

—Research the effectiveness of combination therapies.

—Develop better strategies to gain the most scientific value from clinical trials.

Recommendations on Disease Adaptation and Management:

—Develop better tools for assessing the health status of individuals with MS to increase the reliability and power of clinical trials and to improve individual patient care.

—Find ways to improve the ability of those with MS to function and adapt, and determine the most pressing needs of people with MS.

Recommendations on Building and Supporting the MS Research Enterprise:
—Recruit new researchers to work in MS, including those from allied fields.
—Stimulate collaborations between scientists from different disciplines.
—Stimulate large-scale, expensive, collaborative studies.
—Increase cross-disciplinary research on "quality of life" issues.
—Organize research to more rapidly assess claims for new candidate MS pathogens.

The National MS Society's Research Programs Advisory Committee is thoroughly reviewing the report and will, for our own programs, prioritize the recommendations that have been made, taking into account work already being done, and develop strategies for implementing new programs, where appropriate.

To help disseminate the study's results and plan for the future, the National MS Society also has asked the NAS/IOM to host, at the Society's expense, a conference in April 2001 that will bring together organizations from around the world that fund MS research. The aim is to maximize the dissemination of information in the IOM report, to stimulate discussion about important strategies that might be implemented, and to foster collaborations, where possible, in support of MS research. NIH program officers involved in institutes that support work related to MS will be in attendance, and it will be an opportunity to work toward a coherent, inter-organizational effort to further MS research.

While the IOM study will be an important reference point for the development of future strategies in MS research, it also clearly illustrates, through the example of MS, the need to continue the course of doubling NIH funding over five years (fiscal years 1999–2003).

—MS is an extremely complex disease with no known pathogen or known determinants of its severity and course, and as a consequence, increased understanding of the cause and treatments require research on many fronts. MS is not alone in this regard. Neurological diseases are among the most difficult to study. Although beneficial therapies have been developed in the last decades for Parkinsons's disease, Epilepsy, and more recently for Alzheimers' disease, there is still no cure for any of the degenerative neurological diseases.
—Advances, such as improved ability to create images of the living brain and spinal cord, new understanding of the brain's capacity for repair, and the overall accelerated pace of new discoveries about the cellular machinery of the brain, have renewed the optimism of many investigators about the possibility of developing effective therapeutic strategies for MS and other disorders.
—On the horizon are important new therapeutic strategies: gene therapy, stem cell transplantation and neuroprotection. Much needs to be done in these areas, but progress in understanding and treating virtually all degenerative neurological diseases depends on our ability to capitalize on such new research dimensions.

THE NATIONAL MULTIPLE SCLEROSIS SOCIETY AND THE NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological Disorders and Stroke

The National MS Society has had a long and productive relationship with NIH, particularly with the National Institute of Neurological Disorders and Stroke (NINDS). Our founder, Ms. Sylvia Lawry, who passed away on February 24, 2001, helped spearhead the effort that led to the creation of what is now the NINDS at NIH in 1950 when President Truman signed the bill into law that established the former National Institute for Neurological Diseases and Blindness. Since then, the Society has had a very positive working relationship with the institute—a vital link for us since NINDS currently is responsible for approximately 75 percent of the MS-related research at NIH.

The Society works with NINDS to coordinate grant funding. In cases where scientists seek support for projects from both NINDS and the Society, we have had fruitful negotiations with the agency to assure appropriate levels of funding, without overlapping support.

Intramural scientists from NINDS serve on our scientific advisory committees and help the Society make our research project decisions. These outstanding scientist/physicians dedicate their volunteer time to help the Society make its research funding decisions, and to help ensure that the work of the Society and that of relevant parts of NIH are in concert, and not in opposition.

National Institute of Allergy and Infectious Diseases

While MS is a neurological disease, the root problem in MS is dysfunction of the immune system. Therefore, the Society fosters close working relationships with the

primary institute charged with studies of the immune system, the National Institute of Allergy and Infectious Diseases (NIAID). NIAID funds about 25 percent of the MS-related research at NIH. The Society benefits from a variety of interactions with NIAID. We have participated in the NIH Autoimmune Disease Coordinating Committee that is assessing federal and non-federal support of autoimmune disease research and is charged with plotting a dynamic future research plan.

But perhaps the most significant aspect of our relationship with NIAID is the first-ever collaborative initiative to fund research on "Sex-based Differences in the Immune Response." This collaboration extends the reach of the Society's targeted research initiative on gender differences in MS by encouraging basic and clinical investigation of sex differences in the immune response in MS and related diseases; forging new collaborations to address existing gaps; providing wider visibility of the problem and opportunities; and ensuring increased support for high quality and relevant research.

—The objectives are to identify and define differences in immune response between males and females to increase understanding and treatment of immune-based diseases such as MS.
—The Society and NIAID will co-fund research projects relevant to MS, but the program also will fund projects related to other autoimmune diseases.
—Over the course of this agreement, up to $20 million could be spent on this initiative, of which the Society plans to contribute up to $4 million.
—A Request for Applications (RFA) has been released, and the deadline is August 2001.

NIH FUNDING RECOMMENDATIONS

NIH plays the major role in maintaining our country's preeminence in biotechnology and provides worldwide leadership in health research and discovery. The National MS Society recognizes that new discoveries and breakthroughs could come from any area of biomedical research and could apply to the primary concern of our members: finding new treatments and eventually a cure for MS. Therefore we encourage Congress to focus on NIH as a whole and on agencies of particular relevance to our concern, knowing that a well-funded federal research enterprise will be of great public benefit.

We would like to express our sincere appreciation, Mr. Chairman, for the work this subcommittee has done in the past to promote biomedical research funding. The National Multiple Sclerosis Society believes that in order to take advantage of current opportunities in biomedical and rehabilitation research, Congress must increase funding at NIH by 16.5 percent for fiscal year 2002. This would keep us on track, and bring us another year closer, to our goal of doubling the NIH budget over the five-year period fiscal years 1999–2003. In order to pursue cutting edge research, the Society recommends that this translate into parallel increases of 16.5 percent each for the National Institute of Neurological Disorders and Stroke and the National Institute of Allergy and Infectious Diseases, the primary institutes that conduct nearly all of the MS-related research at NIH.

NEUROSCIENCE CENTER

Last year, Congress approved $47.3 million in funding to begin the construction of the John Edward Porter Neuroscience Center at NIH. This year, the National MS Society asks that Congress provide $26 million to complete Phase I and $10.6 million to start Phase II of construction. The Center will emphasize important cross cutting themes such as neurodegeneration, regeneration and repair of neurons, neurogenetics and pain research. Last year's funding for the Center was incorporated into the NIH Building and Facilities budget, and did not affect funding for research. Likewise, second-year funding for the Center should come out of the same budget. Funding for the Porter Neuroscience Center would continue to increase the pace of discovery in all areas of neuroscience and help translate laboratory discoveries into new and effective treatments.

SUMMARY

The National MS Society recognizes that new discoveries and breakthrough findings could come from almost any area of biomedical research and could apply to the primary concern of our members: finding a cure for MS. NIH plays the major role in maintaining our country's preeminence in the biotechnology industry and provides world-wide leadership in health research and discovery. We thus encourage Congress to focus on NIH as a whole, and on agencies of particular relevance to our concern, knowing that a well-funded federal research enterprise will benefit all of us.

Increasing funding at NIH by 16.5 percent will fulfill our fourth annual objective in the five-year effort to double the biomedical research budget at NIH. We also recommend parallel increases for the two institutes that conduct or fund the majority of MS-related research at NIH: NINDS and NIAID. In addition, in order to take advantage of potential discoveries in all areas of neuroscience and help translate these discoveries into new and effective treatments for patients, we recommend funding the completion of the John Edward Porter Neuroscience Center at NIH. These priorities represent an extraordinarily good use of federal resources that will yield important biomedical and economic benefits.

PREPARED STATEMENT OF THE NATIONAL NEUROFIBROMATOSIS FOUNDATION, INC.

The National Neurofibromatosis Foundation, Inc. (NNFF) is an organization dedicated to improving the health and well-being of individuals and families affected by neurofibromatosis otherwise known as "NF." The Foundation is the oldest and by far largest NF organization in the world. I have been privileged to serve as its President since 1986 and currently serve also as Chairman of the International Neurofibromatosis Association.

NF is a neurological disorder that causes a variety of problems including learning disabilities, skeletal abnormalities, disfigurement, deafness, blindness, loss of limbs, and brain, spinal, and dermal tumors. It also can be fatal. NF does not discriminate. It is found in every racial and ethnic group throughout the world and affects both sexes equally.

Neurofibromatosis is a surprisingly common genetic disorder of the nervous system which causes tumors to grow along nerves anywhere on or in the body. In fact, NF is the most common neurological disorder caused by a single gene. NF is more prevalent than Cystic Fibrosis, hereditary muscular dystrophy, Huntington's Disease, and Tay Sachs combined.

—Two distinct forms of NF exist. NF1 is the more familiar form of the disorder and occurs in one out of every 4,000 births. At least 100,000 Americans of both sexes and all races have the NF1 gene defect. NF2, which generally involves more severe symptoms, occurs in one out of every 40,000 births.

—Symptoms of both forms of NF vary greatly but can include curvature of the spine, enlarged heads, congenital bone defects, blindness, loss of limbs, and tumors of the optic nerves, the brain, and the spinal cord, as well as the vestibular nerves which may cause deafness.

—Recent advances in NF research have linked the disorder to cancer, brain tumors, heart disease, and learning disabilities. In particular, NF causes learning disabilities at about four to five times the frequency found in the general population.

There is still no way to prevent NF and there is no known cure. But prior federal funding has helped lead to important advances. Researchers are hopeful that a cure can be found in the next 10–15 years and believe that this timeframe possibly could be cut in half if more research dollars are made available. The potential that NF research holds for cancer, developmental disorders, and learning disabilities is significant for the more than 100,000,000 Americans with these medical problems.

I am pleased and proud that NF research has been recognized as a model for "Managing Science." It represents an effective partnership between public agencies, most notably the U.S. Congress and the National Institutes of Health (NIH), private organizations and The National Neurofibromatosis Foundation, Inc., and scientists and clinical researchers in the field who have achieved tremendous progress by their collaboration. NF also has a particularly strong and committed grassroots network of individuals affected by NF and their families who are united in a common purpose to promote research and decrease the impact of neurofibromatosis.

NF research has been so productive that scientists have moved from cloning the NF gene to the start of clinical trials within a single decade. Despite these successes, there is still a long way to go to find a cure. The next steps in the neurofibromatosis research agenda include continuing work in basic research, preparing comprehensive natural history studies for NF, and maintaining the all-important process of clinical trials with innovative approaches. With these goals in mind, our first priority continues to be directing limited resources to support research activities that will lead to better understanding, diagnosis, and treatment of neurofibromatosis, and an enhanced quality of life for persons with the disorder.

Congress and the Administration have demonstrated their commitment to scientific advances in this field with funding and directives for improved coordination at the National Institutes of Health. Funds have been appropriated since fiscal year 1996 as part of the Congressionally Directed Medical Research Programs (CDMRP)

in the Department of Defense (DOD) to support neurofibromatosis research by making grants available to NF scientists worldwide through a meticulous peer review process. CDMRP is a unique partnership among the public, Congress, and DOD to mobilize resources and identify untapped opportunities for research that will shape the future of health care in areas of tremendous need including women's health, osteoporosis, and prostate, breast, and ovarian cancer. It is a remarkable testament to the leadership of our Armed Services. We have requested that a total of $25,000,000 be appropriated in fiscal year 2002 under the Medical Advanced Technology account of the DOD Research, Development, Test, and Evaluation budget of the U.S. Army for neurofibromatosis research.

CDMRP is the largest single source of funding for NF1 and NF2 research in the world. But the support that we have received from other sources is also of great importance to the future well-being of individuals and families with NF. In its fiscal year 2000 appropriations bill this Subcommittee added language which expressed to the NIH the commitment of the full Committee and of the Congress to accelerate research to find a cure for NF. NF research has wide-ranging impact beyond neurofibromatosis. It has linked the disease to cancer, brain tumors, and developmental disorders. NF research has also documented the involvement of neurofibromatosis in heart valve formation which may lead to new opportunities and understanding of the genetic and environmental causes of heart disease. It has demonstrated significant promise to uncovering a molecular basis for cognitive impairment and will have broad application to learning disabilities in the general population. This Subcommittee has recognized that the wide variety of symptoms of NF and the significant potential that NF research has for other very large patient populations demands the continued integration of neurofibromatosis research with the basic and clinical research goals of NIH.

Today, I'm asking that you continue to provide clear directives to the National Institutes of Health to express the continuing commitment of the Congress to NF research conducted at NIH, and to ensure that the level of funding to find a cure for thousands of individuals with neurofibromatosis continues to grow every year. NF has been a tremendous research success story for all of those who have invested in it.

Mr. Chairman and Members of the Subcommittee, on behalf of The National Neurofibromatosis Foundation, Inc., as well as the thousands of children and adults with NF, I thank you for your support.

The National Neurofibromatosis Foundation, Inc., a non-profit organization, is the leading resource on NF. NNFF's primary goals are:

—To promote and drive research to find the cause(s) and cure for NF;
—To provide support to patients and their families;
—To promote public awareness and understanding of NF; and
—To promote the development of and patient access to high quality medical care for patients and their families.

PREPARED STATEMENT OF THE NATIONAL ORGANIZATION FOR RARE DISORDERS

Mr. Chairman and members of the Appropriations Subcommittee on Labor, HHS, Education and Related Agencies, thank you for allowing the National Organization for Rare Disorders (NORD) to submit testimony regarding funding for the National Institutes of Health (NIH). We want to express our deep appreciation for all the Subcommittee has done to ensure increased funding for biomedical research—research that has been used to reduce suffering and save lives.

The rare disease community is asking that the Office of Rare Diseases at the National Institutes of Health (NIH) be adequately funded to ensure that ALL Americans, not just a select few, have access to the incredible work being done at the NIH. Today, only ten cents for each and every person suffering with a rare disease or disorder is allocated to the ORD. We are asking for a mere $1 for each man, woman and child who must sometimes wait years for a diagnosis—$25 million to "uncover new knowledge that will lead to better health for everyone."[1] We are also asking that ORD be given permanent status to allow for a diagnostic and research center, and to expand the authority of the office because it does not currently have a permanent line item in the NIH budget.

NORD is a federation of approximately 140 voluntary health organizations and over 70,000 individual patients, healthcare providers and clinical researchers dedicated to helping people with rare "orphan" diseases. An orphan disease is defined

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[1] *Scientific Opportunities and Public Needs,* National Institutes of Health, 1998.

by statute as any disease or condition impacting less than 200,000 Americans.[2] It makes no difference whether you are male or female, rich or poor, young or old, white, African-American, Latino, Asian or American Indian. These diseases affect everyone.

Rare "orphan" diseases include such better known diseases as Sickle Cell anemia, Tay-Sachs disease, Hemophilia, Fanconi's anemia, Tourette Syndrome, Lou Gehrig's disease, scleroderma, etc. It also includes obscure diseases such as Landau Kleffner Syndrome, Wilson's Disease, mastocytosis, Canavan disease, and fibrodysplasia osssificans progressiva (FOP). In a recent article by Thomas Maeder in the Red Herring, FOP is described "as one of the strangest and rarest diseases of all, with about 125 patients in the United States." The body mysteriously "transforms its muscles, tendons, and ligaments into bone . . ." Internal organs are not affected and so patients can live normal life spans unless they "die from complications secondary to their immobility, like pneumonia, falls, or choking on aspirated food."[3]

Our commitment to those 125 FOP patients and the estimated 25 million other people suffering with the approximately 6,000 often debilitating and devastating diseases is the identification, treatment and cure of rare disorders. Approximately 5,000 of those conditions are genetic diseases. In fact, no research is being pursued for most of them. You can imagine the frustration many of these people feel knowing that no one is willing or able to conduct vitally needed clinical studies to develop new treatments or cures.

The mission of the National Institutes of Health is to "uncover new knowledge that will lead to better health for everyone."[4] Yet, millions are being left behind simply because they lack the knowledge or vast resources available to many larger disease groups that allow them to exploit the resources of the NIH. In fact, the National Commission on Orphan Diseases (DHHS, 1989) estimated that only 30 percent of the 25 million patients suffering with rare diseases receive a diagnosis in three to five years after the onset of symptoms. That works out to about 7.5 million patients who are shuffled from specialist to specialist, year after year. Fifteen percent, or 3.7 million people, wait seven years or more. Those statistics are both frightening and unacceptable.

To help fill that void, the Office of Rare Diseases at the NIH was created in 1993. Its mission is to:

—Stimulate and coordinate research on rare diseases
—Compile and provide information on rare diseases to patients and their families, as well as researchers and physicians interested in conducting clinical research
—Co-fund with NIH Institutes and other organizations approximately 50 scientific workshops a year costing between $35,000 and $75,000 each to
  —Stimulate research where none exists
  —Establish research priorities
  —Develop collaborative research protocols
  —Encourage the exchange of ideas among investigators, voluntary patient support groups and NIH Institute staff to stimulate new research, and finally
  —Take advantage of scientific opportunities
—Develop and maintain the Rare Disease Clinical Research Database describing over 1,600 research protocols.
—Develop and maintain the Medical Genetics and Rare Disorders subfile of the Combined Health Information Database (CHID)
—Provide information collected from voluntary patient support organizations
—Coordinate and provide liaison for the NIH with federal and non-federal national and international organizations concerned with rare disease research and treatment of rare diseases.
—Identify current needs in the coordination of rare disease research in cooperation with voluntary health organizations, research investigators and the pharmaceutical and biotech industries
—Bridge the gap between basic and translational research
—Discover opportunities to increase research resources
—Develop novel methods of research planning, coordination and collaboration

This small office, funded with little more than $2.2 million for the 2001 fiscal year, is the only central government resource available to 25 million people. When you do the math, that $2.2 million works out to be less than ten cents for each and every American suffering with a rare disease. And while the entire NIH is enjoying increases of 14 percent and more, the ORD has seen increases of little more than three percent.

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[2] The Orphan Drug Act, Public Law 97–414, January 4, 1983.
[3] *Red Herring,* Adopting Orphan Diseases, by Thomas Maeder, January 16, 2001, p. 130.
[4] Ibid.

We ask today that this Subcommittee consider the creation of one intramural research and diagnostic center for the study of rare diseases. The center should conduct research on rare diseases and conditions; take advantage of emerging research opportunities; and, augment NIH Institutes' research for neglected rare diseases.

We also ask that the responsibilities of the ORD be extended to include:

—Oversight of the intramural research and diagnostic center for the study of rare diseases

—Recruitment of qualified academic scientists to participate in the grant review process for rare disease research proposals

—Support of grants for clinical pilot studies

—Collaboration with industry to develop gene vectors for gene therapy experiments

—Expansion of existing programs to provide support for 100 scientific workshops and symposia annually, and

—Development and maintenance of a central clearinghouse for rare and genetic disease information, written in understandable language for use by patients and their families.

Because rare disease patients are particularly impacted by the cost of diagnosis, treatment and ancillary support services that can reduce a family to poverty, and because patients must often travel long distances to academic hospitals to see the few specialists who work on their particular disease, we also ask that this Committee consider the creation of four regional extramural diagnostic and research centers to expand patient outreach activities and facilitate the development of post-doctoral training fellowships.

Mr. Chairman and members of this Subcommittee, we deeply appreciate Congress' commitment to increase research funding for the NIH by 50 percent over the next five years because many have benefited from the groundbreaking work already being done today. But we respectfully request that you appropriate a minimum of $25 million to the Office of Rare Diseases for the coming fiscal year to help the 25 million Americans who look to you and all members of Congress for help.

Appropriating just one dollar for each rare disease patient in America who is suffering with a rare disease, rather than the current funding level of less than ten cents, is a win-win situation. Patients win when their symptoms are alleviated or cured. Families win when their loved ones no longer suffer. Society, as a whole, wins when patients are able to return to school or work to become productive tax-paying citizens. Pharmaceutical and biotechnology companies win when they are able to develop new therapeutic products. The scientific community wins when the knowledge they gain can be applied to more prevalent diseases. And, finally, the government wins when the drain on healthcare dollars is minimized.

I would like to leave you with a quote from Thomas Maeder's article—"Yet even if the worries of the few were laid aside, and one cared only about bringing the biggest benefits to the greatest number of people, it would still make sense to study rare diseases. We understand health through the observation of illness, and the more illnesses we survey, the more we are likely to learn."[5]

Again, thank you for your continuing commitment to the National Institutes of Health and your recognition today of the unmet needs of those who suffer with rare "orphan" diseases.

SUPPORTING DOCUMENTS

NATIONAL INSTITUTES OF HEALTH, APPROPRIATIONS—FISCAL YEAR 2001

[in thousands of dollars]

Institute, Center, or Division	FY 2000 Estimate	FY 2001 Conference	Percent Change
Cancer	3,310,992	3,757,242	13.5
Heart, Lung, and Blood	2,026,006	2,299,866	13.5
Dental and Craniofacial Research	269,129	306,448	13.9
Diabetes and Digestive and Kidney Diseases	1,141,176	1,303,385	14.2
Neurological Disorders and Stroke	1,029,528	1,176,482	14.3
Allergy and Infectious Disease	1,776,571	2,043,208	15.0
General Medical Sciences	1,353,660	1,535,823	13.5
Child Health and Human Development	859,079	976,455	13.7

[5] Thomas Maeder, p. 128.

NATIONAL INSTITUTES OF HEALTH, APPROPRIATIONS—FISCAL YEAR 2001—Continued

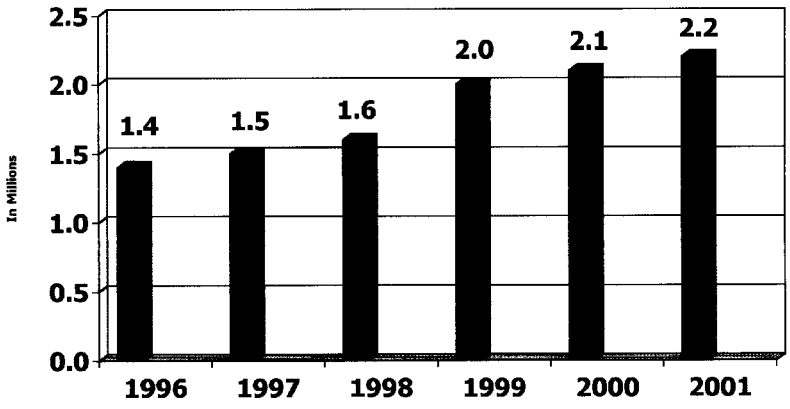
[in thousands of dollars]

Institute, Center, or Division	FY 2000 Estimate	FY 2001 Conference	Percent Change
Eye	450,007	510,611	13.5
Environmental Health Sciences	442,596	502,549	13.5
Aging	687,717	786,039	14.3
Arthritis and Musculoskeletal and Skin Diseases	349,407	396,687	13.5
Deafness and Other Communication Disorders	263,606	300,581	14.0
Mental Health	974,470	1,107,028	13.6
Drug Abuse	687,232	781,327	13.7
Alcohol Abuse and Alcoholism	293,173	340,678	16.2
Nursing Research	89,521	104,370	16.6
Human Genome Research	335,792	382,384	13.9
Research Resources	674,913	817,475	21.1
Complementary and Alternative Medicine	68,997	89,211	29.3
Fogarty International Center	43,319	50,514	16.6
Library of Medicine	215,154	246,801	14.7
Office of the Director	281,941	213,5812	−24.2
National Center on Minority Health and Health Disparities	.....	130,200	N/A
Buildings and Facilities	165,3501	153,790	−7.0
Total	17,789,336	20,312,735	14.2
Office of Rare Diseases	2,070	2,153	3.8

[1] Includes $40 million in advance funding from the previous year.

[2] The Office of the Director shows a significant loss in fiscal year 2001 due to the carve-out of funds for the newly established National Center for Minority Health and Health Disparities.

FUNDING LEVELS FOR THE OFFICE OF RARE DISEASES, NATIONAL INSTITUTES OF HEALTH



PREPARED STATEMENT OF THE NATIONAL PSORIASIS FOUNDATION

Mr. Chairman and Members of the Appropriations Subcommittee: Thank you for allowing the National Psoriasis Foundation (NPF) this opportunity to present written testimony to the committee on the subject of NIH appropriations, particularly as regards skin disease research conducted through the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

We write to urge the committee to approve an allocation for NIAMS of $462.2 million for fiscal year 2002, an increase of 16.5 percent over current funding levels. This increase would further the commitment to double the NIH budget in five years and critically increase the ability of our nation's scientists to uncover the secrets of diseases such as psoriasis and psoriatic arthritis.

We make this request on behalf of more than 7 million American men, women and children with psoriasis and psoriatic arthritis—chronic, debilitating genetic skin and joint diseases. Psoriasis is a common disease that affects one person in forty, and yet it is a disease without a cure and without universally effective treatments. Until a cure or more effective treatments are found, millions of people with psoriasis face a lifetime fighting this disease, which costs our nation billions of dollars annually and, immeasurably, in the tragic emotional and physical toll psoriasis can take on its victims.

Children.—I am 10 years old, and I have psoriasis. It really itches a lot, and I can't do gym at school because it cracks open and it hurts really bad. I look at it and I cry. . . .

Teenagers.—There are many times when I look at myself in the mirror and just cry because I look so bad. I haven't gone swimming for years now. . . .

I live in the South, and I wear long sleeves and pants even in the summer to hide my psoriasis. My best friends have never seen my legs, I'm too ashamed. . . .

The Elderly.—My medicines are so expensive, I often can't get my prescriptions filled. Psoriasis has taken such a toll on my life. Many times I've had to stand in the shower to soak my clothes of off my skin.

—More than three billion dollars are spent annually on psoriasis treatment.

—Each year psoriasis patients make approximately 2.4 million visits to dermatologists.

—Each year several hundred people with debilitating psoriasis are granted disability by the Social Security Administration.

—One person in five with psoriasis has disease that interferes with their ability to perform everyday tasks, including employment and childcare.

Psoriasis is chronic, unpredictable and often unrelenting. Treatments may be successful for only relatively short periods of time for only some people. The thick, red, scaly patches on any or all parts of the body can limit daily activities and interfere with physical, occupational and psychological functions. Skin affected by psoriasis may itch, burn, sting and easily bleed. Physically, psoriasis can range in severity from mild to disabling. Three-quarters of a million of the people diagnosed with psoriasis are under the age of ten.

As many as 20–30 percent of people with psoriasis—more than one million people—also suffer from an associated arthritic condition, psoriatic arthritis. Psoriatic arthritis can cause significant disability, disfigurement and impairment of quality of life. The occupational impact of psoriasis and psoriatic arthritis not only poses a significant economic burden for this nation but also a significant hardship for the person with psoriasis.

Moderate-to-severe psoriasis, which affects as many as 2 million American men, women and children, dramatically inhibits a person's ability to maintain a normal, healthy, active lifestyle. Plaques on large areas of their skin may restrict their movement and the pain and itching often disrupts their sleep and their ability to work. Psoriasis on the palms of the hands or the soles of the feet can be disabling, preventing people from grasping a pen, holding their child, walking or standing.

These people have psoriasis that cannot be controlled by simple topical treatments. To manage their disease they require expensive, inconvenient phototherapy (ultraviolet radiation) treatments in a doctor's office, or oral systemic medications that put the patient at risk of serious side effects. Some types of psoriasis require hospitalization and can even be life threatening.

Emotionally, psoriasis can be devastating. The social rejection and physical suffering of psoriasis can lead people to suicide. Many psoriasis sufferers struggle throughout their lives with pain, embarrassment, and shattered self-image.

Like diabetes, arthritis and heart disease, psoriasis requires lifelong treatment. Indeed, a recent survey shows that 48 percent of Americans would actually prefer to have heart disease, asthma or diabetes, all of which are life threatening, instead of psoriasis. Unlike diabetes or heart disease, however, psoriasis is not a top priority

for many researchers or pharmaceutical companies. But thanks to focus and funding provided by NIAMS, recent research has identified several possible sites for the genes that may cause this inherited condition. Scientists tell us that a real cure for psoriasis will come from these critical genetics studies.

Other research has begun to pinpoint the autoimmune component of the disease, providing valuable targets for drug development. Many of the same autoimmune processes that researchers have discovered at work in diseases such as rheumatoid arthritis and Crohn's disease are also active in psoriasis. For instance, researchers are now finding that testing new therapies in psoriasis can be an effective way to determine both if a new drug is safe and effective for psoriasis, and also if it may work in these other diseases. This research must be aggressively supported, as research in one disease will very likely benefit others.

Effective treatments and a cure for psoriasis are within reach. Sufficient funding will enable medical science to find a cure for this chronic, costly and devastating disease. This not only will benefit the 7 million American children and adults now suffering with this chronic disease, but also will help the 200,000 people who are diagnosed each year with new cases of psoriasis.

Better treatments or a cure for psoriasis will result in savings both to the public and the government in treatment costs, lost workdays and Social Security disability claims. Beyond these valuable dollar measurements, an increase in federal spending for such biomedical research will directly result in an immeasurable improvement in the quality of life for these millions of affected Americans.

Therefore, on behalf of the members of the National Psoriasis Foundation, and the 7 million Americans with psoriasis, we again strongly urge you to approve $462.2 million for NIAMS, an increase of 16.5 percent over current funding levels for fiscal year 2002. This increase will have significant health and socioeconomic benefits for the millions of Americans who are affected by psoriasis and by other diseases under the purview of NIAMS.

Thank you for your time and your support.

PREPARED STATEMENT OF THE NATIONAL SLEEP FOUNDATION

Mr. Chairman, distinguished Members of the Subcommittee, thank you for allowing me to submit testimony for the hearing record on behalf of the National Sleep Foundation. I am the Medical Director for the Center for Sleep Disorders at Doctor's Hospital in Massillon, Ohio. Since 1994, I have also been a coordinator for the Wake Up America Coalition focusing on reducing drowsy driving crashes in Ohio.

The National Sleep Foundation (NSF) is an independent, non-profit organization. NSF works with thousands of sleep experts, patients, and drowsy driving victims throughout the country to prevent health and safety problems related to fatigue and untreated sleep disorders. The Foundation's interest in the Subcommittee's work is based on NSF's relationship with the Centers for Disease Control and Prevention (CDC), and specifically with the National Institute on Occupational Safety and Heath (NIOSH) and the National Center for Injury Prevention and Control (NCIPC). NSF is asking the Subcommittee to consider providing an additional $1.5 million in fiscal year 2002 funding between NIOSH and NCIPC to address sleep deprivation and fatigue-related injury in this country.

SLEEP AND PUBLIC HEALTH

We recognize the many competing priorities that the Subcommittee must consider as it writes the appropriations legislation for fiscal year 2002. At first glance, sleep and fatigue issues may not appear to be an immediate concern to the nation's health and safety. However, all you need to do is stop and ask yourself, how do I perform when I am tired? Have I ever driven while drowsy? Do I know someone with a sleep disorder? Can a child learn when they can't stay awake in class? As a sleep physician, I can tell you first-hand that insufficient sleep and sleep disorders have a profound impact on millions of people's lives.

Sleep represents a third of every person's life, and it has a tremendous impact on how we live, function, perform, and think during the other two-thirds of their lives. Sleep is as vital as the air we breathe and the food we eat, yet for many, it is last on the "to do list." Too many of us forget that lack of adequate, restful slumber has serious consequences at home, in the workplace, at school, and on the highway. Tragically, drowsy driving claims more than 1,500 lives and accounts for at least 100,000 crashes in the United States every year. Untreated sleep disorders and sleep deprivation contribute to accidents, impaired work productivity, academic performance, reduced quality of life, poor health, and even death.

FATIGUE AND PREVENTABLE DEATH AND INJURY

We know that tens of thousands of lives are endangered, if not lost, each year because of fatigue. Some of them are high profile. For instance, fatigue was cited in disasters such as the Exxon Valdez oil spill in 1989, and the commercial airline crash in Little Rock, Arkansas in 1999. Some of the losses do not make the evening news, but they are tragic just the same. Just last year, nine Boy Scouts and two Troop leaders from New Kensington, Pennsylvania, were hurt when their van flipped over after the driver simply fell asleep at the wheel when coming back from a camping trip. People who don't drive automobiles are not immune from the danger. In 1998, a 6-year-old Kirkwood, Pennsylvania, Amish girl was killed on Route 896 in Bart Township after a driver fell asleep and smashed into the back of a buggy in which she was riding. These crashes, along with workplace accidents, happen every day throughout America. The tragedy is that these accidents are eminently preventable.

Fatigue or sleep deprivation is an impairment, comparable in effect to alcohol and drugs. New research tells us that a person who has been awake for 24 consecutive hours demonstrates the same impairment to judgment and reaction time as an adult who is legally drunk with a blood alcohol concentration of 0.10 percent. Furthermore, people do not realize that alcohol interacts with sleep deprivation to form a deadly combination. An adult with only four or five hours of sleep may think he or she is drinking responsibly when they have one or two drinks after work, but in this case, what he or she does not know can kill them or someone else. Like drugs and alcohol, fatigue needs to be addressed as a public health issue.

RAISING AWARENESS ON SLEEP AND FATIGUE IMPLICATIONS

The National Sleep Foundation has worked with volunteers like myself for the last decade to raise awareness, have people diagnosed and treated, and minimize fatigue-related injuries. NSF, in cooperation with many partners, has successfully mounted state programs in New York, Arkansas, California, Washington, Oregon, and Idaho that target fatigue-related injuries. In New York, NSF worked with state and federal agencies and other partners to launch the nation's first statewide public information and injury prevention program related to the dangers of sleep deprivation. In March, NSF worked with over 80 diverse national organizations, state and federal agencies and more than 350 sleep centers to hold a National Sleep Awareness Week, prior to Daylight Saving Time, when Americans lose a precious hour of sleep. This comprehensive, award-winning public education campaign, now in its fourth year, generates tremendous public awareness of how good sleep contributes to health, safety, and productivity.

While public awareness is desperately needed, a strong federal partner with the expertise and ability to disseminate tested and proven education, training, and injury prevention programs to communities like New Kensington and Bart Township are needed even more. The CDC is the partner that NSF and public health officials need to help us address the comprehensive and complex health and safety problems related to sleep issues.

The problem is complex and far-reaching. Complex in that, while there are many unanswered questions about the relationship between sleep, rest, and physical performance, the sleep research community has established that sufficient sleep is not optional. The costs are as immediate a disabling farm equipment accident and as debilitating as mental disorders, seemingly unassociated with sleep patterns. Far-reaching in that the NSF has identified several significant steps we need to take in the public health field. Public education, physician and police training, school-based programs, workplace safety—these are some of the obvious program pieces that the Foundation sees a need to initiate.

We have data telling us that lack of sleep affects the nation on many different levels—from the airline pilot in the skies to the child in the classroom, from the solider in battle to our farmers in the field. But this research does no good if we cannot translate it into education and injury prevention programs for the general public. We believe that the CDC can and should play a vital role, working with the sleep community, to address these problems by developing a Sleep Action Plan that would set national priorities around sleep issues in public health and safety. The proposed plan would better identify the specific public health problems associated with sleep and sleep deprivation, gather the relevant data to inform policy decisions, and recommend policy direction and plans for implementation.

AWARENESS IN MEDICAL COMMUNITY

The National Institutes of Health estimates that more than 40 million Americans suffer from chronic sleep disorders, and millions of others suffer intermittent sleep problems related to other medical problems like depression, diabetes, Parkinson's Disease, arthritis, and cancer. The overwhelming majority of these people are undiagnosed and untreated due to a lack of public understanding of symptoms and the training of physicians in medical schools. A Foundation survey found 58 million Americans report suffering excessive daytime sleepiness at levels that interfere with day-to-day activities.

We believe increasing awareness on the role of sleep and the prevalence of sleep disorders in the medical community is a crucial element of addressing the problem. One example of how a physician education initiative can make a difference in people's lives is from Walla Walla, Washington. Several primary care physicians in Walla Walla, Washington, were trained to look for and recognize symptoms of sleep apnea, one of the more common and subtly debilitating sleep disorders. With this training, physicians were able to diagnose and ultimately recommend treatment to hundreds of people for sleep apnea and other sleep disorders. A control group of physicians without specific training only diagnosed a tiny fraction of these cases. The moral of the story is not that there are many people with sleep disorders in Walla Walla, but that countless Americans needlessly suffer from sleep disorders. These people are one step away from serious tragedy because their physicians have not been provided with the training they need to diagnose and treat them. Accurate data from the health care community along with additional training would show the extent of the problem and allow us to target physicians who are on the front lines of our health care system to tackle this problem before it gets further out of hand.

The lack of knowledge evident in Walla Walla prior to the community-based intervention by sleep physicians was confirmed in a recent study by the National Sleep Foundation. The NSF released data in January 2001 that indicated that while 98 percent of primary care physicians believe that questions about a patient's sleep should be part of a routine checkup, only half of the doctors stated that they ever asked such questions. Maybe more telling is that most physicians admitted that their colleagues were likely to only talk about sleep if the patient initiated the conversation.

VULNERABLE SUB-POPULATIONS

One of the largest groups affected by fatigue is young adults. Twenty years of research shows us that older adolescents require about nine hours of sleep a night to maintain proper alertness during the day. Sleep specialists also indicate that during puberty, a shift in the biological clock occurs, making it difficult for teenagers to get to sleep before 10 p.m. In fact, studies have found that the average high school student does not go to bed until midnight. This pervasive sleepiness creates what is called a "sleep debt," which profoundly affects health, safety, productivity, and learning abilities and makes teens the largest at-risk group for fall-asleep car crashes. Evidence tells us that America's "sleep debt" is on the rise, but we, as a nation, lack the basic resources to address this problem.

Another sub-population at risk for sleep loss is overweight children. As the Members of the Subcommittee may know, America's children are more obese than ever. The CDC has stated that this health issue is reaching epidemic proportions. As a result of this alarming weight gain, my colleagues and I are seeing more and more children developing obstructive sleep apnea at younger ages. Left untreated, sleep apnea leads to higher healthcare utilization and is associated with cardiovascular disease, diabetes, stroke, depression, and other very serious medical conditions. People with untreated sleep apnea also have up to a seven times greater risk of falling asleep behind the wheel of an automobile.

SUMMARY

Current CDC resources within the National Center for Injury Prevention and Control and the National Institute on Occupational Safety and Health are allocated for other projects that are of equal importance to the country. It is with this recognition that we ask the Subcommittee to increase the overall budget at NCIPC and NIOSH by $1.5 million to allow CDC to act as the coordinating body for the development and implementation of the five-year Sleep Action Plan. This plan will allow the NSF, CDC, and other federal agencies to develop and distribute accurate, medically sound information and programs to local communities. This information, coupled with training for those involved with public health and safety at the state level, will begin to turn the tide of injuries, health problems, and costs associated with

sleepiness and sleep disorders. We are ready and willing to take up this challenge, but we need your help.

Thank you for consideration of this request.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

SUMMARY OF FISCAL YEAR 2002 RECOMMENDATIONS

Continue the effort to double funding for the National Institutes of Health by providing an increase of 16.5 percent, to $23.7 billion for fiscal year 2002. Increase funding for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) by 16.5 percent to $1,518,443,525 for fiscal year 2002.

Prioritize glomerular injury research at NIDDK (including clinical trials), raise professional and public awareness about glomerular injury, and encourage more aggressive scientific attention to all kidney diseases.

Urge NIDDK to develop programs to attract talented researchers to the field of glomerular injury.

Mr. Chairman, and members of the subcommittee, I am pleased to present testimony on behalf of the NephCure Foundation (NCF).

We are a relatively new, non-profit organization with a mission of supporting research and public awareness on glomerular injury, which is related to the filtering mechanism of the kidney. I serve as president of the foundation, and have a son, who has had a glomerular disease since he was eleven months old. Although he is now 24 years old and in remission, eighty percent of those in his situation lose their kidneys or their life by the age of five.

What is glomerular injury?

Mr. Chairman, each kidney contains about one million tiny filtering units called nephrons. Nephrons are the key to the kidney's filtering function, processing a constant flow of waste-laden blood, sorting out the vital fluids, from the toxic and unnecessary elements.

When someone suffers from a glomerular disease, this vital process is impaired. In some instances, an individual will lose protein and sometimes red blood cells in the urine, have high cholesterol levels, and experience severe swelling in the body from too much fluid. Incidence of this disruptive Nephrotic Syndrome is increasing, and this perplexes physicians who cannot identify the cause or cure.

Sometimes damage occurs to the nephrons, specifically, scarring of the glomeruli, which are microscopic capillaries in the nephron. The severe form of this glomerular injury is Focal Segmental Glomerulosclerosis (FSGS). Presently, there is no treatment to reverse this damage. FSGS can lead to end stage renal disease—total, or near total, permanent kidney failure. Costly dialysis treatments become necessary and kidney transplants may be required for severe cases.

The Toll of Glomerular Injury

Glomerular injury affects tens of thousands of patients in the nation, most of them young. While it is unclear exactly how many Americans are impacted, the incidence of glomerular injury is on the rise. Severe forms of glomerular injury are costly to diagnose and treat, and at this time the only relief for these patients is with heavy medication, usually steroids, which have strong and unpleasant side effects and only work for about 30 percent of patients.

Problems of misdiagnosis often occur with glomerular injury. Most patients and parents have stories about the unusual length of time between the first symptoms and diagnosis. The early signs of glomerular injury, swollen eyelids, are often mistaken for allergic reactions. Health care professionals don't appear to be fully knowledgeable about this disease.

The physical changes, extreme swelling of the face and body, can adversely affect all aspects of a young person's life. With a stronger commitment to research and educational awareness, suffering can be minimalized and hopefully eliminated.

There is hope for scientific breakthroughs

At a meeting co-sponsored by the NephCure Foundation, preeminent scientists from around the world have shared their findings about the podocyte, a major filtering cell, with tentacle-like feet. The relationship between the podocyte and the glomerulus may be a key to understanding glomerular injury.

Recently, researchers have discovered certain molecules that are essential to the podocyte's function. As this becomes better understood, scientists are hopeful of finding better ways to treat glomerular diseases, and prevent their progression to more grave conditions.

This spring, NIDDK will begin to establish clinical trials, which will test various treatments for hundreds of FSGS patients. But there is a need for more funds to strengthen the basic science behind these studies. Researchers need to study tissue and fluids from those patients to advance their knowledge of the molecular causes of FSGS.

What needs to be done?

Respectfully, Mr. Chairman, the NephCure Foundation urges this subcommittee to:

—Continue the support for doubling the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

—Provide the funding and recommendations for the National Institute of Diabetes and Digestive and Kidney Diseases to aggressively pursue a scientific program which will advance research into glomerular injury, conduct clinical trials, raise public awareness, and recruit talented scientists to this field of research.

Thank you for the opportunity to appear before you today.

Mr. Chairman, we hoped to have Melanie Stewart here to testify today, but her health would not allow her to be here. Her father, Brad Stewart, will read Melanie's statement.

My name is Melanie Stewart. I'm 13 years old and have had FSGS since I was six. Until a year ago I spent most of my life in the hospital or hooked up to a dialysis machine for 8 hours every day. My kidneys finally died last year, so my dad gave me one of his. I've done my best to keep it by taking 20 pills a day, fighting off infections, hemorrhages, and a blood clot in my heart. The kidney my Dad gave me is failing.

There are thousands of kids just like me who would like a chance at a normal life. For all of us, I'm asking for your help in finding a cure for this disease.

Thank you for listening.

PREPARED STATEMENT OF NEW YORK UNIVERSITY

On behalf of New York University, I appreciate the opportunity to speak in support of public investment in basic research and, in particular, to salute the National Institutes of Health, whose funding of biomedical and biological research is so important to the health and well being of our nation.

The NIH has benefited in recent years from significant budget increases that have enabled important new NIH initiatives and funded path breaking research conducted by both NIH as well as university-based researchers. NIH supports established as well as junior investigators, funds research as well as facilities and instrumentation, and shapes emerging areas of biomedical research. NIH funding is critical both for its direct support of research, as well as its indirect impact in enabling extramural (university-based) researchers to attract additional funding from other federal agencies, private foundations, and industry for research and science infrastructure. We at NYU applaud the national goal of doubling the NIH budget to $30 billion by 2003, and urge Congress and this Committee to support that proposal. A strong NIH is absolutely essential to meet the new challenges in biology, biomedicine, and health care.

At New York University, NIH funding has supported leading-edge research across a range of areas from molecular genetics of plants to computer modeling of DNA structures to neural visual pathways to language comprehension. I would like today to underscore biomedical genomics, an important and pervasive area of contemporary biomedical research that is a very important priority for NIH and is, as well, an area in which NYU is well-positioned to make major contributions.

The implications of the NIH National Genome Project for America cannot be overstated. Its scope of investigations and applications encompasses every living thing—humans, animals, and plants—and has the potential to revolutionize disease diagnostics and therapy, agricultural applications, environmental conservation, and indeed, our most cherished notions of life.

ADVANCES IN GENOMICS

The genome is the recipe or blueprint for life. During the last decade—and particularly, during the last few weeks alone—the unraveling of the genetic code has opened up a vast range of new opportunities for evolutionary and developmental biologists, neurobiologists and chemists to understand what genes are, what they do, and how they do it. Genomics is revolutionizing biology and is dramatically changing the way we characterize and address biological questions. As a field which straddles biology, chemistry, and mathematics, genomics is growing extraordinarily rap-

idly and transforming these disciplines, as well as the social and behavioral sciences.

In its first stage, the revolution in genomics was characterized by a period of intensive development of techniques to analyze DNA, first in simple models, like yeast, bacteria, the worm, and the fruitfly, then in the mouse, and now in humans. The structure and function of genes are similar in these models, making comparisons useful. The second phase was characterized by the use of these tools to address whatever biological question was most easily approached, given the state of technique development. It may be described as structural genomics—which comprises the mapping and sequencing of genomes and is mainly driven by technology. The scientific community is now poised to enter the third phase of the genomics revolution in which investigators bring perspectives from other fields, like immunology, genetics, and neurobiology to pursue investigations that are driven by hypothesis rather than technique. This third phase is generally termed functional genomics and uses the map and sequence information already collected to infer the function of genes. Functional genomics integrates basic and clinical science: the strategy is to exploit genomics approaches to address the relationship between the genes identified in model organisms—like the worm, or the fruitfly—and the genes responsible for human disease states.

At New York University, we think the key issues facing genomics today are how to translate the enormous quantities of gene sequence data into knowledge of gene function. The answers lie, we believe, in comparative functional genomics, an approach that looks for the occurrence of the same genes in different species that share certain structures or functions, and provides a powerful method for understanding the function of particular genes. Comparative functional genomics uses two primary modes of analysis: (1) identifying what has been conserved over long evolutionary distances, and (2) determining crucial differences that distinguish two closely related species. This focus can provide the key to understanding the genetic basis of disease states that are dependent on numerous genes and to unraveling the complex regulatory networks for crucial biological functions.

STRENGTHS AT NEW YORK UNIVERSITY

New York University and other major research institutions are poised to make important contributions to the next phase of genomics research.

Studies in comparative functional genomics, the thrust of NYU research, is necessarily multidisciplinary, and indeed, involves multiple institutions. This approach synergizes medically related research programs, such as those at the NYU School of Medicine and its affiliated Mount Sinai School of Medicine, with basic science research programs such as those at NYU's Faculty of Arts and Science. This approach recognizes that an essential feature of emerging genomics studies is an intimate tie of biology to computer science. The mass of data involved in genomics strains computational capacity and analytic tools. This has spawned a new scientific discipline, bioinformatics, whose focus is developing entirely new algorithms for large-scale database management, alignments, pattern recognition and data processing for application to genomic sequences. Accordingly, genomics studies at NYU are essentially rooted in computational investigations at its Courant Institute of Mathematical Sciences.

NYU has substantial strengths in areas important to genomics, including evolutionary biology, neurobiology, developmental genetics and applied mathematics research, imaging and computation, and extends this expertise through active collaboration and formal affiliations with premier metropolitan area institutions, including The New York Botanical Garden, which houses the world's largest collections of well-characterized specimens from the plant kingdom, and Cold Spring Harbor Laboratory, one of the world's centers for molecular biology and genomics research. NYU Medical School has outstanding programs in developmental genetics, molecular neurobiology, pathogenesis and structural biology. And Mount Sinai Medical School has an internationally acclaimed program in human genetics and has begun to use genomics approaches to identify the origins of human genetic disorders. The multidisciplinary perspective that characterizes genomics—particularly comparative functional genomics—requires this kind of concentration of strengths in biological, neurobiological, and computational sciences, and established frameworks for interdisciplinary and interschool collaboration.

The nation's largest private university, with 13 schools and over 49,000 students, NYU is a leading center of scholarship, teaching and research. It is one of 29 private institutions constituting the distinguished Association of American Universities, and is consistently among the top U.S. universities in funds received from foundations and federal sources. NYU encompasses a pre-eminent science faculty and generates

substantial external funding from federal and state agencies as well as the private sector. These investigations have attracted millions of federal dollars from the NIH, NSF, ONR, and EPA. In addition, NYU has received major funding from the most prestigious private foundations supporting the sciences, including the Howard Hughes Medical Institute, the W. M. Keck Foundation, the Alfred M. Sloan Foundation, and the Beatrice and Samuel A. Seaver Foundation. Faculty members have, as individuals, won prestigious awards, including HHMI Investigator, NSF Presidential Faculty Fellow, NIH Merit Awardee, McKnight Foundation Scholar in Neuroscience, and MacArthur "Genius" Fellow.

RESEARCH APPLICATIONS AND NATIONAL BENEFITS

Concentrated studies in comparative functional genomics can be a major resource for the research and development activities of academic organizations and commercial firms; can provide a strong framework for direct and indirect economic development in vital, high-tech industries; and can offer benefits to our citizens from improved health care, and technology development. Further investment in state-of-the-art equipment, and in facilities where computer scientists, physical chemists, and geneticists can readily interact with each other is essential for the development of this field.

Advances in Biomedical and Other Research Fields.—The understanding of the human genome is a field which is particularly fertile with applications to cell biology, embryology, developmental biology, study of cancers and many other heritable diseases, immunology, endocrinology, neurology, and population genetics. Genomics brings together laboratory scientists in all these fields with formerly unrelated disciplines, and can stimulate expansion in key directions in genetics, physical chemistry, evolutionary studies, and diagnostics. Functional genomics research has created a need for information processing structures that efficiently compare multiple strands of DNA, each represented by thousands of kilobytes of data, and allow groups of strands to be represented graphically in a way that highlights their common elements and differences. These research challenges overlap with the fields of machine vision, robotics, and combinatorial mathematics. As an example, computer scientists at NYU are working closely with molecular geneticists and business entrepreneurs to develop a library of genomics software tools. Some of these tools are already being considered by medical researchers for use in diagnosing tumors, which have a genetic structure different from healthy tissue.

Biomedical Applications for National Health Needs.—An investment in genomics research will have a heavy payoff in the nation's well-being by advancing the frontiers of knowledge, finding new cures and treatments for diseases, and helping to develop new diagnostic technologies. For example, it is known that heart cells dying from oxygen deprivation cause heart attacks. It is also known that mice are usually more susceptible to low-oxygen heart attacks than humans. The hearts of certain breeds of mice, such as the high-altitude deer mouse, have the surprising genetic capability to adjust themselves to endure oxygen deprivation. Studies conducted by genomics researchers at NYU are focused on isolating the gene that allows this adaptation and considering the implications for heart attack prevention. Clinical applications like this hold enormous promise to revolutionize medicine and our understanding of both normal development and disease. Genomics research may lead to lifesaving technologies for diagnosis, prevention, and cure of diseases and disorders such as diabetes, heart disease, cancer and infectious disease. In particular, genomics science has the potential to revolutionize the development of mass screening tests for genetic disorders, ultimately making it possible to identify the hereditary contribution to common diseases, predict individual responses to drug intervention, and design drugs that are customized for individual use.

Economic Development.—In a now familiar dynamic of university-centered economic growth, industry draws on the faculty's entrepreneurial energies, their expertise in training the personnel needed to staff high-technology firms, and the fundamental scientific research that can translate into practical applications. High-tech firms spring up near a research university and, in turn, attract or spin off additional high-tech firms in the same or related fields. The interaction of scientists across firms makes the spread of information quicker and the development of projects more rapid. Initial firms and newer firms share a growing pool of highly trained personnel. The expansion of the skilled labor pool makes hiring easier; the existence of the pool attracts still more firms. Once a core of high-tech industries locates in an area, venture capitalists identify that area as promising. The flow of capital—a key ingredient for high-technology growth—increases. Once the process of agglomeration begins, it can be expected to grow on itself and become self-reinforcing.

University funded genomics studies have the potential to identify and characterize genes of scientific and economic importance in pharmaceutics, biotechnology, industrial processing, and agrigenomics, including those directly applicable to human health and well-being. New data about the function of genes has widespread commercial applications, including, the development of novel human and veterinary therapeutics and diagnostics; the generation of data to provide better management of patient care, such that medicine becomes more "customized" as it becomes possible to determine which individuals will benefit from which therapies; and agricultural applications, including the development of crops with improved characteristics such as resistance to herbicides, lack of moisture, and other adverse conditions, or improved growth capabilities.

R&D investment in genomics is already energizing bio-technology, pharmaceutical, biomedicine, agbiotech, computer software, and engineering enterprises. As the genomics research base expands, there is likely to be a generation of new commercializable technologies. Genomics studies will meet critical needs of existing companies for basic research leading to developments in pharmaceuticals, industrial processing, and bioinformatics, specifically, large scale functional genomics studies to validate genetic targets and bioinformatics studies to guide drug discovery efforts. Genomics research is also likely to spawn the growth of new companies, including bioinformatics and software companies and genomics platform companies that generate specific genomic data for product development.

Research and development funding for genomics will also spur job growth. Academic R&D, although itself not directed towards specific commercial application, provides the focus for attracting industry and serving as a base for commercial spinoffs. A conservative approximation that uses state employment multipliers maintained by the U.S. Commerce Department's Bureau of Economic Analysis points to immediate employment impacts of academic R&D. The BEA calculates that each $1 million in R&D grants supports roughly 34.5 full and part time jobs [1] directly within the university and indirectly outside the university as the university's expenditures ripple through the local and state economy.

Investment in genomic science is a strategic and efficient vehicle for advancing fundamental studies in a wide variety of scientific fields, facilitating biomedical applications that can greatly enhance the public welfare, and energizing existing and new industries. The commitment of this committee to support the National Institutes of Health and its genomic initiative is greatly appreciated. We urge Congress to continue its commitment to doubling the NIH budget. We firmly believe that a federal investment in these and other biomedical research fields repays itself many times over.

PREPARED STATEMENT OF JAMES AND MARGARET NYEHOLT

Dear Mr. Chairman: Thank you for allowing us to testify as to why orphan diseases—particularly Canavan disease—desperately need government funding for medical research. Canavan disease is a model disease for other neurodegenerative diseases such as Alzheimer's, Parkinson's, MS, and ALS. Medical breakthroughs against Canavan disease have the potential to also benefit so many Americans suffering from other debilitating neurological diseases. In the case of Canavan disease, we are dealing with a 100 percent fatal illness that affects children. Most Canavan children do not survive their 10th birthday.

When our precious grandson (Max Randell) was diagnosed with Canavan disease (CD) at 4 months old, our lives were forever changed. We sat in a room with our daughter and son-in-law as our family was told that our darling Max would disintegrate before our eyes. We were told that Max had a fatal progressive brain disorder affecting the formation of myelin or white matter of the brain. We learned that the childhood victims of CD were among the most profoundly disabled people in the world. We sat in horror as the doctors went on to tell us that because CD is progressive, the children eventually lose all motor function, becoming blind, paralyzed, and require feeding tubes. Canavan children's brains slowly dissolve into a spongy mass, and even the most elementary signals cannot reach their destination. As respiration slows to the point where the lungs can longer function, they usually succumb to a

[1] The multiplier is for 1995 and is based on 1987 benchmark input-output accounts for the U.S. economy and 1994 regional data, adjusted for 1995 inflation. See the latest (March 1997) edition of the BEA publication *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II)*. These multipliers are frequently used in studies of the economic impacts of individual universities and colleges.

common illness such as pneumonia. We were also told that there was no treatment or cure for this devastating illness.

We decided to fight back against this disease. Without government help, our family has tirelessly fundraised for the past three years to fund groundbreaking medical research for clinical interventions against Canavan disease. During the course of the past three years, we have formed a public charity devoted to finding a treatment and cure to give these children a chance. We know there is hope, as our grandson participated in an experimental therapy (solely supported through fundraising efforts) where four out of fifteen children produced new myelin. These remarkable results were confirmed by MRI's and additional follow-up tests. Max is one of these children, and we have personally witnessed his gaining vision (his whole world opened up) and the great improvements in his quality of life. These improvements are now fading and we are desperately fundraising to support another trial. We need our government's help to fund research to give these children a chance at the life they so deserve.

The Canavan children love life; they are very loving and social children, although they are trapped in bodies that can respond only in very limited ways. These children are fighters and we are fighting for them, however without government help, by granting additional funds to the NIH (with encouragement to grant more research funds towards medical interventions for the children battling CD) we cannot move forward.

We are in our late fifties. We have spent much of our retirement savings to help to save Max and the Canavan children, and we are exhausted and reaching out to our government for help. Both of us have worked all of our lives, never asking for any type of government help. We both work full time, and are devoted parents and grandparents. Most evenings we are up until 2 AM writing fundraising letters to support medical research to treat and cure Canavan disease. Over the past two years, Jim has lost a kidney due to Kidney Cancer, yet we still devote endless time to trying to save these precious children. We are fueled by our love for our grandson (and the other Canavan victims we have met), as well as the knowledge that advancements against Canavan disease will truly aid in developing treatments for other neurodegenerative diseases.

Medical research is overwhelmingly expensive to be solely funded by private donations. Mr. Chairman, we are hopeful that (coupled with granting additional funds to the NIH) you will also encourage them to make an effort to grant more research funds towards therapeutic medical interventions for the little victims of Canavan disease. Without government grants we cannot raise the millions of dollars necessary to continue to support crucial medical research. The Canavan children are running out of time. By helping us to save these children's lives, millions of other Americans suffering from degenerative brain diseases also stand to benefit from this promising research.

PREPARED STATEMENT OF DR. CHRISTINA O'CONNOR

My name is Dr. Christina O'Connor from Lake Bluff, Illinois. Dentistry has been my pursuit and profession for over half of my life. I have become latex allergic by wearing latex gloves in my dental practice. I started working in dental offices during high school and college. After graduating from Loyola University with a degree in psychology, I earned a Certificate in Dental Hygiene at Loyola University and began to work as a dental hygienist. While in a community outreach program in Newfoundland, Canada, as a hygienist, working with poor children, I knew I could do more to help people as a dentist. I decided to go to dental school. I graduated from Loyola Dental School in 1985 and completed a general dentistry residency and fellowship program at Northwestern Memorial Hospital Dental Center. Later, I became an Assistant Clinical Professor in Dentistry at Northwestern Memorial Hospital Dental Center where I practiced until 1994. In addition to dental patient care, I was an infection control officer.

During my early years of practice, AIDS emerged as a national health problem. The Center for Disease Control mandated universal precautions to protect the practitioner and the patient from blood-borne pathogens. The use of latex gloves, glasses, and masks as well as protective clothing, became the standard of care. Dentists all over the country washed and gloved their hands between every patient. In the dental center where I practiced, latex gloves were snapping off and on constantly as dentists, hygienists, and dental assistants moved from patient to patient.

I noticed blister-like formations on the backs of my hand when I used latex gloves. My hands were always red, and a rash would appear within 24-hours of wearing latex gloves. The rash forced me to change to non-latex gloves. Even though I had

no direct contact with latex, I developed labored breathing, wheezing, itchy swollen eyes, and asthma when others used powdered latex gloves in my presence. My shortness of breath, coughing, and labored breathing lasted for several hours after work. I needed inhaled bronchodilators to help me to breathe.

I was forced to retire in June of 1997 when a leading latex allergist diagnosed me as having Type I Ig–E cell-mediated latex allergy after a skin prick test for latex allergy was performed. The allergist explained that the skin rashes experienced earlier were evidence of a Type IV allergy to latex. He explained that continued exposure to airborne latex from powdered gloves even after I stopped using latex gloves myself, caused the conversion to Type I (immediate hypersensitivity) latex allergy. My choices were very limited. I was to avoid latex and its dust to save my life. With a deep sense of loss, I retired from my dental profession.

Today, I know I am not alone. There is an epidemic of latex allergy emerging. Scientific literature estimates the prevalence of latex allergy among healthcare workers to be between 8 percent to 17 percent, and between 1 percent to 6 percent in the general population. One study sponsored by the American Dental Association Health Foundation estimated average prevalence among dental professionals to be 6.2 percent based on a health-screening program in 1994 and 1995. The American Dental Association has not released latex allergy data from this study for the subsequent years 1996, 1997, 1998, and 1999 so it is difficult to ascertain whether the prevalence is increasing or declining among this group of dental professionals. The American Dental Association refuses to disclose this current prevalence data on latex allergy.

Today, I know powdered latex gloves produce "secondhand latex exposure" similar to the secondhand smoke phenomena seen in the tobacco industry. The Food and Drug Administration in 1997 issued a report on glove powder stating that the latex protein can bind with glove powder and become airborne causing respiratory allergic reactions in latex allergic individuals and "may represent an important agent sensitizing non-allergic individuals." An article in the Journal of the American Medical Association in 1997 stated: "Since the institution of universal precautions, latex glove protein has emerged as a major allergen in health care facilities. Airborne exposure of health care workers to latex protein allergens may be increased by the use of powdered gloves compared with non-powdered gloves."

The National Institute for Occupational Safety and Health Alert in 1997 and the Occupational Safety and Health Administration Technical Information Bulletin in 1999 on latex allergy have sought to shed light on this emerging health problem and to offer preventive strategies in the workplace. The American College of Allergy, Asthma, and Immunology launched a nationwide campaign to educate healthcare workers and other high-risk groups like spina bifida patients, individuals who have had multiple surgical or medical procedures, to the risk inherent in latex.

The Allergy Report from the American Academy of Allergy, Asthma, and Immunology of March 2000 reported: "The increasing prevalence of latex allergy is related to more frequent use of latex gloves resulting from universal precautions and changes in the manufacturing process." The Allergy Report also stated: "During the past five years, increasing evidence has accumulated that latex allergy has become a major occupational health problem, which has become epidemic in scope among highly exposed healthcare workers, and in others with significant occupational exposure." With all of these people affected with latex allergy, there are still many questions left unanswered. We need research for all areas of latex allergy including its prevention, immune mechanism, disease progression, and the long-term outcome of latex allergic patients.

Latex allergy is a life long, life threatening condition. The biggest risk is anaphylactic shock—a life threatening condition resulting in hives, severe swelling of the eyes, mouth, lips, and tongue as well as difficulty breathing, severe chest tightness, and potentially, respiratory failure. Since 1989, the Food and Drug Administration has received reports of 15 deaths due to latex enema cuffs. During the past ten years, the Food and Drug Administration has received over 2,000 reports of adverse events involving latex gloves. Five deaths were included in these reports, in addition to the fifteen deaths previously reported. There is no treatment, no cure for latex allergy.

I live a life of avoidance. All I can do is avoid all latex products that may be inhaled, ingested, or touched. This presents a sizable challenge for all latex allergic patients and me since there are over 40,000 products that contain natural rubber latex. I avoid paramedics, hospitals, doctor's offices, and dental offices that use latex gloves and latex medical equipment. An accidental or inadvertent exposure with latex can push me into anaphylactic shock so I carry with me two epinephrine injectable pens, latex-free gloves and latex free emergency medical equipment. A hospital emergency room or an ambulance where latex gloves have been used can

be a real threat to me. In my community, police officers and paramedics arrive on an emergency scene already wearing latex gloves.

Access to safe medical care is impossible for the latex allergic patient when latex gloves and latex medical equipment are all that is available. There is no time in an emergency medical situation to determine whether a patient is latex allergic. There are safe and affordable latex alternatives that offer protection from bloodborne pathogens for the patient and the healthcare deliverer. Latex-free products should be the standard of care for the emergency medical service, fire fighters, and law enforcement.

I want to ask for your help in financial support for awareness, for education, and for research into all aspects of latex allergy. Research is desperately needed to formulate a multi-disciplinary approach to latex allergy prevention involving hospitals, public health departments, emergency medical systems, government regulatory agencies, and manufacturers. Research is desperately needed to develop treatment models for those who suffer from this emerging public health problem. Finally, research is desperately needed to determine the best means of educating employers and employees to phase out latex gloves from work settings and tasks that do not involve contact with infectious material. There is widespread and indiscriminate use of latex gloves in non-medical industries such as food handlers, daycare workers, auto mechanics, housekeeping personnel, and hair stylists.

PREPARED STATEMENT OF THE PANCREATIC CANCER ACTION NETWORK, INC.

Mr. Chairman and Members of the Subcommittee. My name is Paula Kim, I am the Co-Founder & Chairman of the Board of the Pancreatic Cancer Action Network or "PanCAN". In March of 1998, my father died from pancreatic cancer—a mere 75 days after diagnosis. Watching the devastation of this disease first hand, and encountering a severe lack of information, scientific progress and advocacy support, sparked my desire in 1999 to co-found PanCAN. PanCAN is a non-profit organization and the first and only national patient based advocacy group for pancreatic cancer. Our staff of three is also fueled by grass roots volunteers across the country focused on creating awareness and eradicating pancreatic cancer.

BACKGROUND

Increased emphasis on and awareness about pancreatic cancer is a good idea for several reasons. First, there is currently no early detection method for pancreatic cancer. Second, treatment options are severely limited and generally palliative. The term "palliative" is what doctors say when they try to make someone comfortable while he or she is dying from a disease. Third, there is an extreme shortage of trained investigators working specifically on pancreatic cancer research.

Pancreatic cancer is one of the most aggressive cancers and has one of the lowest survival rates among all cancers. Pancreatic cancer is the 4th leading cause of cancer death for men and women in this country. About 29,000 Americans are diagnosed with it each year, and nearly the same number die each year from this horrible disease. The incidence of the disease among African Americans remains disproportionately high. The typical pancreatic cancer patient has vague symptoms, presents with metastatic disease and has a life expectancy of less than one year following diagnosis.

Our nation's experience in dealing with AIDS, breast cancer and prostate cancer has shown us that a focused effort and targeted funding can have an enormous impact on combating a specific disease. Pancreatic cancer has not attracted much interest because so many of the people most familiar with it are in cemeteries and because the research funding has been the lowest funded per mortality of all major cancers.

These facts, along with the recently completed National Cancer Institute (NCI) Progress Review Group Report for Pancreatic Cancer, clearly identify the overdue and desperate need to accomplish the following: develop Centers of Excellence, recruit and train investigators, develop public and professional education about the disease, support research that identifies new methods of detecting and treating pancreatic cancer, and provide patient support and information services.

On behalf of PanCAN and the thousands of pancreatic cancer victims and their loved ones, I summon your help and seek to impress upon you that ongoing emphasis and action is needed to address the magnitude and urgency of this disease. In order for the research community to make progress on battling pancreatic cancer, we must first get them to the starting line. Your consideration of our recommendations will help facilitate this process, and we are extremely grateful for your support.

FISCAL YEAR 2002 NEED

For fiscal year 2002, we urge your support in promoting the specific actions with the following Federal agencies:

National Cancer Institute

We commend the National Cancer Institute (NCI) for its report on the Pancreatic Cancer Progress Review Group. This report is an agenda for action to attack pancreatic cancer. Pancreatic cancer is the 4th leading cause of cancer death for men and women.

However, we remain concerned that while there are over 29,000 new cases of pancreatic cancer each year, 28,900 people die each year from this disease. It is one of the most fatal forms of cancer but is one of the lowest funding priorities at NCI. We seek your support to direct the NCI to develop, and present to the Congress within six months, a professional judgment budget in line with the NCI Progress Review Group for pancreatic cancer research for fiscal year 2003–fiscal year 2008. In addition, we seek your support to direct the NCI to develop an initiative for the awareness of pancreatic cancer that includes both scientific and lay materials to disseminate, thus helping to increase public and research awareness about this tragic disease. Also, we would request that NCI consult closely with the research community, clinicians, patient advocacy groups and Congress in the preparation of this report.

National Institute of Diabetes & Digestive & Kidney Diseases

We seek your support to urge the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to collaborate with the National Cancer Institute on mutual research areas and awareness programs for the scientific and lay communities. We specifically seek your support in directing the NIDDK to establish translational research activities to understand the inter-relationships of pancreatitis, diabetes, and pancreas cancer.

Centers for Disease Control and Prevention

We seek your support to encourage the Centers for Disease Control (CDC) to work with the National Cancer Institute to determine possible areas of collaboration in epidemiology, translational research, and awareness and registry programs. We would further request that you direct the CDC to report back to you on initiatives in these areas when they testify before Congress next year.

It would be most beneficial if the CDC would also plan and implement awareness programs for orphan cancers for patients and community oncologists. Patients diagnosed with these cancers, such as esophageal, kidney, liver, multiple myeloma, pancreatic, and stomach, currently have lowest life expectancy rates of all diagnosed cancers, yet community oncologists generally lack specific knowledge about these malignancies. We suggest that the CDC develop comprehensive community oncologist education programs to help doctors better identify orphan cancer symptoms and make more accurate, timely diagnoses.

Because pancreatic cancer adversely affect ethnic minorities and the medically underserved, we suggest that the CDC to determine the feasibility of integrating hematological (leukemia, lymphoma, multiple myeloma), digestive system (liver, pancreatic), and genitourinary (kidney, genital) cancers screening and awareness programs into existing activities.

Lastly, we would encourage the CDC registries program to establish, along with the states, high-risk registries for the digestive cancers (liver, pancreatic) and other cancers with significantly low survival rates following diagnosis.

CLOSING REMARKS

Mr. Chairman and Senators on the Subcommittee, thank your for allowing me this opportunity to outline specific action steps which our Federal agencies may take to further increase the awareness about pancreatic cancer and accelerate efforts to eradicate this terrible disease. I have attached draft legislative language for your consideration so that the recommendations outlined above may be incorporated in the Fiscal 2002 Labor/HHS/Education Appropriations report.

Best wishes and good health to each of you.

PREPARED STATEMENT OF THE PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Chairman Specter and Members of the Subcommittee: People for the Ethical Treatment of Animals (PETA) is the world's largest animal rights organization, with more than 700,000 members. We greatly appreciate this opportunity to submit testi-

mony regarding fiscal year 2002 appropriations for the National Institutes of Health. Our testimony will focus on nicotine experiments on animals.

Studies on human beings have documented the effects of smoking on disease processes, organ systems, longevity, and other health issues. Conducting nicotine experiments on animals is duplicative, meaningless, and wasteful.

We would like to request that the subcommittee include report language ensuring that no funds under the appropriations act shall be used for nicotine or tobacco experiments on non-human animals.

In fiscal year 1996, the National Institutes of Health funded 123 grants totaling $28,099,418 for research primarily concerned with cigarette smoke or nicotine. Forty percent of these grants (49 of the 123) involved non-human animals. As you know, funding is limited for medical research and health programs. Why waste American tax dollars on nicotine experiments on animals when those funds could be much better spent on prevention programs, public education, or clinical studies?

CURRENT AND ONGOING NICOTINE EXPERIMENTS ON ANIMALS FUNDED BY THE NATIONAL INSTITUTES OF HEALTH

Pregnancy studies

In his abstract entitled, "Fetal nicotine exposure effect on primate lung," researcher Eliot R. Spindel writes, "The deleterious effects of maternal smoking during pregnancy are all too well established," including "overwhelming evidence that smoking during pregnancy directly and adversely affects lung development."

However, "overwhelming evidence" did not stop Spindel from applying for and receiving a four-year grant from the National Institute of Child Health and Human Development to conduct nicotine experiments on pregnant rhesus monkeys. In order to "characterize the effects of chronic exposure to low levels of nicotine throughout pregnancy on lung development and subsequent pulmonary function," pregnant monkeys were given doses of nicotine "consistent with that of smokers." Afterwards, the infants' lungs were examined to determine the effects of chronic nicotine exposure on lung development and function.

Spindel hopes that his study will "provide an important tool in smoking control and will begin to better explain the link between maternal smoking and altered neonatal respiratory function," despite the fact that evidence already in existence has failed to alter the "unfortunate prevalence of smoking during pregnancy."

Eliot Spindel is with the Oregon Regional Primate Research Center in Beaverton, Ore. His project started in February of 1999 and is scheduled to conclude in January 2004. (Source: NIH Computer Retrieval Information on Scientific Projects, June 2000.)

The public health message that can be gleaned from this experiment—that pregnant women should not smoke—was already well established before these experiments began. From a public health standpoint, it is difficult to avoid the conclusion that these experiments are, at best, costly and trivial. Experiments like these are frightening, stressful, and ultimately fatal for the animals involved. If helping human babies is our goal, such experiments should be replaced with aggressive public health measures.

Addiction studies

In his abstract entitled, "Stress induced reinstatement of nicotine-seeking behavior," James D. Valentine writes, "Many believe that stressful life events can contribute to drug use in humans, and, recently, animal models have been developed for studying this phenomenon."

According to Valentine, "exposure to unavoidable stressors can dramatically affect drug-seeking behavior, including relapse to drug-seeking in drug-free animals." While a variety of "drugs of abuse" have been used to examine this phenomenon, the "effect of unavoidable stress on nicotine-seeking behavior has yet to be examined."

As a result, Valentine applied for and received a grant from the National Institute on Drug Abuse to, "determine if exposure to unavoidable stress will reinstate nicotine-seeking behavior in rats."

Valentine is with the Minneapolis Medical Research Foundation, Inc. His project started in July of 1998 and was scheduled to conclude in June 1999. (Source: NIH Computer Retrieval Information on Scientific Projects, June 2000.)

"Unavoidable stressors" as mentioned above can involve a wide variety of obstacles, dangers, and painful experiences which the animals are forced to endure before they are killed. Stressors in past nicotine experiments have included:

—placing animals on a hot plate heated to 126 degrees F;

—starvation until between 15 and 20 percent of the animal's body weight is lost;

—placing an animal in a large, deep tank filled with a paint and water mixture (so that the animal cannot see what is beneath him). The animal's task is to struggle to find a clear Plexiglas "escape platform" below the surface on which he can stand to keep his head above the liquid.

One has to question the value of Valentine's experiment, as it has already been well established that nicotine is a highly addictive substance, and there is little doubt that rats would seek it just as they do cocaine, heroin, and other highly addictive substances. It would have been more helpful to society if this money had been used to create addiction treatment programs for people for whom stress has already "reinstated nicotine-seeking behavior."

Other examples

Here are two more examples of the numerous grants that NIH has bestowed for nicotine experiments on animals.

A grant of $183,628 in 1996 was given to Hakan W. Sundell at Vanderbilt University to use nonsedated, mechanically ventilated lambs to see if ventilation effects of nicotine exposure relate to SIDS in humans. (This grant was given despite our knowledge that maternal smoking accounts for about 30 percent of all SIDS cases.)

A grant of $152,166 in 1996 was given to Leonard L. Howell at Emory University to see how caffeine and nicotine interact in rhesus monkeys. Again, clinical studies of human beings who smoke and use caffeine would be far more relevant.

SUMMARY

Nicotine experiments on animals cause immeasurable suffering and divert funds from efforts that benefit human health, such as aggressive prevention, education, and addiction treatment programs.

Please include language in the report accompanying the fiscal year 2002 Labor-HHS-Education Appropriations bill stating that none of the funds under this appropriations act shall be used for nicotine or tobacco experiments on non-human animals.

If you do not feel that that would be possible, please consider including the following stipulations in the report:

If any of the funds under this appropriations act are to be used for nicotine or tobacco experiments on non-human animals, the following criteria must be met before the experiments can begin:

—The secretary or administrator of the agency responsible for conducting the experiment shall provide a report to Congress with the following information:
  —the purpose of the experiment and a description of its anticipated benefits to human health;
  —the number and species of animals required;
  —the source from which the animal(s) will be procured;
  —an explanation of why the number of animals cannot be reduced;
  —a detailed description of what procedures the animal(s) will undergo;
  —a rating (none, mild, moderate, or severe) and detailed description of the pain and distress that the animal(s) will experience;
  —a statement of whether or not analgesics or other painkillers will be used (and if not, an explanation of why not);
  —a description of all elements in the experiment considered to be stressors to the animal(s);
  —an explanation of what will happen to the animal(s) after the experiment is completed;
  —a list of all databases that were searched to ensure that the experiment is not replicating any experiment(s) that has/have already been performed;
  —a statement that, in the opinion of the secretary or administrator, there is no possible way that the topic of the experiment could be researched without using live animals, and an explanation of why this is, including an explanation of why this experiment would be more relevant to human health effects than human clinical studies or epidemiological studies would be;
  —a description of any non-animal research methods that are currently under development which may be a viable alternative to the experiment, and an explanation of why the experiment cannot be postponed until that non-animal method becomes available for use;
—this report shall be published in the Federal Register for a 60-day period during which the public may submit comments;
—this report, along with all public comments submitted during the aforementioned 60-day period, shall be reviewed by the House Appropriations Committee and by the Senate Appropriations Committee. After reviewing the report and

the public comments, a two-thirds majority in each committee must vote to approve the use of funds for the experiment.

If the above three criteria are not met, the funds may not be used for the experiment.

Without these stipulations, tax dollars will continue to be wasted on duplicative, meaningless experiments that cause animals to suffer and that do nothing to benefit human health.

Thank you for your consideration of our request.

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA AND THE ASSOCIATION OF POPULATION CENTERS

Thank you, Mr. Chairman for this opportunity to present the position of the Population Association of America (PAA) and the Association of Population Centers (APC) to the Subcommittee on Labor, Health and Human Services and Education on fiscal year 2002 funding for the National Institutes of Health (NIH), specifically the National Institute on Aging (NIA), and the National Institute of Child Health and Human Development (NICHD). You are a long-standing friend of both organizations. We are grateful to you for your recognition and support of demographic research.

As you know, PAA is a scientific and educational society of professionals working in demographic research. APC is a consortium of 30 leading American population research centers. In addition to their academic roles, members of both organizations provide federal, state and local government agencies, as well as private sector institutions, with data and research to guide decision-making. Two population research centers are based in Pennsylvania—one in Philadelphia and one in State College.

Demographic research covers many issues important to our nation, such as retirement, health disparities, disability and long term care, child care, immigration, labor force participation, worker retraining, family formation and dissolution, and population forecasting. The United States is undergoing far-reaching shifts in its demographic composition and distribution. Such changes are not always recognized or understood until they confront society with new and immediate needs—often requiring federal and state expenditures. Incorporating demographic, social and behavioral research into long term policy discussions allow such changes to be tracked and anticipated in a manner that promotes more coherent and efficient planning and policy implementation.

The National Institute of Child Health and Human Development (NICHD) and the National Institute on Aging (NIA) provide primary support for demographic research at NIH. We would like to take this opportunity to share with you information concerning the implications of an aging population, the effects of welfare reform on children and families, immigration, fatherhood and adolescent health.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NICHD has a well-established and successful population research program. NICHD is currently funded at $977 million with approximately $74.5 million of that budget dedicated to research funded through the Demographic and Behavioral Sciences Branch in fiscal year 2000. Among the many areas of demographic research supported by NICHD are families and household composition; marriage and family change; fertility and family planning; teen pregnancy; mortality; HIV prevention; and population movement, distribution and composition. NICHD also funds a highly regarded population research centers program. Population research centers provide a critical core of professionals who conduct research in a cost-effective manner. Further, the centers' training programs are an essential source of population scientists who bring fresh perspectives, ideas and improved methodologies to demographic research.

NICHD-supported demographic research provides important, ongoing information critical to policymakers. We are pleased to provide information in this testimony that focuses on the Fatherhood Initiative, the effects of welfare reform on children and families, profiles of immigrants, and adolescent health.

Fatherhood

In the past, males were often overlooked in research that focused on family formation and functioning. NICHD, in conjunction with the Federal Interagency Forum on Child and Family Statistics and the National Center on Fathers and Families, launched a Fatherhood Initiative to review the capacity of the federal statistical system to conceptualize, measure and gather information from men about how they be-

came fathers and how they provide economic and emotional support to their children.

Among the results of this effort are the inclusion of men in the National Survey of Family Growth and the development of a father's component in the Early Childhood Longitudinal Survey and the inclusion of basic research on fathers in the Early Head Start Research and Evaluation Project. NICHD is also supporting research to understand factors leading to stable unions among unmarried fathers and mothers.

The roles fathers play in the lives of their children are strongly affected by the father's relationship to the mother: the access of fathers to their children is highest when parents are living together. The Fragile Families Study has found that unmarried fathers are generally engaged with their children at birth and aspire to be good fathers, contrary to popular myth. Additionally, in cases of divorce, a NICHD funded research has shown that many fathers have enormous desire to maintain contact with their children, and with intervention can continue to be major influences in the lives of their children.

Welfare Reform Effects on Children and Families

The 1996 welfare reform act and the subsequent changes in the welfare programs of nearly every state constitute the greatest shift in social policy for low-income families with children since the Social Security Act of 1935. Since the passage of welfare reform legislation, welfare caseloads nationwide have dropped dramatically, yet we know very little about how these changes affect these children and families. NICHD supports a wide range of research that examines how communities, families and children are interrelated and adapting to changes in social policy.

The Fragile Families and Child-Well Being Study started collecting data in 2000 and will continue through 2004. Initial waves of data will inform research on prenatal care, mother-father relationships, expectations about fathers' rights and responsibilities, attitudes toward marriage, social support and knowledge of local policies and community resources. The Three Cities Study of Welfare Reform and the Well-Being of Children studies the effects of the 1996 Welfare Reform bill on children in three cities, Boston, San Antonio, and Chicago, over the period 1999–2002.

Research on Immigration

Understanding the trends in immigration and the characteristics of immigrants is vital for making informed policy decisions. NICHD, the Immigration and Naturalization Service (INS), the National Science Foundation (NSF), and the National Institute on Aging (NIA) have cooperatively funded a New Immigrant Survey Pilot Study (NIP). This study will provide immediate policy relevant information on immigrants in the U.S. and serve as the foundation for long-term research on immigrants.

Much of the conventional wisdom on immigrants has been repudiated in recent NICHD supported studies. For example, legal immigrants are better schooled, on average, than the native born; the proportion with postgraduate education is almost three times larger than among the native born, at the same time, there is also a substantial group without a high school education. Overall, however, the quality of legal immigrants entering the U.S. is improving. Influenced by changes in immigration laws and changing economic conditions, the skill composition of immigrants to the U.S. has risen.

Adolescent Health

Our knowledge of adolescent health has been greatly enhanced by the National Longitudinal Study of Adolescent Health (Add Health), a comprehensive study, begun in 1994, of adolescent health and well-being funded by NICHD and 17 other federal agencies. This study provides information that is valuable to parents, educators, researchers and policy makers.

One of the key findings from the Add Health study is that "family-connectedness" plays a central role in protecting adolescent health: adolescents who feel loved and cared for by their parents and are satisfied with their family relationships are least likely to smoke, drink or use illegal drugs; least likely to become sexually active at a young age; least likely to be emotionally distressed or contemplate suicide; and least likely to engage in violence.

Family and Child Well-Being Research Network

We would also like to bring you up-to-date on NICHD's Family and Child Well-Being Research Network—an interdisciplinary data system focusing on child- and family-related research that relies on cross-agency cooperation. The network is comprised of scientists from nine universities collaboratively working with federal officials from NICHD, the Office of the Assistant Secretary for Health, of the Department of Health and Human Services (HHS), the Administration of Children and

Families of HHS, the Census Bureau and the Department of Education. This network currently addresses a variety of questions about the interrelations between parent characteristics, family structure and organization, neighborhood attributes and different forms of social support. The network is committed to increasing the visibility of basic research findings to those involved in formulating public policy. Projects such as the Family and Child Well-Being Research Network perform the important task of helping synthesize research into sensible policy solutions.

The Network, in cooperation with federal statistical agencies and the research community developed a comprehensive set of indicators of child well-being. The information from these indices are compiled annually in the report "America's Children: Key National Indicators of Well Being." This report provides a much improved information base that summarizes the changes in the overall well-being of American children and families on an annual basis.

NATIONAL INSTITUTE ON AGING (NIA)

The NIA also has a well established and widely respected demographic research program, which provides crucial information on the implications of an aging of the American population for our country. Currently, the NIA is funded at $786 million, with approximately $115 million of that budget dedicated to the Behavioral and Social Research Program—training, career development, and demographic, economic and epidemiological research in fiscal year 2000. As the U.S. population ages and Congress contemplates sweeping changes in Medicare and Social Security, the demography of the elderly steadily becomes more important. The NIA has a strong history of supporting the collection of data, which allows demographers to study questions of concern to policymakers. Chief among these is the NIA-supported studies, the Health and Retirement Study (HRS). You have been a solid supporter of this important prospective panel study since its inception in the early 1990s, Mr. Chairman, and we would like to express our gratitude for your support.

Health and Retirement Study (HRS)

The Health and Retirement Study (HRS) was launched in 1992 with baseline interviews for a representative sample of persons born between 1931 and 1941. These respondents were interviewed again in 1994, 1996 and 1998. Last year HRS completed its most recent round of data collection, HRS2000 and even now is preparing to go back into the field in 2002.

In 1993, the HRS was augmented by the AHEAD (Asset and Health Dynamics of the Oldest-Old) which sampled the cohorts born before 1924, individuals who are the oldest-old segment of our population with high rates of chronic disease, disability, and health care costs. The older AHEAD respondents were interviewed in 1995, 1998 and 2000. In 1998, samples of two other cohorts were added, those born between 1924 and 1930, the so-called children of the Depression, and those born between 1942 and 1947, or the "early baby-boomer cohort". With the addition of these cohorts, HRS is nationally representative of the population over age 50. Since 1998, the entire study is referred to as the HRS.

The original HRS focused on mid-life work and health dynamics. Biennial data are now available for all respondents on health, disability, work, health insurance, pensions and retirement plans, and transfers of time and financial help across generations of the family. The HRS has been used by NIA-supported researchers to explore issues related to health, work and retirement; mid-life savings and the prospects for late-life economic security; cognitive changes, health insurance coverage, and use of health care services. Data provided by very old respondents has been useful for studying how families redistribute their resources across generations, and how these flows interact with public sector transfers. These data inform policy decisions on initiatives such as Medicare/Medicaid coverage for long-term care and prescription drug benefits.

Health Status and Health Care

We have long known that Americans are living longer than ever before, and new research shows that older Americans are living better as well. A recent NIA funded study showed that while memory problems increase with age, fewer seniors were identified as having significant memory or cognitive problems in 1998 than in 1993. Both men and women experienced improvements over the past decade and marked improvements were seen in those over 80. These preliminary findings suggest that severe cognitive impairment in the senior population has declined over time. This study follows earlier studies which demonstrated a similar decline in the rates of physical disability among the senior population.

The majority of Americans over age 65 rates their health as good or excellent and report being satisfied with the health care they receive, still, many seniors face

chronic health conditions or disabilities and utilize home care to help meet their needs. While most home care is still provided informally and free of charge by family and friends, recent trends have shown a decline in the use of informal home care as the sole means of help and an increase in the use of combined formal or paid assistance and informal help. The 1990s saw dramatic increases in paid home health care for older Americans. There are however a number of disparities in home care assistance. Research has found that on average, disabled women receive significantly fewer hours of informal care than disabled men, and the dominant provider is a child rather than the spouse, as it is for men.

Federal Forum on Aging Related Statistics

Finally, PAA and APC are interested in and support the current efforts to strengthen the Federal Interagency Forum on Aging-Related Statistics. The NIA leads the forum, which is a consortium of nine federal agencies working together to improve the quality and usefulness of data on older Americans. The forum is an example of NIA's interest in supporting NIH's innovative endeavor of streamlining federal databases, making data accessible to the business community as well as academic researchers. Only by allying these two groups can the data produced by the federal government be brought to bear on the real problems of older Americans.

CONCLUSION

PAA and APC would like to thank you for the opportunity to present this information. Demographic data and research are important tools for policymakers that can both save public funds and promote more informed decision-making. If this vital research is to continue producing relevant and timely information, adequate funding and Congressional support are needed.

The Population Association of America and the Association Population Centers support an increase in the range of 15 percent to sustain the momentum of demographic research in the National Institutes of Health as part of the broadly based support to continue five year process of doubling of NIH's by 2003. PAA and APC continue to support an even distribution of any increase in funding for NIH among the institutes.

PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

INTRODUCTION

Mr. Chairman, thank you for the opportunity to submit written testimony regarding fiscal year 2002 appropriations for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

I am Linda Carr, president of the Pulmonary Hypertension Association (PHA). Pulmonary hypertension is a rare disorder of the lung in which the pressure in the pulmonary arteries (the blood vessels in the lungs) rises above normal levels and may become life threatening. Symptoms of pulmonary hypertension include shortness of breath with minimal exertion, fatigue, chest pain, dizzy spells and fainting. When pulmonary hypertension occurs in the absence of a known cause, it is referred to as primary pulmonary hypertension (PPH). This term should not be construed to mean that because it has a single name it is a single disease. There are likely many unknown causes of PPH.

Secondary pulmonary hypertension (SPH) means the cause is known. Common causes of SPH are the breathing disorders emphysema and bronchitis. Other less frequent causes are the inflammatory or collagen vascular diseases such as scleroderma, CREST syndrome or systemic lupus erythematosus (SLE). Congenital heart diseases that cause shunting of extra blood through the lungs like ventricular and atrial septal defects, chronic pulmonary thromboembolism (old blood clots in the pulmonary artery), HIV infection, liver disease and diet drugs like fenfluramine and dexfenfluramine are also causes of pulmonary hypertension.

Pulmonary hypertension is frequently misdiagnosed and has often progressed to late stage by the time it is accurately diagnosed. Pulmonary hypertension has been historically chronic and incurable with a poor survival rate. However, new treatments are available which have significantly improved prognosis. Recent data indicate that the length of survival is continuing to improve, with some patients able to manage the disorder for 15 to 20 years or longer.

As PHA's new president, I come to this role standing on the shoulders of giants. Ten years ago when three women with PH founded this organization, there were less than 50 diagnosed cases of this disease. It's not that PH wasn't there, so much as it was—for the most part—unknown, even in the medical community.

Today, PHA includes:
—Over 3,600 patients, care givers and medical professionals
—An international network of over 50 support groups
—An active and growing patient hotline
—An new and fast-growing research fund
—A host of numerous electronic and print publications

Centers for Disease Control and Prevention

PHA applauds the subcommittee for its leadership in encouraging CDC to initiate a professional and public PH awareness campaign in the fiscal year 2001 Labor, Health and Human Services, and Education (L–HHS) conference report. Currently, we are working with officials from the CDC to establish this important program that will better inform health care professionals and the general public about PH, its symptoms, and treatment options. The following is a description of the specific initiatives we hope to launch in collaboration with CDC:

(1) Increasing awareness and understanding of PH among primary care physicians is critically important, because these practitioners are usually the first point of contact for PH patients. If the primary care doctor misses the symptoms, then the chance for early diagnosis depends upon the intuition and persistence of the patient. They have a chance, if they aggressively pursue diagnosis by trained and aware specialists. If they are not aggressive, or if they are in a health plan that requires their general practitioner to prescribe the referral, they are more likely to go undiagnosed until it is too late to control their illness.

We are in the process of developing and implementing several targeted strategies for reaching these providers, including:
—Written and video diagnostic tools for placement on the Internet.
—A postcard mailing to be sent to all primary care physicians, medical schools and medical centers in the United States drawing attention to the new web resources.
—A simplified and visually attractive version of the proper diagnostic procedures, which will be sent in a second mailing to all primary care physicians, medical schools and medical centers in the United States.
—Advertising in publications general practitioners are likely to read. The emphasis will be the urgency and ease of early diagnosis and the ease of accessing diagnostic tools via the Internet.
—A CD–ROM that explains pulmonary hypertension from a variety of angles. We would like to make 100,000 of these available to the medical community and patients through our web site on an as requested basis and at conferences and through targeted mailings.

(2) Due to the advancements in treatment for PH, it is important that we also focus on educating cardiologists and pulmonologists. Our strategies for reaching cardiovascular specialists include:
—Publication of the first Pulmonary Hypertension Journal focused on educating a wider population of doctors on issues related to the diagnosis and treatment of the illness.
—Placement of additional detailed information on the illness on the web. The PH Journal and other publications will promote this availability.
—Expansion of PHA's international conference on pulmonary hypertension (the largest PH conference in the world).
—Expansion of PHA's Pulmonary Hypertension Resource Network. This program is focused on increasing awareness of PH among nurses through peer education.

(3) Finally, PHA is committed to increasing PH awareness among the general public through the development of the following initiatives:
—A series of 10, 15 and 30 second public service announcements on PH. These PSAs will be in both audio and video form.
—A PH media relations manual.
—An organ donation awareness campaign (unfortunately, many PH patients die before finding a suitable organ donor).
—Expansion of PHA's web-site.

We look forward to working with CDC to implement these and other initiatives aimed at increasing awareness of PH in the United States and throughout the world. For fiscal year 2002, we encourage the subcommittee to continue to support the important mission of the CDC with an overall appropriation of $5 billion (an increase of $1.1 billion over fiscal year 2001) Moreover, we urge you to provide $1 million (level funded from fiscal year 2001) within CDC's Cardiovascular Disease program (a division of CDC's Chronic Disease Prevention program) for the continuation of the PH public and professional awareness initiative.

National Heart, Lung and Blood Institute

Mr. Chairman, PHA commends the leadership of the National Heart, Lung and Blood Institute (NHLBI) for its support PH research. Just last year, two separate groups of scientists funded by NHLBI simultaneously identified a genetic mutation associated with primary pulmonary hypertension.

The two groups, independently reported that defects in the BMPR2 gene, which regulates growth and development of the lung, are associated with PPH. The defects in the gene lead to the abnormal proliferation of cells in the lung characteristic of PPH.

Although both studies suggest that only one gene is involved in PPH, neither group identified the defects in BMPR2 as the sole cause of PPH. In addition, since many people without a known family history of PPH get the disease, both groups suggested that other factors may interfere with control of tissue growth. Now that we have pinpointed a gene, we can focus on learning how it works. Hopefully, that information will enable researchers to devise better treatments and perhaps eventually a preventive therapy or cure.

Mr. Chairman, PHA would like to thank you and the subcommittee for your leadership in support of funding for the National Institutes of Health. Moreover, we would like to thank the subcommittee for the inclusion of committee recommendations on PH research at NHLBI in the fiscal year 2002 Senate L–HHS report. For fiscal year 2002, PHA joins with the Ad Hoc Group for Medical Research Funding in supporting a 16.5 percent increase for NHLBI. Finally, we request that the subcommittee provide $25 million in fiscal year 2002 for PH research at the institute to enhance basic research, gene therapy and clinical trails of promising new therapies.

CONCLUSION

Mr. Chairman, once again thank you for the opportunity to present the views of the Pulmonary Hypertension Association. We look forward to continuing to work with you and the subcommittee to improve the lives of pulmonary hypertension patients. If you have any questions or would like additional information please do not hesitate to contact me or the PHA National Office in Silver Spring, Maryland (301) 565–3004.

PREPARED STATEMENT OF THE RESEARCH SOCIETY ON ALCOHOLISM

The Research Society on Alcoholism appreciates the opportunity to present its views about the importance of alcohol research within our nation's priorities for health and improving the quality of life. The Research Society on Alcoholism is a professional society of over 1,200 members who are committed to understanding and intervening in the negative consequences of alcohol through basic research, clinical protocols and epidemiological studies.

The cost of alcohol abuse and dependence on American society and individual lives is staggering. The cost to the nation is estimated at approximately $185 billion annually. Not only are the fiscal costs real and powerful, but alcohol misuse is costly in other ways as well. Specifically, it is associated with 50 percent of all homicides, 40 percent of all motor vehicle fatalities, 30 percent of all suicides and 30 percent of all accidental deaths. Furthermore, the cost to productive life is astounding. A recent review of estimates of Disability—Adjusted Life Years (a means of estimating loss in productive daily living) indicates that alcohol abuse and dependence is the fifth leading cause of lost life-years in the United States. It follows conditions which are not unrelated from alcohol abuse and dependence such as ischemic heart disease, traffic collisions, certain cancers and HIV/AIDS. For some subgroups, such as the American Indians with whom I work, the costs associated with alcohol misuse may be even higher and may be directly linked to some of the major health problems in this group such as hypertension and diabetes.

Despite, or perhaps because of, the widespread impact and effects of alcohol, it has been impossible to identify a single cause or solution to alcohol's negative consequences. There is no doubt that alcohol abuse and dependence are affected by a number of factors including genetic risk, socio-cultural characteristics, psychiatric and general health co-morbidity and individual differences in the acute and chronic effects of alcohol. The only hope for better understanding and thus more effective education, prevention, intervention, treatment and long-term recovery is through research.

The Research Society on Alcoholism wants to thank the Congress, and this Committee in particular, for the strong support the National Institute on Alcohol Abuse and Alcoholism (NIAAA) received in current fiscal year. Because of this committee's

historic support of the growth of biomedical research, and the investment in NIAAA more specifically, the alcohol research community has made tremendous strides in clarifying many of the factors which we now know contribute to risk to alcoholism and the overall negative consequences of alcohol abuse and dependence. Specifically, because of this support we have seen significant advances in disentangling the genetic influence and role of family history in alcohol dependence, we have begun to identify the critical components of effective treatment, and we have begun to explore effective integrated treatments for those who suffer from the most severe forms of the disease. Given our scientific understanding of alcoholism only a few decades ago, this is truly remarkable progress.

While recognizing these advances, we believe the need to continue the effort and national commitment to this issue. The leadership of the Research Society on Alcoholism has framed a set of priorities which, if adequately supported, will move the field significantly forward in all areas of NIH priority.

Specifically, we strive to more accurately evaluate risk for alcohol dependence and measure the effectiveness of early education and primary prevention efforts. In regard to treatment, we are moving toward a systematic evaluation of integrated treatments which engage more traditional therapies, the use of pharmacotherapies (such as naltrexone) and the use of support and self-help groups. This focus does not imply that all alcoholics require this level of treatment, but it is important that we develop more effective treatments and develop means of identifying those who are most in need of these interventions. Newer pharmacotherapies are now available which significantly decrease drinking and increase sobriety while still newer medications (e.g., acamprosate; now under study) appear to reduce craving and thus enhance the newly recovering person's ability to sustain abstinence.

Technology has its place in these identified priorities, as well. Imaging and computerized testing will provide the means for understanding the underlying brain systems and enable a more standard assessment across research protocols. Relatedly, the developing imaging techniques will facilitate our understanding of "craving" and provide the means for its characterization as the "brain event" that it is.

Basic studies of alcohol metabolism with specific subgroups continues to be a critical area for study. Additionally, neuroimaging studies including brain electrophysiology, positron emission tomography and developing technologies will shed light on new ways of conceptualizing the disease process of alcohol dependence and facilitate the distinction between alcohol abuse and dependence.

The Human Genome project as well as the Consortium on the Genetics of Alcoholism Study (the latter funded by NIAAA) have turned our nation's attention to the role of genes and the possibility of discovery. Alcoholism will not easily lend itself to a simple genetic application. It can, however, be better described, the subtypes better identified and the differential risk for various interactions between alcohol and other medical disorders better clarified through these technologies.

Finally, we endorse the concern regarding health disparities as it is experienced in the research of substance abuse and dependence. We know that there appears to be an increased risk within certain ethnic/racial groups, however, it is unclear why this risk exists and whether or not the risk applies to all members of the group. For example, the Indian Health Service estimates that the age-adjusted alcoholism mortality rate for American Indians is 63 percent higher than the rate for all other races in the U.S. Initial studies with other racial groups have identified specific strengths and vulnerabilities which are important to further explore if we are to address the needs of all Americans.

Recommendations.—Given the costs of alcohol abuse/dependence as well as the significant advances over the past decade, we believe that the continued support of NIH and NIAAA are imperative to our nation's quality of life. Consistent with the Ad Hoc Committee for Biomedical Research Funding, the Research Society on Alcoholism is urging that Congress support a $3.4 billion, or 16.5 percent, increase for NIH in fiscal year 2002 to maintain the congressional campaign to double the NIH budget by 2003. Within this funding level, the RSA requests a $79.4 million, or 23 percent, increase to NIAAA for fiscal year 2002; this increase would bring the total NIAAA budget to $420 million. This request represents the professional judgement of the alcohol research community and is justified on the basis of the historic under funding of NIAAA, significant advances in recent years, and the promise of opportunity in the present.

The Research Society on Alcoholism thanks you for the opportunity to present our views.

PREPARED STATEMENT OF ROTARY INTERNATIONAL

Chairman Specter, Senator Harkin, members of the Subcommittee, thank you for this opportunity to testify on behalf of Rotary International in support of the polio eradication activities of the U.S. Centers for Disease Control and Prevention. The effort to eradicate polio has been likened to a race—a race to reach the last child. As in any race, discipline, commitment, and endurance are indispensable elements of success. This race requires the discipline to remain focused on the task at hand. We cannot allow ourselves to become complacent as we approach the finish line. Though we sense victory is near, a single misstep could jeopardize all we have accomplished. This race requires the commitment to make the sacrifices necessary to achieve success. The major partners in the global polio eradication effort have joined with national governments around the world in an unprecedented demonstration of commitment to this historic public health goal. As the initiative runs its course, total victory can only be guaranteed through continued and unwavering commitment to the goal of a polio-free world. This race requires the endurance necessary to maintain our current activities. We cannot allow the great distance we have traveled to diminish our resolve. Though we may be weary from a race that has now lasted years, our adversary is weakening. The victory over polio is closer than ever!

I would like to take this opportunity to thank you Chairman Specter, Senator Harkin, and members of the Subcommittee for your tremendous commitment to this effort. Without your support of the CDC's polio eradication activities, the battle against polio would be impossible.

The global eradication strategy is working. In 1985, when Rotary began its PolioPlus Program, 125 nations around the world were polio-endemic. At the end of 2000, only 20 countries remained polio-endemic. The Western Hemisphere has now been polio-free since 1991, and the Western Pacific region was certified polio-free in October of 2000. Europe will be the next block of countries to be certified polio-free with the rest of the world anticipated to be certified polio-free not later than 2005. Today polio is confined only to Sub-Saharan Africa, parts of the Middle East, and South Asia (Exhibit A).

Thanks to the polio eradication efforts over the last decade, more than three million children who might have been polio victims are walking and playing normally. Tens of thousands of public health workers have been trained to investigate cases of acute flaccid paralysis and manage immunization programs. Cold chain, transport and communications systems for immunization have been strengthened. A network of 148 polio laboratories has been established.

Significant challenges lie before us. Continued political commitment is essential in polio endemic countries, to support the acceleration of eradication activities, and in donor countries, so that the necessary human and financial resources are made available to polio-endemic countries. Access to children is needed, particularly in countries affected by conflict. Truces must be negotiated if National Immunization Days (NIDS) are to proceed in these countries. Polio-free countries must maintain high levels of routine polio immunization and surveillance. The continued leadership of the United States is critical if we are to overcome these challenges.

Rotary International is a global association of more than 29,000 Rotary clubs, with a membership of over 1.1 million business and professional leaders in 163 countries. In the United States today there are some 7,500 Rotary clubs with over 380,000 members. All of our clubs work to promote humanitarian service, high ethical standards in all vocations, and international understanding.

In the United States, Rotary has formed the USA Coalition for the Eradication of Polio, a group of committed child health advocates that includes Rotary, the March of Dimes Birth Defects Foundation, the American Academy of Pediatrics, the Task Force for Child Survival and Development, and the U.S. Fund for UNICEF. These organizations join us in expressing our gratitude to you for your staunch support of the international program to eradicate polio. Over the past several years, you have steadily increased your appropriation for the polio eradication activities of the Centers for Disease Control, and for fiscal year 2001 you appropriated a total of $91.4 million for the CDC's overseas polio eradication efforts. This investment has made the United States the leader among donor nations in the drive to eradicate this crippling disease.

FISCAL YEAR 2002 BUDGET REQUEST

For fiscal year 2002, we respectfully request that you provide $106.4 million for the targeted polio eradication efforts of the Centers for Disease Control and Prevention, a $15 million increase from the fiscal year 2001 funding level. This $15 million increase is necessary to respond to the rising cost of oral polio vaccine, which has increased to as much as $.096 from $.072 per dose. In addition, we must continue

to meet the enormous costs of eradicating polio in its final stronghold—sub-Saharan Africa. The underdeveloped and conflict-torn countries of Africa represent the greatest challenges to the success of the global Polio Eradication Initiative. This appropriation will allow the CDC to help African nations accelerate polio eradication activities, improve surveillance for polio and other diseases, and support peace-building cease-fires for National Immunization Days. Without the additional $15 million, we may not be able to purchase sufficient levels of oral polio vaccine, prolonging the need to continue expensive NIDs and routine immunization worldwide. The time for the final assault against polio is now.

ERADICATING POLIO WILL SAVE THE UNITED STATES AT LEAST $230 MILLION ANNUALLY

In 1998 the Chairman of the House Committee on International Relations commissioned the General Accounting Office to investigate the soundness of WHO cost estimates for the eradication or elimination of seven infectious diseases. The United States was a major force behind the successful eradication of the smallpox virus, and the GAO concluded that the eradication of smallpox has saved the United States some $17 billion to date. Even greater benefits will result from the eradication of polio.

Although polio-free since 1979, the United States' public and private sectors currently spend at least $230 million annually to protect its newborns against the threat of importation of the poliovirus, in addition to its investment in international polio eradication. Globally, over $1.5 billion U.S. dollars are spent annually to immunize children against polio. This figure does not even include the cost of treatment and rehabilitation of polio victims, nor the immeasurable toll in human suffering which polio exacts from its victims and their families. Once polio is eradicated and immunization against it can be discontinued, tremendous resources will be unfettered to focus on other health priorities.

PROGRESS IN THE GLOBAL PROGRAM TO ERADICATE POLIO

Thanks to your leadership in appropriating funds, the international effort to eradicate polio has made tremendous progress.

—Since the global initiative began in 1988, more than 3 million children in the developing world, who otherwise would have become paralyzed with polio, are walking because they have been immunized.

—The number of polio cases has fallen from an estimated 350,000 in 1988—of which 35,000 were reported—to approximately 3,500 reported cases in 2000 (Exhibit B). More than 180 countries are polio-free, including 4 of the 5 most populous countries in the world (China, U.S., Indonesia and Brazil).

—Almost 2 billion children worldwide have been immunized during NIDs in the last 5 years, including 150 million in a single day in India.

—Approximately 3,500 confirmed polio cases were reported to WHO for 2000. As a result of routine polio immunization, NIDs and house-to-house mopping-up activities, there has been a 99 percent decline in reported polio cases since 1998.

—Of the three types of wild poliovirus, Type 2 has not been seen since October of 1999, and appears to have been eradicated.

—All polio-endemic countries in the world have conducted NIDs. The achievement of successful NIDs and implementation of APF surveillance in Somalia and Sudan shows that polio eradication strategies can be implemented even in countries affected by civil unrest.

THE ROLE OF THE U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Rotary commends the CDC for its leadership in the global polio eradication effort, and greatly appreciates your Subcommittee's support of the CDC's polio eradication activities. For 2001, you appropriated a total of $91.4 million for the CDC's global polio eradication activities. Because of Congress' unprecedented support, in 2001 the CDC is:

—Supporting the international assignment of more than 110 long-term epidemiologists, virologists, and technical officers to assist the World Health Organization and polio-endemic countries to implement polio eradication strategies, and 16 technical staff to assist UNICEF and polio-endemic countries. This includes 30 CDC staff provided directly on assignment to WHO and UNICEF.

—Providing nearly $50 million to UNICEF for approximately 530 million doses of polio vaccine and $9 million for operational costs for NIDs in some 60 countries in Asia, Eastern Europe, the Middle East and Africa. A 33 percent increase in polio vaccine costs in 2001 has reduced the number of doses that can be procured with CDC funds. Many of these NIDs would not take place without the assurance of the CDC's support.

—Providing over $13 million to WHO for surveillance, technical staff and NIDs' operational costs, primarily in Africa. As successful NIDs take place, surveillance has emerged as a critical need to determine where polio cases are continuing to occur. Good surveillance can save resources by eliminating the need for extensive immunization campaigns if it is determined that polio circulation is limited to a specific locale.
—Training virologists from all over the world in advanced poliovirus research and public health laboratory support. The CDC's Atlanta laboratories serve as a global reference center and training facility.
—Providing the largest volume of both operational (poliovirus isolation) and technologically sophisticated (genetic sequencing of polio viruses) lab support to the 148 laboratories of the global polio laboratory network. CDC has the leading specialized polio reference lab in the world.
—Serving as the primary technical support agency to WHO on scientific and programmatic issues regarding: (1) laboratory containment of wild poliovirus stocks following polio eradication, and (2) when and how to stop polio vaccination worldwide following global certification of polio eradication in 2005.

OTHER BENEFITS OF POLIO ERADICATION

Increased political and financial support for childhood immunization has many documented long-term benefits. Polio eradication is helping countries to develop public health and disease surveillance systems useful in the control of other vaccine-preventable infectious diseases. Already, much of Latin America is free of measles, due in part to improvements in the public health infrastructure implemented during the war on polio. The disease surveillance system—the network of laboratories and trained personnel built up during the Polio Eradication Initiative—is now being used to track measles, Chagas, neonatal tetanus, and other deadly infectious diseases. NIDs have been used as an opportunity to give children essential vitamin A, as well as polio vaccine. The campaign to eliminate polio from communities has led to increased public awareness of the benefits of immunization, creating a "culture of immunization" and resulting in increased usage of primary health care and higher immunization rates for other vaccines. It has improved public health communications and taught nations important lessons about vaccine storage and distribution, and the logistics of organizing nation-wide health programs. Additionally, the unprecedented cooperation between the public and private sectors serves as a model for other public health initiatives. Polio eradication is the most cost-effective public health investment, as its benefits accrue forever. The world will begin to "break even" on its investment in polio eradication only two years after the virus has been vanquished.

RESOURCES NEEDED TO FINISH THE JOB OF POLIO ERADICATION

The World Health Organization estimates that $1 billion is needed from donors for the period 2001–2005 to help polio-endemic countries carry out the polio eradication strategy. Of this total approximately $550 million has been committed, leaving a funding gap of approximately $450 million. In the Americas, some 80 percent of the cost of polio eradication efforts were borne by the national governments themselves. However, as the battle against polio is taken to the poorest, least-developed nations on earth, and those in the midst of civil conflict, many of the remaining polio-endemic nations can contribute only a small percentage of the needed funds. In some countries, up to 100 percent of the NID and other polio eradication costs must be met by external donor sources. We are asking that the United States continue to take the leadership role in meeting this funding gap.

The United States' commitment to polio eradication has stimulated other countries to increase their support (Exhibit C). Belgium, Canada, Germany, and Italy are among those countries that have followed America's lead and made special grants for the global Polio Eradication Initiative. Japan has also expanded its support to polio eradication efforts in Africa. Germany has made major grants that will help India eradicate polio. In 1999 the United Kingdom announced two grants totaling U.S. $94.6 million for polio eradication efforts in India and Africa. In the last year, the Netherlands has committed nearly $50 million for global polio eradication. The Dutch Government pledged $8.4 million for surveillance in India, Pakistan and the Democratic Republic of the Congo, followed by a year-end allocation of $40 million for surveillance in 2000.

By the time polio has been eradicated, Rotary International expects to have expended approximately $500 million on the effort—the largest private contribution to a public health initiative ever. Of this, $402 million has already been allocated for polio vaccine, operational costs, laboratory surveillance, cold chain, training and

social mobilization in 122 countries. More importantly, we have mobilized tens of thousands of Rotarians to work together with their national ministries of health, UNICEF and WHO, and with health providers at the grassroots level in thousands of communities.

Your discipline, commitment and endurance have brought us to the brink of victory in the great race against this ancient scourge. Polio cripples and kills. It deprives our children of the capacity to run, walk and play. Other great health crises loom on the horizon. The work you have done and that which we ask you to continue will ensure that today's children possess the strength and vitality to run the race on behalf of future generations.

Thank you for this opportunity to present written testimony.

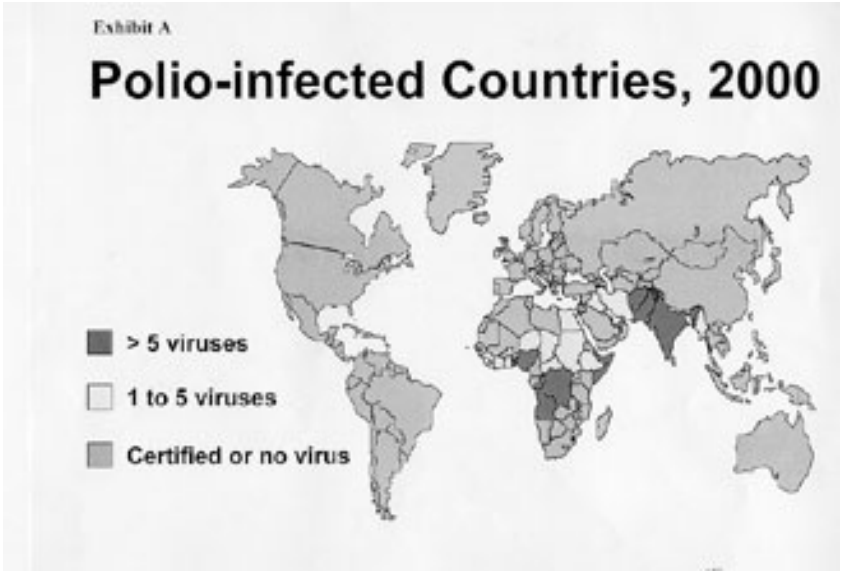


Exhibit C

MAJOR POLIO-SPECIFIC GRANTS*
(in US dollars)
1996 – 2001
(by fiscal year announced)

	1996	1997	1998	1999	2000	2001	Total
Australia	938,000	2,795,000	171,500				3,904,500
Belgium	5,100,000			1,516,000			6,616,000
Canada	1,400,000		40,740,000	4,100,000			46,240,000
Denmark	40,000,000	6,000,000					46,000,000
European Union	704,000	400,000		6,000,000			7,104,000
Finland	330,000		100,000				430,000
Germany		451,000	24,000,000				24,451,000
Italy	750,000	100,000		1,000,000			1,850,000
Japan	22,430,000	25,720,000	13,040,000	23,720,000			84,910,000
Korea			900,000				900,000
Netherlands		248,000			8,400,000	40,000,000	48,648,000
Norway	2,120,000	700,000	208,500				3,028,500
Portugal					400,000		400,000
Sweden	481,000	400,000					881,000
Switzerland	177,000	1,300,000					1,477,000
Taiwan				5,000,000			5,000,000
United Kingdom	78,600,000	1,550,000	31,160,000	94,668,000	50,000,000		255,978,000
USA	47,200,000	72,200,000	81,200,000	94,839,000	127,200,000	118,900,000	541,539,000
Public Sector Total	**200,230,000**	**111,864,000**	**191,520,000**	**230,843,000**	**186,000,000**	**158,900,000**	**1,079,357,000**
Private Sector Total**	**9,000,000**	**342,000**	**3,090,000**	**82,700,000**			**95,132,000**
GRANTS TOTAL	**209,230,000**	**112,206,000**	**194,610,000**	**313,543,000**	**186,000,000**	**158,900,000**	**$1,174,489,000**

*Grants in excess of US$100,000 intended primarily for polio eradication activities. These may be direct bilateral grants to polio-endemic nations, or multi-lateral grants through international organizations such as WHO or UNICEF. Some are for multiple years.

**Donations from 4 vaccine manufacturers, ACIH, United Nations Foundation, DeBeers, and the Gates Foundation

In addition to these polio-specific grants, many countries are supporting the WHO Expanded Programme on Immunization, which combats several infectious diseases, among them polio.

Since 1985, Rotary International's PolioPlus Program has committed $402 million to global polio eradication. Revised January 2001

PREPARED STATEMENT OF THE SCLERODERMA RESEARCH FOUNDATION

The Scleroderma Research Foundation appreciates the opportunity to submit this written statement urging Congress to provide increased federal support to the National Institutes of Health (NIH) for the aggressive pursuit of basic research programs on scleroderma.

The Scleroderma Research Foundation has, on its own, mobilized and developed a high quality scientific and medical research program dedicated to the pursuit of a cure for scleroderma, all without government support. The advances made by the Scleroderma Research Foundation have led to the identification of several key areas of investigation that could further focus the path to a cure, if only the research receives the support it deserves. As this progress has developed, significant government help has been sorely lacking. A commitment from Congress and the NIH is needed to leverage and build upon the key advances that have been achieved, and to bring us closer to saving lives.

We ask for a commitment by Congress to provide concentrated federal support at the NIH to aggressively pursue basic research programs on scleroderma. A goal of $10 million annually would constitute a minute portion of total health research spending, yet would more than double the current available funds for scleroderma research. More important, this level of funding would support needed advances in the current state of knowledge in the field.

The Scleroderma Research Foundation also calls for an appropriation of $23.7 billion for the NIH in fiscal year 2002. This 16.5 percent increase represents the fourth step toward doubling the NIH budget by fiscal year 2003. This continued growth will allow the NIH to realize the promise of new technologies and better meet the challenges of improving the health of the nation's people.

Scleroderma is a serious, but overlooked and under-funded disease. It is conservatively estimated to afflict at least 350,000 Americans (many organizations estimate as many as 750,000 scleroderma patients in the United States, given recent advances in diagnostics). More than 80 percent of scleroderma patients are women, between the ages of 30 and 50, but scleroderma is also a disease that strikes—and kills—children and men. Yet, the NIH is projected to fund scleroderma research this year at only $4.74 million.

Scleroderma is a chronic, degenerative disorder that leads to vascular deterioration, tissue loss, and fibrosis in the body's connective tissue. There are different

types of scleroderma, but even in the disease's limited forms, scleroderma can be disfiguring, debilitating, and painful. In its most serious form, systemic sclerosis, the disease causes severe damage and serious complications for the body's digestive, respiratory, circulatory, and immune systems. Almost 70 percent of patients with systemic sclerosis die in less than seven years after their initial diagnosis.

A diagnosis of scleroderma is all the more chilling for patients when they learn there are no effective treatments for the vast majority of cases and no cure for the disease. Scleroderma has a particularly complex phenotype affecting different organs. The failure of a long list of medications in scleroderma patients points to the critical need for basic scientific research to unlock the mysteries of this disease.

When the Foundation was created in 1987 there were no diagnostic tools for scleroderma, and research on the disease was almost nonexistent. In a little over a decade, the Scleroderma Research Foundation has successfully met the challenge of raising pivotal funds, brought together top scientists to direct and execute cutting edge, basic research programs and targeted the most direct approach to finding a cure for scleroderma. The $5 million invested in research by the Scleroderma Research Foundation has all come from private sources, especially scleroderma patients, their friends, families and supporters.

The Foundation's research programs have made critical discoveries in the three major areas of pathogenesis of scleroderma: the immune system, blood vessels, and extracellular matrix.

—Autoantibodies have been found that are unique to scleroderma patients and are not found in other autoimmune diseases. Further research is needed to understand why and how these antibodies form.

—The study of blood vessel pathology has identified key receptors that mediate the vascular hypersensitivity known as Raynaud's phenomenon, a primary feature of scleroderma and a precursor to extensive vascular damage.

—Hardening of the skin, or fibrosis, is another prominent feature of scleroderma. Investigators have identified a decrease in an inhibitory molecule that may explain the mechanisms leading to excessive hardening of the skin.

—New genetics studies have been initiated to determine if there are host factors that can influence the onset of scleroderma. Advances in genetics present new opportunities for scleroderma research, including the development of scleroderma genotypes and the search for genetic mutations or aberrations.

These discoveries point the way to future investigations that cannot be carried by the Scleroderma Research Foundation alone. We have made significant progress, but have far to go in understanding this disease. We have made enough progress, however, to know that scleroderma is a solvable problem. The Scleroderma Research Foundation has been successful in bringing together the appropriate scientists in specialized fields. The advances in molecular and cellular sciences have created tremendous potential, compared to ten years ago, for discovering the triggers of this disease. Today, the right people and technologies are in place to cure scleroderma. Your partnership is needed to secure the necessary resources to get the job done and start saving lives.

Thank you for providing the opportunity to present this statement. The Scleroderma Research Foundation welcomes any questions or requests for further information.

PREPARED STATEMENT OF THE NATIONAL TASK FORCE TO END SEXUAL AND DOMESTIC VIOLENCE AGAINST WOMEN

The Sexual Assault, Rape and Incest Issues Committee of the National Task Force to End Sexual and Domestic Violence Against Women urges the Senate Appropriations Committee, Labor, Health, and Human Services, Education Subcommittee to appropriate the $80 million for Rape Prevention and Education Grants authorized under the Victims of Trafficking and Violence Protection Act of 2000, specifically:

Title IV—Strengthening Education and Training to Combat Violence Against Women

Sec. 1401 Rape prevention and education.

Congress made a commitment by passing the Violence Against Women Act of 2000 to provide increased resources to sexual assault service providers and to continue and expand rape prevention programs. FULL FUNDING OF THIS GRANT PROGRAM IS CRITICAL TO CONTINUING THIS IMPORTANT WORK.

The funds authorized under the Act are used for prevention and education programs for the following:

—Educational seminars

—Operation of hotlines
—Training programs for professionals
—Preparation of informational material
—Education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities
—Education to increase awareness about drugs used to facilitate rapes or sexual assaults
—Prevention/education efforts targeting underserved communities and individuals with disabilities

Rape Prevention and Education funding also supports the National Sexual Violence Resource Center, a project of the Pennsylvania Coalition Against Rape. The Center is a clearinghouse of information and resources related to all facets of sexual violence, including stranger and non-stranger rape, drug-facilitated rape, statutory rape, sexual harassment and child sexual abuse. The Center collects and facilitates resource-sharing among organizations across the country. Every month, the Center receives over 100 requests for information from state and territorial sexual assault coalitions, local rape crisis centers, government entities, allied national organizations and the media.

Sexual violence is a critical social epidemic confronting our Nation:

An estimated 302,100 women and 92,700 men are forcibly raped each year in the United States (Tjaden, Patricia and Thoennes, Nancy, November 1998).

13.3 percent of college women indicated that they had been forced to have sex in dating situation (Johnson, I., Sigler, R., 2000. "Forced Sexual Intercourse Among Intimates").

In a 1998 study of which school students, over half of all males and 42 percent of all females believed that sometimes it is "acceptable for a male to hold a female down and physically force her to engage in intercourse" (Warshaw, 1998).

The majority of rapes nationwide are perpetrated against young women and girls. Full funding of the Rape Prevention and Education grants is an indispensable tool for keeping women and girls safe from sexual violence. Thank you for giving us the opportunity to present our perspective.

PREPARED STATEMENT OF THE SJOGREN'S SYNDROME FOUNDATION

SJOGREN'S SYNDROME

Sjogren's (SHOW-grins) syndrome is one of the most common autoimmune disorders, striking 4 million Americans. Ninety percent are women, and most are middle aged and older when diagnosed. However, Sjogren's crosses all ages, ethnic groups, and socioeconomic boundaries. Anyone can have this disease. There is no cure and few treatments beyond palliative measures, yet the suffering and disability is tremendous, and the potential consequences serious.

In Sjogren's, the immune system turns against one's own body. Moisture-producing glands are primary targets, resulting in hallmark symptoms of dry eyes and dry mouth. These symptoms alone can be devastating. If not treated, dry eyes can lead to corneal ulcers and abrasions and potential blindness. Untreated dry mouth can lead to rampant cavities and loss of teeth. Once teeth are lost, those with Sjogren's have few options—dentures often don't work in a mouth that's dry and susceptible to infection. Problems with swallowing, digestion, and reflux are also common in Sjogren's.

But Sjogren's syndrome is not confined to symptoms of dryness. Sjogren's can affect any organ in the body, including the skin, lungs, pancreas, and liver, endocrine glands, and gastrointestinal, vascular, nervous, and urinary and reproductive systems. Autoimmune thyroid and autoimmune liver disease are not uncommon in one who has Sjogren's. Sjogren's can cause debilitating joint and muscle pain and fatigue, and maternal antibodies associated with Sjogren's can cause heartblock in babies of mothers who have the disease. Finally, Sjogren's can result in lymphoproliferative disorders, or lymphoma, there being a 44 times higher rate of non-Hodgkins lymphoma in those who have Sjogren's.

WHAT IS IT LIKE TO LIVE WITH SJOGREN'S SYNDROME

A Sjogren's syndrome patient, Kim Vaughn, wants to tell you what it's like for her to live with the disease. She writes:

"I'm a model, a former Mrs. Georgia America, and the mother of two energetic boys. I'm a wife, a daughter, a sister. But what I know you can't see if you were to look at me is that I have a disease called Sjogren's syndrome. This disease has not only affected my life, but it has affected the lives of every member of my family.

Sjogren's syndrome is an autoimmune disease. While it can affect any organ in the body, it targets the moisture producing glands. Can you imagine your eyes being constantly dry because you can't produce tears? Can you imagine what it's like not to have saliva, so that you can't eat many common foods? Can you imagine being so exhausted every night that you collapse at 8:00 p.m.? It's hard enough to raise two boisterous boys with a normal energy level.

I live with pain.—Joint and muscle pain are a big part of Sjogren's syndrome. I know it's hard for people to understand the impact of pain and fatigue, and it might seem minor to have dry eyes and dry mouth, but these symptoms are devastating. To have your eyes and mouth dry all the time, be susceptible to infection, always have to carry and use moisturizing eyedrops and drinking water wherever I go . . . these things greatly affect quality of life.

I live with fear.—Will I be one of the 5 percent with Sjogren's who gets lymphoma and leaves a wonderful husband and kids behind, because this disease doesn't seem urgent or important enough? Because my symptoms can't be seen? When I was pregnant, I had to worry if my child would have fetal heartblock because of my Sjogren's. Would I have the energy to take care of an infant, to nurture a baby from infancy to adulthood? Are my children genetically susceptible to this disease?

I was one of the lucky ones because I was diagnosed quickly—it only took a year and a half. Sjogren's might be a common autoimmune disease, but most women suffer for years before being diagnosed. When we're finally diagnosed, there's not much to be done for it but treat the symptoms, many times ineffectively or only for a little while. Why?

The Sjogren's Syndrome Foundation greatly appreciates your continued support of federally funded medical research. Please help us to take advantage, now, of the escalating breakthroughs in medical research to unlock the mysteries of autoimmunity—particularly the mysteries of Sjogren's syndrome."

QUALITY OF LIFE

Quality of life might be hard to measure, but it is critical to one's well-being, to the ability to live a full life without potentially crippling psychological and physical anguish and affecting employment and enjoyment of life.

Quality of life is surely compromised when one is frequently in pain and suffers from severe fatigue, spends hours in doctors' offices and undergoing testing, and when one faces fear of complications. Other quality-of-life issues include having one's eyes and mouth hurt all the time and succumb to infection, not always being able to focus clearly, swallow easily, go out to eat, or talk for long periods or take a walk because one's throat and mouth get dry quickly. The incidence of depression increases when quality of life diminishes.

Most of the palliative treatments to which patient Kim Vaughn refers are over-the-counter medications, which are not reimbursable by insurance. This creates an additional financial burden on those who suffer from Sjogren's syndrome. High costs of medical testing, frequent doctors' visits to a range of specialists, and prescription medications, might or might not be largely covered by insurance. Those who are chronically ill face lifetime insurance caps and often find work options reduced.

Let's take a look at the impact of just one of the common symptoms of Sjogren's—dry eye: A year 2000 study by Dr. David Sullivan of The Schepens Eye Research Institute, Harvard Medical School, found that more than 37 percent of employed dry eye patients say their symptoms interfered with their work and more than 60 percent say symptoms interfered with leisure activities. The same 60 percent say their lifestyle has been adversely affected, and of these, more than 40 percent suffer from depression. Some 40–45 million Americans, most of them women, have dry eye, and the numbers double from those in their 50s to those 75 and older.

THE NUMBERS

Autoimmunity is a huge problem. Autoimmune diseases make up the third largest disease category in the United States, affecting 5 percent of the population, and include some 70 to 80 diseases, many of which overlap and share symptoms. Sjogren's syndrome is one of the most prevalent.

The numbers of those with Sjogren's syndrome are probably higher than scientists estimate. It is often unrecognized and, thus, underdiagnosed and misdiagnosed. Among the reasons—the disease crosses many medical specialties, symptoms often seem unrelated, and Sjogren's can mimic or co-exist with other autoimmune organ-specific disorders. Dryness might be attributed incorrectly to the aging process. Other complaints of fever, joint and muscle pain, and fatigue, and the waxing and waning of symptoms are sometimes seen as insignificant to physicians not well informed about Sjogren's syndrome. It often takes years of seeking help before a diag-

nosis is made; a recent national health study showed an average of 6.3 years from onset of symptoms to diagnosis. Add to this the fact that the baby-boomer generation is now entering the age of high risk for Sjogren's, and the number of patients will surely increase.

RESEARCH OPPORTUNITIES

Scientists still do not know the cause of Sjogren's syndrome, but recent developments have taken us a step closer to understanding the disease and finding new treatments. For example, inflammatory infiltrates have long been believed to cause decreased tears and saliva in Sjogren's, but new research shows there might be a very different reason. The glands that produce moisture might, in fact, be rendered dysfunctional by specific autoantibodies, antibodies that target one's own self. These antibodies targeting muscarinic receptors have been found to cause dry eyes and mouth in animal models. Similar antibodies have been implicated in other Sjogren's complications, such as fetal heartblock in babies born to mothers with Sjogren's.

Other new developments will enhance both clinical and basic Sjogren's research. The first is an agreement by an international committee of scientists working to develop standards for defining the disease, an effort organized and supported by the Sjogren's Syndrome Foundation.

Second is the potential for a registry on Sjogren's and inclusion of Sjogren's in a database on autoimmunity. NIDCR is looking into the possibility of starting a database specifically on Sjogren's, and NIAMS and NIAID already fund one for autoimmune disease, but Sjogren's was not originally included. They are now working with us on ways to do just that. If Sjogren's is included in databases, we'll be better able to understand the genetics of Sjogren's and autoimmune diseases and other aspects of autoimmunity.

We're in a new information age, and it's time we gathered data that will answer the critical need for epidemiological studies on Sjogren's. We have no statistics!

Finally, as an NIDCR scientific workshop held last fall on Sjogren's demonstrates, we can inspire groups of scientists from around the world to work together, develop the means to share research, and expand our base of knowledge.

There's a wonderful Sjogren's Syndrome Clinic housed at NIDCR, and indeed, most of the research on Sjogren's is being done at the dental and eye institutes. Sjogren's syndrome crosses many specialties and encompasses systemic manifestations, and because of that, we would like to see NIAMS and NIAID become more actively involved in this disease.

We rely on the National Institutes of Health (NIH) to help educate physicians and the public. Our foundation and the NIDCR co-hosted a continuing education conference for healthcare providers this fall—the first one ever at NIH. NIDCR held a scientific workshop at the same time, and NIAMS published its first information booklet on Sjogren's this year. These are wonderful, but these are only firsts. We MUST continue and expand these initiatives.

We're seeing an explosion in medical and scientific opportunity right now. We have incredible opportunities ranging from immunology to cell biology, from drug development to genetic engineering, through which genetic makeup might eventually be changed to actually block autoimmune disease. The human genome project opens up new avenues for discovering the genetic links in autoimmune disease. We have unprecedented opportunities for research in the areas of immunomodulation, gene therapy, and creation of artificial glands. We MUST take advantage of this.

NATIONAL INSTITUTES OF HEALTH AND APPROPRIATIONS

Sjogren's syndrome is one of the most prevalent autoimmune diseases. Yet, astonishingly, the prevalence does not match the low dollar figure spent on research and education.

Sjogren's syndrome ranks ninth when we compare the number of extramural grants at the National Institutes of Health (NIH) for autoimmune disease. There are twice as many clinical trials for lupus, another autoimmune disease, as are being done for Sjogren's syndrome, but Sjogren's affects twice as many people.

The most recent figures available from the NIH Autoimmune Diseases Coordinating Committee show that out of an approximately $18 billion budget for NIH, $398 million was allocated for autoimmunity. Yet autoimmunity is the third largest disease category in the U.S. Of the total amount for autoimmunity, over 90 percent went to just three autoimmune diseases—rheumatoid arthritis, juvenile diabetes, and multiple sclerosis. Lupus received the next largest amount, leaving about $45 million for 76 other autoimmune disorders, including Sjogren's syndrome.

We ask your committee as it works on the next Appropriations bill, to add the words "Sjogren's syndrome" any time another autoimmune disease is mentioned by

name. Sjogren's is one of the most prevalent autoimmune diseases, is an ideal scientific model, and yet over and over again it is left out.

We are working to change the visibility of and attention for Sjogren's syndrome, and we hope after our testimony, you, as members of the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, will recognize the importance of this disease.

We applaud you for supporting medical research at the NIH and working towards doubling the NIH budget over 5 years. We applaud you for your support and allocation of dollars for autoimmunity. We are grateful for your support of the NIH Autoimmune Diseases Coordinating Committee. Finally, we urge you to consider research costs not just in dollars, but the human cost, the tremendous burden of disease on families, and especially the specific burden of a prevalent and devastating disease—Sjogren's syndrome.

HOW CAN THE SENATE APPROPRIATIONS SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES HELP

A first and important step by Congress was establishing the Autoimmune Diseases Coordinating Committee at the National Institutes of Health. But we would like to see NIAMS and NIAID take on a larger role in the many systemic aspects of this disease.

We ask that NIAMS and NIAID recognize that research in Sjogren's syndrome is part of their mission and should be included in their portfolio of grants.

PREPARED STATEMENT OF THE SUDDEN INFANT DEATH SYNDROME ALLIANCE

Chairman Specter, thank you for the opportunity to address this subcommittee and explain what Sudden Infant Death Syndrome and the importance of federal funding for SIDS programs and research means to me. My wife and I lost our son Chandler in 1997, and we are compelled to do everything and anything possible to ensure no one has to suffer the loss of a child again. Mr. Chairman, we need your help, your commitment, and your support to help solve the mystery that is SIDS.

Despite the fact that SIDS cases have been documented for years, organized scientific research into SIDS only began in the mid 1970's. Three decades later scientists are now beginning to make significant progress in unraveling the enigma of SIDS. For instance, we now know that in many SIDS related deaths there is an abnormality in a region of the brain which is thought to control heart and lung functions. In these cases, this irregularity may have hampered normal respiratory activity, and while not the sole cause of SIDS, it may have contributed to a larger respiratory problem leading to death.

As a direct result of SIDS research and the "Back to Sleep" educational and awareness campaign, SIDS deaths have been reduced by 38 percent since 1992, concurrent with the increase in awareness regarding infants being placed on their backs to sleep-leading to the greatest decline in infant mortality rates in over 20 years.

However, our research and educational campaign is far from finished. Each year more than 3,000 infants in the United States die from SIDS and it continues to be the number one cause of death for children between one month and one year of age. SIDS is a major component of the United States infant mortality rate. In spite of this fact, we do not yet understand the causes of SIDS nor do we possess a guaranteed method for its prevention.

The primary federal agency responsible for conducting SIDS research and the "Back to Sleep" public awareness campaign is the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health. In addition to federal funding of SIDS research, there are other federal agencies involved in the SIDS effort. Since 1975, the Maternal and Child Health Bureau (MCHB) within the Health Resources and Services Administration (HRSA) has supported specific programs for SIDS family counseling and for public and professional education about SIDS. The Centers for Disease Control and Prevention (CDC) has established a standardized death scene investigation protocol for SIDS incidents. Additionally an Interagency Panel on SIDS has been established, which includes: NIH, HRSA, CDC, Indian Health Services, Food and Drug Administration, U.S. Consumer Products Safety Commission, Department of Defense, Administration for Children and Families, and the Department of Justice to help coordinate all federally funded SIDS activities.

The SIDS Alliance is grateful for the Subcommittee's past support of SIDS activities, especially the support of NICHD. We urge you again to provide the additional funding necessary for the second year of the third Five Year SIDS Research Plan

to ensure that NICHD can continue to address critical SIDS research initiatives. Specifically the SIDS Alliance is supporting a funding increase to $23.7 billion or 16.5 percent for NIH overall, and a 16.5 percent increase for NICHD to $1.137 billion. We ask that the increases for NIH do not come at the expense of other Public Health Service Agencies. Further research is essential to find the reasons for, and means of preventing the tragedy of SIDS.

I urge the Subcommittee to support SIDS educational, awareness, and counseling activities that take place at the MCHB, and the death scene investigation protocol demonstration projects at the CDC. These programs are a vital "flip-side" to the good research that NICHD does. Without prevention awareness, counseling, and standardized investigation procedures, good research does not translate into meaningful advances for SIDS victims and their families.

HIGHLIGHTS OF FEDERALLY FUNDED SIDS ACTIVITIES

National Institute of Child Health and Human Development (NICHD)

Childcare has become increasingly important in the social fabric of the United States, so have child care centers and homes. To address this issue the NICHD has initiated the "Back to Sleep Child Care Project," sending publications and other "Back to Sleep" materials to over 280,000 child care centers and licensed homes throughout the United States. Response to these mailings has been overwhelming, resulting in a 20 percent increase in the volume of requests for Back to Sleep materials.

Studies on the risk factors for SIDS among African American and American Indian populations conducted in collaboration with the CDC and the Indian Health Service have yielded valuable information for targeted interventions to reduce infant mortality in these communities. SIDS among minority populations continues to be a top priority for the NICHD. Surveys show that the proportion of African Americans placing their infants to sleep on their stomachs continues to decrease, however, African Americans are still twice as likely to place infants on their stomachs as compared to other populations. Discussion groups are underway in African American communities across the country to assess the "Back to Sleep" campaign message, and to improve message delivery. In addition, during fiscal year 2001, the NICHD established new initiatives on health disparities in minority populations. SIDS and related fetal and infant deaths are part of the initiatives targeted at eliminating health disparities in infant mortality.

A new component of the "Back to Sleep" campaign focusing on reducing SIDS among African American was launched in late 1999. The goal is to develop and implement a community-based initiative. The National Black Child Development Institute (NBCDI) joined with the NICHD, the campaign sponsors, and several other organizations in the outreach initiative. A culturally appropriate resource kit, which includes a training guide, has been developed, and the first national training workshops have been held. Plans for fiscal year 2002 include training at the local level through affiliate African American organizations, and regional infant mortality summits. In addition, discussions have begun for a community partnership campaign targeted to reducing SIDS among American Indians in fiscal year 2002.

The mechanism of SIDS is still unknown; there are no clinical or biologic tests to identify a newborn at high risk of succumbing to SIDS; and more work is needed to increase the implementation of "Back to Sleep" among all caregivers and in communities with high rates of infant death. To address and focus its efforts on these challenges, the NICHD is in the process of developing and implementing its third SIDS Research Five-Year Plan. Meetings regarding various aspects of the five-year plan have been held throughout the past two years and are expected to continue. The plan will be divided into five parts: Introduction, Etiology/Pathogenesis, Prognostics/Diagnostics, Prevention, and Health Disparities. A draft of the Introduction and the Etiology/Pathogenesis section will be open for public comment on the web during the month of March 2001. The remainder of the draft plan will be on the web for public comment in April.

Plans for research initiatives in fiscal year 2002 include (1) continued research on mechanisms of pathogenesis through studies in animal models, postmortem tissue, and high-risk infants. This includes a prospective study to define a battery of physiologic and genetic markers that will predict SIDS and to determine whether SIDS is part of a larger family of autonomic nervous system disorders; (2) analysis of epidemiological and physiological data collected during the second five year research plan to improve our understanding of environmental and intrinsic risk factors; (3) a community-linked health disparities initiative to investigate related aspects of mortality from late fetal life through early childhood; (4) improve risk reduction and

efficacy of "Back to Sleep" through continued research, monitoring, and outreach in at risk communities.

Maternal and Child Health Bureau (MCHB)

The MCHB supports a number of SIDS and Other Infant Death related services and programs, including the following activities:

—National SIDS Resource Center, a major source of current information about SIDS.

—Maternal and Child Health Service Block Grant (MCH), which grants funds to states providing a range of services to SIDS families. Block grant funds support activities like: contact families immediately after death, discussion of autopsy results with the family, and support and counseling through the first year of bereavement. Unfortunately, in many jurisdictions across the country, funds for these services have been decreased or eliminated due to budgetary difficulties.

—Field training and curriculum to health care providers for case management of families who have experienced an infant death, and the development of model programs, particularly for the underserved and minorities. Demonstration grants have been established in four states to target services for specific populations: California, Massachusetts, Missouri, and New York.

—National SIDS & Infant Death Program Support Center to address SIDS service issues at the federal level on an ongoing basis. The SIDS Alliance was chosen to run this center, which opened in 1999, and has experienced notable success.

Centers for Disease Control and Prevention (CDC)

To develop a better statistical figure on SIDS cases, Congress recommended in 1993 the establishment of a standard death scene protocol to offset discrepancies on unexplained infant deaths between states. It was hoped that this protocol would be adopted by states not only for statistical measure, but to help avoid awkward and emotionally charged misunderstandings at the death scene. In 1996, CDC published the protocol, and since that time several states have adopted the standard. It is SIDSA's long term goal to ensure that all states fully adopt the protocol. To help realize this goal, SIDSA would like CDC to heed Congress' recommendations for the past two years and implement demonstration projects that follow these guidelines in several communities nationwide. We would also encourage CDC to implement a nationwide survey to measure how many locales have implemented the protocol independently and to analyze the results thus far.

In conclusion, we are all too painfully aware that SIDS has historically been a mystery, leaving in its wake devastated families and bewildered physicians. Not only have there been no answers on the cause of SIDS, but there have been no answers on how to effectively prevent its occurrence. Today we are beginning to find some of the answers on cause and prevention, and therefore reduce the risk of SIDS. Because of the "unknown", however, babies are still vulnerable even when parents and care givers take the cautionary steps to prevent SIDS deaths. This tragedy will continue if research efforts are stalled or halted, especially when we are at the point where so much progress has been made. Now is the time for a re-energized effort against this tragic syndrome.

On behalf of the thousands of families who have been devastated by the loss of a baby to SIDS, and the millions of concerned and frightened parents, we ask for your support, and thank you again for allowing us to present this testimony. If you have any questions, please do not hesitate to contact us.

PREPARED STATEMENT OF THE TRUST FOR AMERICA'S HEALTH

Mr. Chairman, and members of the Committee, I wish to provide a real perspective on our nation's ability to respond to health emergencies like the pediatric leukemia cluster in Fallon, Nevada and health concerns related to multiple sclerosis in Wellington, Ohio.

My name is Dr. Shelley Hearne and I serve as the executive director of the Trust for America's Health—a new nonprofit health advocacy organization taking action to prevent disease and protect the health and safety of our communities. I am very proud to have former Governor Lowell Weicker, Representative Louis Stokes, and Chairman John Porter along with many other national leaders in public health serve on our Advisory Council.

By way of background, I am an environmental health scientist—serving for almost twenty years in government, non-profits, and as a faculty member of the Johns Hopkins School of Public Health. Most recently, I was the executive director of the Pew Environmental Health Commission.

Let me be candid. Our public health service is falling short in its duty to watch over the safety and health of Americans, particularly when it comes to chronic diseases that may be associated with environmental factors.

Chronic diseases such as cancer, asthma, Parkinson's, birth defects and diabetes are responsible for 7 out of 10 deaths in this country. More than a third of our population, over 100 million men, women and children, suffer from chronic disease. By 2020, studies estimate that chronic disease will strike 134 million Americans and cost $1 trillion a year. And the Centers for Disease Control and Prevention (the "CDC") estimates that 70 percent are preventable.

Despite the human and financial toll of chronic diseases on our country, we have no national approach to track these diseases and respond effectively to cluster crises. Our federal, state, and local agencies only coordinate tracking and responding to infectious diseases such as polio, yellow fever and typhoid—diseases that a national tracking and response system helped to eradicate back in the late 1800s.

Let me give you some examples of chronic disease clusters and concerns from around the country and the problems we face in responding to them.

In Fallon, Nevada, twelve children have been stricken with an acute form of leukemia since 1997. This occurrence rate is higher than the expected average of this disease in a town the size of Fallon. Residents as well as health officials suspect that this cancer may be linked to environmental factors such as a high level of naturally-occurring arsenic in the water or possibly an infectious virus.

In my home state of New Jersey, between 1993–1997, parents in Brick Township identified 53 cases of autism out of 6000 children between the ages of 3 and 10 years. For years, parents complained to politicians and health officials about a feared autism cluster in their community. Health agencies are still trying to determine if this is a problem.

And in Wellington, Ohio, 25 citizens have been diagnosed with multiple sclerosis (MS) in a town of 4,200. This rate is higher than the national average based on recent studies. Residents worry about the toxic exposures from a local iron foundry and the nearby landfill.

In each case, our public health officials lacked the disease occurrence data, personnel, training, and lab capacity to detect these health emergencies and respond to them.

Many chronic diseases are preventable, and each of the above mentioned clusters and health concerns might have been a preventable tragedy. But, because we have no coordinated national tracking of chronic disease, we are unable to identify disease clusters and respond quickly to these health emergencies. As a result, we are hamstringing our scientists from finding solutions and effectively taking action—regardless if it's childhood leukemia in Fallon or multiple sclerosis in Ohio.

Let me describe the existing status of our fractured state health tracking networks.

—Even though studies have shown that birth defects are the number one cause of infant mortality, 17 states do not track birth defects—Pennsylvania, Ohio, Mississippi, New Hampshire, Louisiana, Vermont, Rhode Island, Indiana, Minnesota, South Dakota, North Dakota, Wyoming, Montana, Idaho, Nevada, Oregon, and Washington.

—Only eight states and the District of Columbia track developmental diseases such as cerebral palsy, autism and mental retardation even though the National Academy of Science estimates that 25 percent of these diseases in children are caused by environmental factors—California, Kentucky, Mississippi, Nebraska, New Jersey, North Carolina, South Carolina, and South Dakota.

—Even though studies have shown autoimmune diseases like Lupus to be increasing, only four states report tracking this disease—Arizona, Massachusetts, New Mexico, and South Dakota.

—For years most states did not track cancer. Tracking began in the early 1990's when the CDC allocated money to the states to start cancer registries. Uniform standards for the state cancer tracking networks were just established in 1997.

—More than half of the states do not track asthma even though studies have shown that asthma attacks are the number one cause of school absenteeism and that asthma has increased 75 percent between 1980 and 1994.

The Pew Environmental Health Commission based out of the Johns Hopkins School of Public Health studied ways to strengthen our nation's public health defenses and proposed creating a Nationwide Health Tracking Network.

The Nationwide Health Tracking Network consists of five components:

Coordinating essential data collection systems.—The first component builds on existing health and environmental data collection systems and establishes data collection systems where they do not exist. The Network would coordinate with the local, state and federal health agencies to collect this critical data.

In all fifty states, the Network would track:
—Asthma and other respiratory diseases;
—Developmental diseases such as autism, cerebral palsy, and mental retardation;
—Neurological diseases such as Alzheimer's, multiple sclerosis, and Parkinson's;
—Birth defects; and
—Cancers, especially in children.
The Network also would track exposures to:
—Heavy metals such as mercury and lead;
—Pesticides such as organophosphates and carbamates;
—Air contaminants such as toluene and carbamates;
—Organic compounds such as PCB's and dioxins; and
—Drinking water contaminants, including pathogens.

Developing an Early Warning System.—The second component is an Early Warning System that would immediately alert communities to health emergencies such as lead, pesticide and mercury poisonings. The existing system of local health officials, hospitals and poison centers that alert our communities to outbreaks like food illness and the West Nile virus would also warn our communities about these health emergencies.

Creating Rapid Response Teams.—The third component consists of improving our response time to identified disease clusters and other health emergencies. The Network would coordinate federal, state and local health officials into Rapid Response Teams to quickly investigate these health emergencies, providing the teams with the trained personnel and necessary equipment.

Addressing unique local health problems.—The fourth component is a pilot program consisting of twenty regional programs that would investigate local disease clusters and emergencies outside of the Network. These programs would alert the public and health officials to new developing disease clusters. These pilots programs also would serve as possible tracking models to be included in the Network.

Creating community and academic partnerships.—The fifth component creates relationships with our communities and with regional academic centers. Community relationships would ensure that the tracking data is accessible and useful on a local level. The academic partners would assist with training the workforce, analyzing data, and developing links between the tracking results and preventative measures.

[The background and basis for this Network and other Commission findings are also available on the website at http://healthyamericans.org or http://healthtrack.org]

This Network would provide our communities, scientists, doctors, hospitals and public health officials with the missing data on where chronic diseases are occurring and whom they are striking. This basic, but yet critical, information would enable us to develop effective prevention strategies to protect the health of our citizens.

Data from the Network will also allow us to spend our limited research dollars more effectively by identifying which chronic diseases are increasing and where they are clustering. We have doubled our research dollars in the National Institutes of Health, yet these scientists do not have the most basic information about how often and where chronic disease occurs. Without a Network, our scientists will remain in the dark, unable to develop effective prevention strategies.

Developing prevention strategies for chronic diseases is critical to reducing the $325 billion our country spends on these diseases. In less than fifteen years, the cost of chronic disease is expected to rise to $1 trillion. The estimated cost of the Network is about $275 million or less than 1 dollar per every man, woman and child. This is the most cost effective use of tax dollars today—investing in ways to prevent the leading and most costly diseases in this country.

The public strongly supports the concept of nationwide tracking. A recent public opinion poll by Princeton Survey Research Associates revealed that nine out of ten (89 percent) registered voters support the creation of a national health tracking system. The American public is so concerned about this issue that 63 percent feel that public health spending is more important than cutting taxes. Seven out of ten registered voters (73 percent) feel that public health spending is more important than spending on a national missile defense system.

Over thirty key health organizations have endorsed the Network, ranging from Aetna US Health Care to the American Heart Association to the Association of State and Territorial Health Officers.

The American Chemistry Council supports the concept, noting ". . . data generated by a national tracking program can shift the focus from debate and speculation about disease trends to intervention and prevention based on scientific evidence."

Most local health departments face declining funding, inadequate training for staff, limited or no laboratory access, and outdated information systems. The CDC,

the Agency for Toxic Substances and Disease Registry (the "ATSDR") and other federal agencies have not been able to adequately help our local health departments. For instance, most states do not have a chronic disease investigator. Recently in Fallon Nevada neither the CDC nor the ATSDR could give Nevada written guidance, standards or protocols on how to investigate their childhood cancer cluster. Our federal health agencies have never developed a concrete response program to these growing disease cluster demands.

We are concerned that the Administration's proposed budget recommends severe cuts for the nation's chronic disease prevention programs. Overall, the Administration is recommending $109,000,000 cut from last years budget for the CDC, most of it coming from the National Center for Chronic Disease Prevention and Health Promotion. We need to be going in the exact opposite direction. Health defense should be the country's number one commitment.

In order for us to identify clusters before they grow, we must take rapid action. The CDC must be given the direct mandate to aggressively respond to communities' concerns like those in Fallon and Wellington with modern tools and health tracking. And Congress must prioritize $275 million per year—just a tenth of one percent of the overall spending of health care dollars in this country.

Without this type of investment, we will only watch asthma, certain cancers and other chronic disease rates continue to raise. There will be many more Fallons. And that will be the greatest tragedy of all.

PREPARED STATEMENT OF THE UNITED FRESH FRUIT & VEGETABLE ASSOCIATION

United Fresh Fruit & Vegetable Association appreciates the opportunity to testify in strong support of increased funding for nutrition, physical activity, and obesity at the Centers for Disease Control and Prevention (CDC). As the national trade organization representing the views of producers, wholesalers, distributors, brokers and processors of fresh fruits and vegetables, United has worked aggressively for many years to enhance federal programs and policies to address the staggering costs associated with poor diets and physical inactivity.

According to the U.S. Department of Health & Human Services (HHS), unhealthy eating habits and physical inactivity are now the nation's second leading actual cause of death and are primary factors in the skyrocketing rates of obesity and number of overweight persons. Unhealthy eating and physical inactivity are also major causes of heart disease, cancer, stroke, diabetes, high blood pressure, and osteoporosis. In fact, HHS estimates that unhealthy eating and inactivity contribute to between 310,000 and 580,000 deaths each year, 13 times more than gun-related deaths and 20 times higher than deaths due to illicit drug use.

The costs of diseases caused by unhealthy diets and physical inactivity are enormous. Annual costs related to cancer, coronary heart disease, obesity, diabetes, stroke and osteoporosis now total nearly $550 billion. For Medicare patients alone, the Health Care Financing Administration (HCFA) estimates that coronary heart disease costs taxpayers $9.8 billion per year and strokes cost an additional $3.7 billion. Furthermore, when assessing the costs of diet related diseases only, the U.S. Department of Agriculture (USDA) has estimated that healthier diets could prevent at least $71 billion per year in medical costs, lost productivity, and lost lives. It is important to note that this estimate only takes into account diet-related coronary heart disease, stroke, cancer and diabetes and not other diet-related diseases.

It is obvious that the challenges faced by today's healthcare delivery system have changed enormously, and over the past century, the leading causes of death have shifted from infectious to chronic diseases. These diseases are expensive to treat; and many of them cannot be cured so they require years of expensive treatments.

The CDC has stated that of the 30-year increase in life expectancy between 1900 and 1999, only five years can be attributed to curative medicine, and the remaining 25 years of the increase represent advances in public health and preventive measures. However, today's health care system is still geared almost exclusively toward treatment of disease. Despite the proven success of preventive medicine, spending by state and federal governments averaged $1,390 per person per year for disease treatment and only $1.21 per person per year for preventive measures. We are not advocating that these numbers should be reversed. We are, however, recommending that the United States begin to make sound investments in preventive measures for the well-being of all Americans. A modest investment in programs that can change diet and activity patterns can prevent enormous long-term spending on treatment in the future.

Leading health experts have asserted their firm belief in the benefits of a nutritious diet and physical activity. The National Academy of Sciences (NAS), CDC,

USDA, Surgeon General, and others have affirmed that Americans must change their diets and become more physically active if the rates of illness and premature death are to be reduced.

With research documenting health benefits of increased fruit and vegetable consumption and increased exercise to reduce the risk of cancer and numerous other serious illnesses including heart disease, stroke, obesity and high blood pressure, we support aggressive action to further these important health messages. For example, studies show that people who eat five or more servings of fruits and vegetables each day have one-half the cancer risk of those who eat fewer than two servings. In the area of physical activity, it is documented that a regimen of at least 30–45 minutes of brisk walking, bicycling, or even working around the house or yard will further reduce risks of chronic illness including coronary heart disease, hypertension, colon cancer, and diabetes.

However, only one in four Americans consume five or more servings of fruits and vegetables per day and children ages six to 12 are eating only two-and-a-half servings of fruits and vegetables a day, half of the minimum amount recommended by national guidelines. In the area of physical activity, research indicates that 60 percent—well over half of Americans are not regularly active. Worse yet, 25 percent of Americans are not active at all. With such statistics and limited funding available for federal campaigns to change these behaviors, poor diets, physical inactivity and obesity will soon be the number one cause of preventable deaths and avoidable health care costs.

Current trends document this assumption with at least one-third of all cancer, 20-to-40 percent of heart attack and stroke, and as much as 80 percent of Type 2 diabetes being diet-related, and the diet- and exercise-attributable costs of these four conditions nationally are comparable to tobacco. Additionally, obesity which is a primary marker of poor eating and exercise habits, has been declared an epidemic by CDC. This country desperately needs to attack the problem of poor diet and physical inactivity with an initiative of similar scope and duration to that mounted against tobacco over the last decade. The longer we wait to start, the harder it will be to reverse, and the more we will pay as health care becomes more expensive.

To reverse these dangerous trends and begin to elevate this issue at the federal level, United Fresh Fruit & Vegetable Association supports multi-year appropriations totaling $350 million for CDC to expand and build upon ongoing national and state intervention initiatives within the Division of Nutrition and Physical Activity. This funding level will allow CDC to implement a national coordinated nutrition and physical activity plan in every state and a corresponding national media education strategy. Only through such aggressive funding increases will CDC in coordination with state departments of health be able to put in place a national strategy that encourages healthy eating and increased physical activity that is supported by coordinated communications efforts at the federal level. Presently, nutrition and physical activity are the only major chronic disease risk factors without dedicated funding for state intervention programs. While some states do have programs in place for obesity prevention, nutrition and physical activity, these efforts will remain very limited and ineffective without substantial federal funding. The expertise of the CDC in the implementation of effective intervention strategies, health communications, education, and prevention research will enhance the success of state-based efforts by providing states with additional federal resources to leverage their efforts and ensure the implementation of best practices.

We are well aware of budget constraints facing the Committee. However, we strongly encourage the Committee to carefully examine the need to take aggressive action to implement a national coordinated nutrition and physical activity strategy to address the staggering costs of chronic diseases. When you look at the costs associated with heart disease, cancer, diabetes, stroke, high blood pressure, and osteoporosis which total $405 billion a year, we think that $350 million is a very small investment to make in the future health of our nation.

We look forward to working with the Committee on this critical issue and hope that this request can be accommodated to the maximum extent possible during the coming fiscal year. Thank you for your time and consideration.

Prepared Statement of the University of Medicine and Dentistry of New Jersey

The University of Medicine and Dentistry of New Jersey (UMDNJ) is the largest public, freestanding health sciences university in the nation. Our statewide system is located on five academic campuses and consists of eight schools (3 medical, a dental, nursing, public health, health related professions and a graduate school of bio-

medical sciences). UMDNJ also comprises a University-owned acute care hospital, three core teaching hospitals, an integrated behavioral health care delivery system, a statewide system for managed care and affiliations with more than 200 health care and educational institutions across the state. No other institution in the nation possesses the resources that match our scope in higher education, research, health care delivery, and community service initiatives with federal, state and local government entities.

The University's priority projects are statewide in scope and include collaborations both within the University system and with our academic and health care partners. Our mission is focused on building "Centers of Excellence" that will expand our research, enhance our educational programs and provide access to quality health care services for all New Jerseyans. Our projects also underscore UMDNJ's commitment to eliminating racial disparities in health care delivery, which is why our first priority initiative is the Institute for the Elimination of Health Disparities.

The Federal Government has identified striking disparities in the overall health and life expectancy of racial and ethnic populations in the United States. Despite dramatic improvements in health care, disparities still exist among racial and ethnic groups. In recognition of the importance of health disparities to the health of all citizens, UMDNJ supports the efforts of the federal government in a number of initiatives aimed at eliminating health disparities.

UMDNJ has long been recognized for its leadership in providing educational opportunities and health care services to under-represented communities throughout our state. We are a leader in minority student education, minority faculty recruitment and patient care services to minority populations through our core and affiliated hospitals, clinics and community-based programs.

UMDNJ is developing an Institute for the Elimination of Health Disparities that will have statewide impact. The mission of the Institute is to eliminate health disparities through training minority health care providers, improving research on minority health, increasing the number of minority scientists and improving outcomes in health service delivery to minority populations.

The Institute is based in Newark, the largest city in New Jersey with a diverse population, socio-economic status and special health care needs. Newark is also home to UMDNJ-University Hospital, a Level I Trauma Center and the state's only public safety net hospital serving the largest number of indigent patients. In addition to Newark, the Institute will provide services in our host communities of Camden and New Brunswick, which also have large diverse populations.

Leadership of the Institute is provided by the UMDNJ-School of Public Health in partnership with all schools of the University and with our Centers of Excellence including the Cancer Institute of New Jersey; the Environmental and Occupational Health Sciences Institute; the National Pediatric & Family HIV Resource Center; the Hispanic Center of Excellence, the Minority Oral Health Research Center; the Chandler Health Center (a Federally Qualified Health Center); and the Center for Healthy Families and Cultural Diversity. The Institute will also collaborate with state, county, city, community and private organizations to extend its visibility and outreach.

The Federal Government has identified six broad areas that disproportionately affect racial and ethnic populations including infant mortality, cancer, cardiovascular disease, diabetes, HIV/AIDS and childhood immunization. The Institute will focus its research, training and education programs on initiatives related to these areas, and will work to implement other programs that will improve overall health outcomes.

UMDNJ is ideally positioned to lead New Jersey's efforts to eliminate racial and ethnic health disparities. We are requesting $5 million over 5 years to carry out the mission of the Institute for the Elimination of Health Disparities on behalf of the citizens of New Jersey and the nation.

Our second priority is the Cancer Institute of New Jersey.

The Cancer Institute of New Jersey was established in 1990 with a $10 million capital grant from the federal government. Over the past decade, CINJ has grown to become one of the nation's most successful cancer institutes and New Jersey's only NCI-designated clinical cancer center. New Jersey has been especially devastated by cancer where incidence and mortality rates are high compared to national averages. Since it opened its doors, CINJ is successfully fulfilling its mission through innovative advances in research and patient care. CINJ's basic and clinical research are conducted in collaboration with its clinical partners and other academic institutions, community physicians and health care professionals. CINJ's provider network of 20 hospitals stretches across the state and services reach people in every county in New Jersey.

CANCER INSTITUTE OF NEW JERSEY

One of CINJ's significant accomplishments is the creation of the Dean and Betty Gallo Prostate Cancer Center established with funding from the federal government. The Center honors the late Congressman Dean Gallo, who succumbed to prostate cancer in 1994. The Gallo Prostate Cancer Center has garnered $9 million in federal appropriations over the past 3 years and is the state's only specialized prostate health resource located at an NCI-designated cancer center.

Because African-American males are 2.5 times more likely to die from prostate cancer than white males, the Gallo Prostate Cancer Center has partnered with the 100 Black Men of New Jersey organization to offer prostate cancer screenings in minority communities throughout the state. A major goal of the Gallo Prostate Cancer Center is to expand its educational awareness and health screenings to every county in New Jersey.

Additional resources are needed to accelerate the Gallo Center's promising research and to expand its services to the community through education and prevention programs. This expansion is hindered by a critical lack of space in CINJ's New Brunswick facility. Constructed in 1996 to accommodate 16,000 patient visits, CINJ is now seeing 37,000 patients per year with more than 3,000 new patients seeking care. Based on this rate of growth, CINJ anticipates between 50,000 to 60,000 patient visits per year and 5,000 new patients by the year 2003.

UMDNJ has responded to this need for additional space by approving the construction of a 120,000 square foot addition to CINJ's New Brunswick facility. This new space will house the Gallo Prostate Cancer Center as well as provide more space for the treatment of other types of cancer, research, teaching and support staff. We have commitments of $16 million toward the construction cost of approximately $30 million and request $10 million in federal participation to expand the Cancer Institute of New Jersey facility to house the Gallo Prostate Cancer Center.

Another priority initiative is the Child Health Institute of New Jersey.

The UMDNJ-Robert Wood Johnson Medical School has developed the Child Health Institute of New Jersey as a comprehensive biomedical research center focused on the health and wellness of children. The Child Health Institute (CHI) has garnered close to $5 million in federal funds over the past two years and has been awarded a $1.9 million facility grant from the National Center for Research Resources of the NIH in fiscal year 2000. The CHI has received $27 million from private foundations, corporations and individuals, as well as from the state and federal government, to construct a 100,000 square foot research facility in New Brunswick, NJ. The CHI will grow the current research funding base of the Robert Wood Johnson Medical School and strengthen research efforts with clinical departments at the Robert Wood Johnson University Hospital, especially those involved with the new Children's Hospital.

The Child Health Institute will focus research on molecular genetics that direct development of human growth and function. Research will serve as the basis for new treatments, therapies and cures for devastating and debilitating childhood syndromes. Scientists will direct efforts toward the environmental, genetic and cellular causes of diseases in infants and children in a quest to prevent, treat and cure these diseases. Some of the disorders that warrant immediate attention include asthma, muscular dystrophy, diabetes, birth defects and neuro-developmental disorders including autism and spina bifida.

Currently, the Child Health Institute serves as the hub for the New Jersey Governor's Council on Autism at UMDNJ. The Council distributes grants from the State to improve the treatment of autistic children, to educate families and physicians and to investigate causes and possible cures for autism. The Child Health Institute represents the best hope for a sustained campaign against childhood diseases and disorders and provides a unique opportunity to support the health and welfare of this generation and to protect the health of future generations.

Basic science is the key to the future of medicine. As scientists unravel the human genetic code, the impact on America's health is enormous. We are at the brink of discovering which genes cause birth defects and the root causes for disease so that prevention and cures can be realized.

The Child Health Institute has the expertise and the infrastructure in place to achieve major breakthroughs and discoveries that will lead to improvements and cures in childhood diseases.

We request $5 million in federal participation to cap the development of the Child Health Institute of New Jersey.

UMDNJ is committed to scientific research that will benefit the elderly as well as children. That is why our next priority is the Geriatric Research Center.

The Center for Aging at the UMDNJ-School of Osteopathic Medicine (SOM) is an inter-disciplinary center of excellence in geriatric education, clinical care and research. The Center is nationally recognized as a leader in quality care for older individuals through an array of services in the field of aging. Attracting more researchers to the Center is critical to achieving national prominence as a Geriatric Research Center of Excellence. The research programs of the Center will focus on the cellular, biochemical and physiological basis of aging. Research will be directed at the genetic determinants of both aging and diseases common in the elderly. The Research Center will build on existing programs in nutrition, protein loss, injury, Alzheimer's disease to expand basic science research programs in support of the established clinical and educational programs at the Center for Aging. A major drawback is the critical lack of dedicated research space to expand the Center's research laboratories. We seek $5 million in capital and program funds to support dedicated space for the Geriatric Research Center at the Center for Aging at SOM.

Our final priority is to implement a statewide medical response system to respond to catastrophic emergencies as an integral component of the UMDNJ-Center for BioDefense in New Jersey.

UMDNJ has established a Center for BioDefense which achieved $3 million in federal funding over the past two years. That funding is focused on scientific research to understand and identify infectious biological organisms in order to develop treatments for victims of bioterrorist attacks.

New Jersey is the most densely populated state in the nation with more than 8 million residents. New Jersey is home to a myriad of high technology companies and the national headquarters of leading-edge pharmaceutical, radiological and chemical industries. As such, New Jersey is a prime target for terrorist attacks which employ weapons of mass destruction including biological and chemical attacks. Successful mitigation of these events requires a proactive, coordinated effort in planning, training, monitoring and response.

A significant component of the UMDNJ-Center for BioDefense is our expertise in education and training concerning chemical and biological weapons. While emergency medical technicians and paramedics maintain state certification requirements, this does not include continued education in incident command, EMS mass casualty response training, and hazardous material training.

The UMDNJ Center for BioDefense will use the expertise at UMDNJ-University Hospital, the state's Level I Trauma Center, and University Emergency Medical Services (EMS) to provide statewide leadership in training of EMS, first responders and other health professionals and to coordinate a standard regional response to incidents involving weapons of mass destruction, bioterrorism or public health threats. The Incident Support and Operational Planning (ISOP) team will be responsible for training, coordinated communications and response. The unit would also provide technical expertise to assist communities in the development of emergency plans and procedures.

The team will track and disseminate statewide hospital bed status through technology at University Hospital's Regional Emergency Medical Communications System dispatch center. Improvements to the system would include implementing a secure internet-based tracking system, upgrading the existing radio system to integrate with the New Jersey State Police, the Office of Emergency Management, and the Departments of Health and Transportation, as well as implementing an alert network to provide public health agencies with information on potential public health threats. We request funding of $2 million for the Center of BioDefense to assist our efforts to develop a statewide Medical Response System that will strengthen New Jersey's ability to respond to bioterrorism.

Thank you again for your past support and for the opportunity to present testimony of the University of Medicine and Dentistry of New Jersey (UMDNJ) on its priority initiatives in cancer, children's health, geriatrics, biodefense and the elimination of racial and ethnic health disparities.

PREPARED STATEMENT OF DR. WILLIAM H. LIPPY

I would like to express my support for increased funding of Universal Newborn Hearing Screening (UNHS) programs through the Health Resources and Services Administration (HRSA) and the Centers for Disease Control (CDC). President Bush's proposed budget for fiscal year 2002 cut appropriations for these programs, despite the fact that deafness is the most common birth defect in the United States.

Each year 12,000 babies—one in 300—are born with some type of hearing impairment. Technologies such as hearing aids and cochlear implants can alleviate the symptoms of deafness, although these interventions must be made within the first

24 months of life in order to ensure full learning capabilities and language development.

Currently, only 32 states have enacted some type of newborn screening legislation and less than half of all infants are screened for hearing impairment at birth. As a result, deafness is not identified in children until age 30 months, on average, in the United States. Special education costs an additional $420,000 per deaf child by high school graduation, and the combined expenses of deaf education and lost productivity result in average lifetime costs of over $1 million per deaf individual. Newborn hearing screenings average $15–50 in price.

In fiscal year 2001, $8 million was appropriated to HRSA for UNHS, and approximately $6 million was appropriated to CDC. In order to sustain the grants of those states that already receive funding and increase the number of participating states, however, $10 million must be appropriated to both HRSA and CDC specifically for UNHS in fiscal year 2002.

I appreciate your attention to this critical issue and request a response to my inquiry.

PREPARED STATEMENT OF THE UNIVERSITY OF MIAMI, CORAL GABLES, FLORIDA

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity to appear before you today on behalf of my colleagues at the University of Miami School of Medicine.

The University of Miami, a private university founded in 1925, has grown to become a major research and educational institution with strong collaborations and affiliations nationally and internationally. The University consists of 14 schools and colleges with 2,341 faculty and 13,715 undergraduate and graduate students, with facilities located on five campuses. According to the latest National Science Foundation survey, "Federally Funded Research and Development Expenditures," the University ranks 40th nationally and 18th of all private universities with medical schools. Annual expenditures in support of sponsored programs exceeded $194 million during the fiscal year ending May 31, 2000.

The School of Medicine was established in 1952, and was the first accredited medical school in the State of Florida. It has over 1,000 faculty members as well as a large research, administrative, and support staff. In addition to 619 students enrolled for the M.D. degree, the School of Medicine offers a variety of graduate programs with over 350 enrolled students. With its community partner, Jackson Memorial Hospital, it comprises the second largest medical center in the United States and is recognized for its excellence in research, teaching, and community service. The University of Miami/Jackson Memorial Medical Center complex occupies 67 acres and combines facilities in three hospitals, an affiliated Veterans Administration Hospital, the Diabetes Research Institute, the Sylvester Comprehensive Cancer Center, the Bascom Palmer Eye Institute, and numerous other facilities. Sponsored program expenditures during the past fiscal year exceeded $142 million. NIH statistics for fiscal year 1999 rank the School of Medicine as 42nd among the 123 medical schools receiving funding, with over $59 million committed to our programs. There is an additional $5 million in annual NIH funding at our other campuses. U.S. physicians rank our teaching hospital in the top 10 percent of all teaching hospitals in the nation.

One of the major objectives of the School of Medicine's research programs is to promote interdisciplinary collaboration and translational research. Basic scientists and clinicians interact regularly through structured programs and disease-oriented conferences. These have resulted in innovative research and, more importantly, the translation of our basic laboratory findings to the clinical setting. The University has invested its own funds in numerous projects and facilities dedicated to advancing this objective.

In this regard, the University of Miami respectfully requests the Subcommittee to allocate funding that assists in understanding the incidence and causes of disease among particularly vulnerable populations—children, women, the elderly and ethnic minorities, and especially among African-American, Hispanic, and Native American populations.

HIV/AIDS

Miami and the surrounding South Florida region continue to show strong population growth with an unparalleled ethnic diversity. The incidence of HIV and HTLV infections among this population group is high and requires continuous health support. In turn, this patient population offers a unique opportunity and

challenge for the understanding of disease pathogenesis caused by HIV/HTLV, including the progression to neoplasia and immunodeficiency.

Investigators at the University of Miami School of Medicine have played important roles in helping to understand and resolve the HIV/AIDS crisis locally, nationally and internationally. In addition to studies in the United States, we have collaborative HIV programs in the Dominican Republic, Zambia, China, and India. Examples of significant seminal research studies conducted at the University of Miami produced the following findings: AZT protection of newborns from maternal/fetal transmission of HIV; transmission of HIV through sharing of needles by drug abusers, discovered here, led to initiatives in interrupting this route of transmission; and the effectiveness of the combination of Ifn-a with AZT for the treatment of AIDS related lymphomas was elucidated here recently.

The strong clinical, epidemiological and behavioral research programs at the University continue to attract a high level of competitive funding from the NIH, as evidence of their vitality and strength. However, it has become clear in the research community that further progress in limiting HIV/HTLV morbidity and mortality requires a broader understanding of HIV/HTLV pathogenesis. It is evident that the changes during disease onset and progression, both in the virus and in the immune system of the host, are complex and far from understood. It also is clear that a deeper insight into the virus-host relationship is the only way by which further progress can be made. Some institutions have significant NIH funding for HIV/AIDS research in clinical trials and epidemiological studies; however, with modest funded laboratory research programs.

We ask that the Committee provide resources to support programs through the Health Resources and Services Administration that allow for the enhancement of facilities and equipment that bolster HIV/AIDS basic research and treatment facilities and equipment especially for children, and particularly in entities with recognized excellent epidemiological and clinical programs.

MINORITY RESPIRATORY DISEASE RESEARCH

Vulnerable populations in the United States, especially those located in major metropolitan areas, are experiencing a much higher and more severe level of respiratory disease. Diseases such as asthma, and smoking related diseases such as lung cancer and emphysema, are rising at unprecedented rates. To address these critical issues, unique partnerships that bring together existing national research assets that can focus on developing new treatments and preventative strategies designed to have the maximum impact on vulnerable groups, which include children, women, the elderly and African-American, Hispanic, and Native American populations.

Respiratory diseases including asthma, chronic bronchitis, emphysema, and lung cancer are a growing problem in the United States and worldwide. While mortality from most chronic diseases such as heart disease and cancer has substantially declined over the last few decades, deaths from respiratory diseases have increased and are projected to continue to increase over the next decade. Although many respiratory diseases are attributable to smoking, asthma, which most commonly afflicts young non-smokers, has also had a remarkable increase in incidence and mortality. Respiratory diseases occur most commonly among children and the elderly, and also tend to have the most impact on these vulnerable populations. Population-based surveys have suggested that most of the increase in respiratory disease has occurred among minority populations and children. Also, at equivalent levels of environmental exposure, women are more susceptible to developing respiratory disease than men.

It is not clear why there has been an increase in respiratory disease. Most respiratory diseases are the consequence of complex interactions between environmental exposures and individual susceptibility factors. The pathway from environmental exposure to the diagnosis of respiratory disease may be affected by multiple factors at every step that confound or modify the exposure-disease relationship. The complexity of this system makes it difficult to identify causal relationships or to interpret the significance of these relationships when they are found.

For example, several studies have suggested that exposures that result from crowded inner-city conditions could be responsible for the increased incidence of asthma in African-American children; however, others have suggested that a lack of exposure to common environmental pathogens could result in the immune system hyper-reactivity that characterizes asthma. However, without a complete understanding and inventory of environmental exposures, it is impossible to know what contribution inheritance has had to the increased incidence of disease, or how potential new therapies targeted at immune-system defects will help.

Without a multidisciplinary approach, it is unlikely that researchers ever will be able to identify the true causes of this increase in respiratory illness, much less design effective solutions. To conquer this problem, it is essential that the resources and talents of scientists from a broad spectrum of disciplines work cooperatively, and that the mechanisms of respiratory disease in a variety of regions and ethnic groups be carefully examined.

We urge the Committee to support initiatives through the CDC and Public Health Emergency Fund that will advance long-term organized community-based health utilization studies, especially those that examine the growing incidence of respiratory disease among minority populations. State-of-the-art collaborations with recognized partners that have traditional affiliations with minority populations and that will allow the use of innovative research techniques will help elucidate the significance of specific causative factors across different populations in the affected communities, and beyond.

THE ELDERLY AND ELDER ABUSE

Demographic reports unequivocally document the fact that the fastest growing segment of the U.S. population is those over the age of 65 years, especially the "elderly" elderly, over the age of 80 years. Florida is in the unique position of having the fastest growing elderly population, and South Florida, in particular, of having to deal with the cultural diversity of that population. With the increasing probability of longer life spans, come increasing problems related to chronic diseases and fewer social and economic resources. Elderly individuals are particularly vulnerable and require more medical, legal, and social interventions as well as greater dependence on family caregiving where possible. In response to the needs of older Americans the necessity to develop extensive and integrated services is critical. These services range from assessments of competency and functional capacity and guardianship, to the end of life decision making, to long term care issues, elder abuse, to resource allocation and the economic impact on the aging population and their families.

Though not all encompassing, the importance of education and research in this arena will have significant impact on shaping public policies and on practical approaches to assist the medical and legal fields, including law enforcement, the judiciary, and policy makers.

We urge the Committee to provide funding through the Administration on Aging and the Health Care Financing Administration for programs and projects that address the specific issues of importance to the aging population, including: abuse and neglect, management models for unique care requirements, a focus on the role of families and caregivers, end-of-life care, mental capacity, and research ethics. We would envision programs and projects that would involve collaborations between university schools of medicine and law and clinicians and researchers in related university departments and in community agencies.

Mr. Chairman, we understand how difficult a year this will be for you and the Subcommittee. However, my colleagues and I at the University of Miami respectfully request that you give serious consideration to providing support for initiatives that assist in understanding the incidence and causes of disease among particularly vulnerable populations—children, women, the elderly, and ethnic minorities, and especially among African-American, Hispanic, and Native American populations. Vital initiatives in these areas all have great implications and will provide exceptional benefits to the well being of the nation.

Thank you for allowing me to appear here today.

RELATED AGENCIES/GENERAL TESTIMONY

PREPARED STATEMENT OF THE AMERICAN LIBRARY ASSOCIATION

The American Library Association appreciates the opportunity to present testimony for the record in support of appropriations for library programs through the Library Services and Technology Act, administered by the Institute of Museum and Library Services.

We thank the Subcommittee and you as Chairman for your strong support for libraries in the past and ask for that support again for appropriations for fiscal year 2002.

All Americans benefit from the small, but critical, Federal role that assists libraries to foster an informed citizenry in the service of democracy. Federal support for libraries is concentrated on two key national goals: outreach to those for whom library service requires extra effort or special materials, (such as individuals with dis-

abilities); and, mechanisms to identify, preserve and share library and information resources across institutional or governmental boundaries through technology. The Federal role has traditionally focused on areas which require incentive funding for activities that libraries have difficulty initiating independently, which involve coordinated interstate and intrastate efforts, or which benefit from a national policy initiative.

The library community is capable of astonishing creativity and expertise in support of national goals such as revitalizing the economy, having children start school ready to learn, and developing literate, informed adults. Oftentimes, one of the few sources of funding for innovation available to libraries is Federal funding. It is estimated that library programs generate some $3 to $4 dollars for every Federal dollar invested.

President Bush has said on many occasions in discussing his new education proposals that "we must leave no child behind." America's libraries believe that we can also afford to leave no reader behind. That statement also includes pre-readers such as very young children, those learning to read, young adult and adult learners. That is why we feel so strongly that library programs need additional Federal funding.

Within the overarching theme of "Leaving No Reader Behind," our specific recommendations for fiscal year 2002 are guided by three basic priorities, I am sure you share our vision that:

—We need to ensure equitable access and participation of our nation's readers to library activities and opportunities in their communities. Gaps in access exist not only in rural areas, but also in cities that lack an advanced telecommunications infrastructure.

—We need to support our libraries' continuing efforts to keep pace with the rapidly changing information technology environment. Indeed some of our libraries are at the forefront of the web-based revolution, but many others need to accelerate their initiatives.

—We need to recognize the important contributions that libraries make to the social, civic, and educational health of their communities. Like many schools, libraries often serve as the hubs of their communities and provide important services, training in technology and opportunities for life-long learning, particularly in traditionally under-served areas.

THE LIBRARY SERVICES AND TECHNOLOGY ACT (LSTA)

I am please to convey ALA's deep appreciation to the Subcommittee for the support it has provided in the past for libraries and Federal library programs, particularly your support of the Library Services and Technology Act (LSTA) state grant program; library services to Native Americans; and the national leadership grants program.

FISCAL YEAR 2002 FUNDING REQUEST: $350 MILLION FOR LIBRARIES

The library community has collaborated on developing a draft for the reauthorization of the Library Services and Technology Act and will be working with the House and Senate authorizing committees this year on the reauthorization. The current authorization expires at the end of fiscal year 2002. We are seeking to increase the authorization level to $500 million. As you know, this represents a significant expansion in the Federal government's commitment to the support of our nation's libraries. Today we request your support for fiscal year 2002 for a down-payment of $350 million for library programs authorized under the Library Services and Technology Act.

Libraries are making great strides in preparing for and introducing technology to their users. With this increase more libraries could expand their services to include technology training and access to the world wide web for their users.

It would also enable libraries to provide additional badly needed services to underserved populations in their communities. These outreach efforts can pay off in terms of literacy programs that enable students to achieve success in education and programs for families who may not have used libraries before. Library programs for young children encourage pre-reading skill development and stimulate a love of reading, but only if funds are available for these programs.

It is important to note that funding for the State grant program for libraries has not increased significantly in recent years. In fiscal year 1997 it was $136,369,000; in fiscal year 2001 it is $148,939,000. Library services are not keeping pace with the increases in populations in most States.

In fiscal year 2001, the total distributed to states was $148,939,000 and of that, Pennsylvania received $5,964,319. The state library has already received requests for over $6,892,604, and expects at least requests for $3 million more in the second

round of grant requests in the fall. An increase in state distribution to $350,000,000 would bring Pennsylvania dollars up to roughly $11 million. This doubling of funds could enable more outreach to Pennsylvania's rural areas, more attention to technology, and more resource sharing for all libraries, school, academic and public in Pennsylvania. State libraries always report that the requests for funds are double and sometimes triple the amount actually awarded.

$400 MILLION FOR TITLE VI—INNOVATIVE EDUCATION PROGRAM STRATEGIES

We also ask that you fund the Elementary and Secondary Education Act Title VI block grant at least at the $400 million level. We appreciate your support of Title VI, particularly since it is the only current funding possibility for school libraries. As you know, school library materials are only one option of many in the block grant and less and less of the funds are being used for school library materials.

As a result, many school libraries have old, outdated and inaccurate material on their shelves. In research done in Alaska, Pennsylvania and Colorado, it was found that a good school library media program is an excellent predictor of improved student achievement. That is why we feel it is so important to provide adequate funding for school libraries.

21ST CENTURY COMMUNITY LEARNING CENTERS

We support funding for the 21st Century Community Learning Centers program. School library media centers have the potential to be after-school learning centers. If properly equipped and adequately staffed by professional library media specialists, school library media centers are a perfect place for after school learning. Currently, public libraries as part of a consortium also can function as after school learning centers. Many places, particularly in large urban areas like Chicago, Baltimore, New York and Miami, perform that service, however, the bulk of the grants are used by schools. We support initiatives to allow public libraries and other community organizations to be the lead agency.

IMPACT OF LIBRARIES

No public institution maximizes a modest amount of federal funds to greater public benefit than libraries. Libraries are efficient users of federal dollars. Funds are leveraged to attract other dollars; to demonstrate new and innovative methods of providing service; and to bring new users into the library for learning, literacy and the information needed for more productive daily living.

IMPORTANCE OF TECHNOLOGY

Both school and public libraries have made great strides towards the goal of full Internet access. However, effective public access is far from complete. We believe that the E-rate telecommunications discounts are critical to our nation's libraries. The library community believes that this program must be continued in its current form. The first three years of this E-rate fund have created the stimulus for more schools and libraries to connect to the Internet, particularly in areas where the discounts have been the greatest. The progress has been immense and needs to continue. Over 95 percent of public libraries offer Internet access to their patrons.

Moving the program from its fund status to one supported by the appropriations process would be difficult and likely result in a strain on other important education programs and a reduction of the amount available. Telecommunications providers like BellSouth are so enthusiastic about the program that they are providing training to help schools and libraries apply. Please do not disrupt this program—it works.

Federal funding supports the continuing investment libraries must make in computer hardware and software, electronic content and training for staff and the public. An increase in LSTA program funding to the $350 million level would allow more of the 16,047 library outlets to connect to the Internet and begin to provide training and information access services to families, adult learners, the small business sector and all in the community who need access. Sixty-five percent of all households use public library services each year, according to data from the National Center for Education Statistics.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE WORKFORCE AGENCIES

BUILDING A STRONG WORKFORCE

The members of the National Association of State Workforce Agencies are the state leaders responsible for building and overseeing workforce development activities through the administration of a one-stop center infrastructure and the implementation of workforce-related programs. These programs include labor exchange activities, Internet job matching, unemployment insurance administration, labor market information services, veterans' employment services, job training and welfare-to-work programs. Several critical components of this publicly administered workforce development system—unemployment insurance, employment services and labor market information programs—are financed through taxes on employers. Thus, a strong connection to the needs of the private sector business community is critical to the continued viability of the workforce development system.

The primary emphasis of current workforce development efforts in the states is the connection of employers with job seekers. In each of the states, the workforce development system plays a vital role in the success of the local economy by providing services that build a stronger workforce, enhance employee skills, and promote economic development by helping attract and retain large and small businesses.

In addition, with implementation of the Workforce Investment Act of 1998 (WIA), the new workforce development infrastructure being developed in each of the states strives to address the changing needs of the new economy by empowering individuals to make appropriate job choices including enhancing their skills through training opportunities. At the core of this new paradigm is understanding the needs of business in the new economy and preparing workers who can immediately contribute to the health of a company and allow economic growth to continue.

As state workforce officials strive to marshal the resources within a state and build this much needed system capacity, their role has become even more important as they serve as:

—Leaders and change agents in creating a workforce vision and implementing new services and opportunities for businesses and workers;
—Partners with various federal, state and local officials who each share responsibility for the new workforce development system;
—Overseers of a customer-driven system that focuses on the needs of employers and job seekers;
—Supporters of the one-stop center system who work closely with local planners in developing service delivery systems that match customer wants and needs; and
—Facilitators of systems integration so that services can be provided seamlessly.

While providing leadership and building strong workforce investment systems, state administrators are facing two unique challenges which come as a result of economic forces and highlight the need for adequate workforce system funding. The first is company "churning," where American workers with low skills are displaced while job growth is occurring in high skills industries, and the second is the pending economic slowdown that might turn into a recession.

With these two factors as a backdrop, I want to outline the important need to increase funding for (1) unemployment insurance administration to ensure the economic safety net for workers is strong enough to withstand an economic slowdown, (2) the employment service as the cornerstone of one-stop center systems and the connection between employers and job seekers, (3) WIA training and labor market information to assist customers with market-based solutions to their employment needs, (4) incumbent worker training to assist with business and employer needs in the changing economy, and (5) veterans' employment and training. These funding improvements, along with the system improvements that are occurring, can support employers and workers who are hardest hit by emerging economic changes.

FIRMS "CHURN"

The aggregate economy has seen the largest boom in history, with economic expansion running into its ninth year in 2000. The unemployment rate fell for seven straight years, from 7.5 percent in 1992 to 4.1 percent in 1999. An unemployment rate of 4.1 percent was the lowest level in 30 years. After accounting for inflation, median weekly earnings of full-time wage and salary workers increased last year, marking a third consecutive year of gains in real earnings.

Yet, workforce system builders have seen unique challenges during the good economic times as firms "churn" employees. In a recent survey, the American Manage-

ment Association found that 36 percent of the approximately 2,000 companies contacted created new jobs at the same time that they cut existing jobs.

The demand for skilled labor has forced employers to adapt quickly. Companies that once engaged in employee retraining or waited for employees to leave voluntarily find that the quickest alternative is to replace these workers with new employees who have skill sets currently in demand. This leaves the workforce development system with the large challenge of retooling a whole set of workers with outdated skills, while serving employers with large gaps in their workforce due to a lack of qualified workers.

To solve this problem, the workforce development system is actively engaged in assisting employers with the skills training that workers need to keep updated on new technologies and new workplace production methods. Workers must adapt to new technologies in order to remain competitive in the labor market. An important partner in this effort is the education community, and in many areas of the country, the workforce development system and the community college system have developed programs that assist workers with on-the-job training and skills retraining.

Technology is playing an ever-increasing role in productivity gains made by businesses and the way workers conduct their jobs. Technology is also becoming a critical tool for job seekers and employers looking to hire. The Internet allows job seekers to sift through a whole host of jobs at their convenience, while employers can post jobs and also search through resumes. State workforce agency administrators are proponents of using technology to assist employers and job seekers in making more informed decisions and have implemented job matching and other workforce technology into service delivery systems.

AN ECONOMIC SLOWDOWN?

Recent news headlines point to a coming economic slowdown. While it is not known to what extent the economy will contract, what is known is that the growth rate of recent years is not sustainable. This means that unemployment will grow and workers will lose jobs, even in the high tech sector. Efforts at preparing for a slowdown, and even a potential recession, have been undertaken during the past year. For example, the states are providing leadership in efforts to strengthen and improve administration of unemployment insurance and the employment service system.

UNEMPLOYMENT INSURANCE AND EMPLOYMENT SERVICES

Last year, representatives from the states, United States Department of Labor, business and labor met to craft a package of reforms that included, among other things, repeal of the Federal Unemployment Tax Act (FUTA) 0.2 percent surtax and unemployment insurance and employment services administrative funding improvements.

A hearing was held last September before the House Ways and Means Subcommittee on Human Resources. Because of the short legislative timeframe and the intense budget negotiations that lasted into fiscal year 2001, no further action on unemployment insurance and employment services reform was taken in the 106th Congress.

Because a number of governors have expressed support for this reform, as well as a number of state business organizations, it is our intent to work on a bill this year. Meanwhile, until the long-term structural changes are enacted, states are struggling in the short-term to maintain an essential infrastructure for the unemployment insurance and employment service system that meet the needs of businesses and workers.

These issues get to the core of the success of the nationwide one-stop center system. If unemployment insurance and employment services continue to be neglected, then the essential "job connection" that has successfully moved unemployed and dislocated workers into meaningful employment and assisted single mothers on welfare with job skills and job attachment will be lost. States are now closing offices in local communities and reducing staff—substantially decreasing needed services to employers and job seekers. We urge the Congress to fund fiscal year 2002 unemployment insurance at $2.65 billion, which reflects need based on workload.

We also urge the Congress to fund the Employment Service State Allotments at $933 million and Reemployment Services at $35 million. Our request for Employment Service State Allotments represents the current appropriation of $761.7 million plus the amount that state legislatures have funded—$135,033,684—through state appropriations, plus a four-percent growth allowance. It is a travesty that state legislatures must essentially double tax employers to provide needed employ-

ment services while FUTA taxes are building excessive balances in the unemployment trust fund.

It is also disheartening that Congress does not provide adequate funds for a program that yields measurable cost savings. A recent study of the public labor exchange in Washington and Oregon indicates that direct placement services conducted through the public employment service return as much as two dollars for every one dollar spent. This is a result of reduced unemployment insurance payments as unemployed job seekers gain quicker reentry into the labor market. In addition, the employment service assists employers by filling job vacancies more quickly, enhancing companies' productivity.

This study of Washington and Oregon validates a broader study conducted in 1999 that found similar results:

—Job search assistance participants found a new job more quickly and the duration of unemployment insurance benefit payments was reduced.

—Savings to the government averaged two dollars for every one dollar spent.

—Shorter job searches did not lead to jobs that paid less.

We urge you to address funding shortfalls for the unemployment insurance and employment service system.

WORKFORCE INVESTMENT ACT

In 1998, Congress passed the Workforce Investment Act, the first major reform of the nation's job training system in over 15 years. It was designed to replace the patchwork federal system that developed over the last sixty years with a locally designed and driven system to improve the quality of the workforce, enhance the productivity and competitiveness of the nation and reduce welfare dependency. The Workforce Investment Act took effect on July 1, 2000. It passed by a wide bipartisan majority, in part because it was designed to permit communities and states to build a workforce investment system that respects individual choices, reflects local conditions, and results in increased employment, retention, and earnings of participants, and increases occupational skills attained by participants.

The Workforce Investment Act redesigned the nation's workforce development system to:

—Streamline multiple employment and training programs into an integrated one-stop center system, simplifying access to services for job seekers and employers.

—Empower individuals to get the services and skills they need to improve their employment opportunities through qualified training programs of their choosing.

—Increase accountability of states, localities and training providers for their performance based on job placement rates, earnings, retention in employment, skill gains, and credentials earned.

—Involve local elected officials and the private sector in business-led boards for the local areas focusing on strategic planning, policy development and local oversight.

—Allow state and local flexibility to implement innovative and comprehensive workforce investment systems to meet the needs of their communities.

—Improve youth programs by creating Youth Councils that are linked more closely to local labor market needs and the community.

Partnerships at all levels—local, state and federal—and across the system are the hallmark of the new workforce investment system. All levels are required to coordinate and collaborate with agencies and entities that have not been a part of the traditional workforce development system. Accountability and responsibility for outcomes at all levels of the system now exist, with each level having unique and integral roles and responsibilities.

The goal of the Workforce Investment Act is to provide employment and training services in a one-stop environment. Under the former job training program, the Job Training Partnership Act, training was limited to eligible populations. Under the new law, no eligibility criteria exist, and services are universal. We recognize that, in the first year of implementation, spending on training services is low. However, the only way to address the growing skills gap between employers' needs and workers' skills is through training. We support a fiscal year 2002 appropriation of $988 million for Adult Training, $1.147 billion for Youth Training, and $1.1653 billion for Dislocated Worker Assistance that is essentially a current services budget for WIA programs with a four-percent increase over fiscal year 2001 levels.

KEEPING WORKERS ATTACHED TO JOBS

In addition to providing basic employment and training services, we strongly believe that the workforce system must assist incumbent workers as they upgrade

their skills and keep their individual portfolios viable, while at the same time meeting their company's evolving labor needs. We support $30 million in Workforce Investment Act funds for incumbent worker training. Our competitive advantage in the world economy rests in large measure on upgrading our workers' skills.

LABOR MARKET INFORMATION

Providing labor market statistics for use by job seekers and employers at the local level, rather than just on the national and state level, is a new service expectation. In order to provide more localized information as well as program performance information, considerable enhancements to statistical programs and information systems are needed. These enhancements will pay off as local labor market needs will be more accurately assessed and employment programs can be tailored to meet the needs of local employers. Therefore we support a four-percent increase for the Bureau of Labor Statistics for a total appropriation of $213 million, and a continued investment in One-Stop/ALMIS dollars of $150 million. We also ask that report language contained in last year's appropriation for One-Stop/ALMIS be included as bill language in this year's appropriation bill.

The bill language we request reads, "One-Stop/ALMIS funds will be used to support infrastructure upgrades at the state level for one-stop center system operations, labor market information, and integrated services to employers and job seeker customers." This will ensure that the dollars go to the states, where infrastructure needs are most critical.

MEETING COMMITMENTS TO VETERANS

Our society recognizes the important contribution that veterans have made, and Congress has taken that recognition and turned it into a commitment. Title 38 of the U.S. Code includes provisions for special employment services for veterans. Priority is given to disabled and Vietnam era veterans, through the Disabled Veterans Outreach Program (DVOP) and the Local Veterans Employment Representative (LVER) program, which are administered by state workforce agencies. DVOPs and LVERs also serve our veterans population by helping to ensure a smooth transition for people moving from military service into the civilian workforce.

Title 38 provides formulas to determine DVOP and LVER staffing levels. Since 1990, appropriations for DVOPs and LVERs have not supported the number of positions authorized by the statutory formulas. We strongly encourage support for funding at the statutorily-authorized levels of $121 million for the DVOP program and $102 million for the LVER program. This will help us follow-through on our commitment to the men and women who have served valiantly in the military both in times of war and peace.

CONCLUSION

I do believe we are making significant strides in building the workforce investment system in each of the states. With a potential slowing of the economy, we cannot afford to wait any longer for the improvements that need to be made so that families can be served with their workforce development needs. With additional investments by Congress, I know that we are prepared to help those citizens needing job placement or skills training assistance and those businesses looking for good, solid workers who can improve their economic prospects. Thank you for your interest and support.

PREPARED STATEMENT OF THE NATIONAL TREASURY EMPLOYEES UNION

Chairman Specter, Members of the Subcommittee: My name is Colleen M. Kelley and I am the National President of the National Treasury Employees Union (NTEU). On behalf of the 150,000 federal employees NTEU represents, thank you for permitting NTEU to share our views concerning the fiscal year 2002 budget.

NTEU represents employees in a number of HHS agencies including the Health Resources and Services Administration, Indian Health Service, Substance Abuse and Mental Health Services Administration, Agency for Healthcare Research and Quality, Administration for Children and Families, Administration on Aging, Office of the Secretary, Office for Civil Rights, Program Support Center and the National Center for Health Statistics. NTEU also represents employees in the Social Security Administration's Office of Hearings and Appeals.

As the Chairman knows, funding remains severely constrained at federal agencies, leaving agencies with insufficient resources to complete their missions or adequately reward their employees. Funding shortfalls have resulted in hiring restric-

tions and delayed and canceled employee training, making it difficult for employees to do the best job possible. Moreover, with federal salaries continuing to lag well behind similar private sector salaries, agencies have been unable to hire or keep the expertise they need.

In fact, the looming crisis in the federal government recently caused the General Accounting Office to place human capital management on its High Risk List. The GAO stressed that federal employees are assets to be valued, not costs to be cut. Adequate and stable agency funding coupled with appropriate pay, benefits and incentives are the keys to insuring that the federal government continues to attract and retain the right federal employees.

With surpluses predicted for the immediate future, the opportunity exists to provide adequate resources to federal agencies. Doing so will enable federal employees to carry out their agencies' missions to the best of their abilities and provide first class service to agency customers. Unfortunately, the President's budget calls for an average 4 percent increase in discretionary agency funding, an amount clearly inadequate to address the crisis the federal government faces and move human capital management off the high risk list. If there is room in the federal budget for a tax cut in excess of $1 trillion, clearly there is room to adequately fund federal agencies.

The Administration's fiscal year 2002 budget request for program management at the Health Resources and Services Administration (HRSA) is $154 million. Although this figure represents a $9 million increase over program management funding for fiscal year 2001, the budget also calls for a reduction of 24 FTE in the next fiscal year. I think this shows quite clearly how inadequate the proposed $9 million increase is. HRSA's goal is to bring health care services to some of our neediest populations, including those in underserved rural communities, people living with HIV/AIDS, and those who are uninsured. HRSA provides essential services that are desperately in need of expansion; they cannot accomplish their mission with fewer employees and inadequate resources.

The employees represented by NTEU at the Agency for Healthcare Research and Quality (AHRQ) strive to improve the quality of patient care in our health care system. This agency's goal is to both cut the number of medical errors and explore ways to better use research to improve medical care in our country. The Administration's fiscal year 2002 budget proposal calls for $3 million for program support at the AHRQ, the same amount the agency received in fiscal year 2001. AHRQ will not be able to continue its mission and maintain its current staff without additional funding.

Likewise, the Administration's budget proposes no increase in funding for program management at the Substance Abuse and Mental Health Services Administration (SAMHSA). This agency is at the forefront of efforts to provide early intervention programs designed to discourage young people from using drugs. SAMHSA also plays a critical role in insuring that mental health and drug abuse services are widely available to populations that would otherwise receive no services. If SAMHSA is to adequately respond to the substance abuse and mental health needs in this country, they will require an increase in funding. In fiscal year 2001 the agency received $67 million and 632 FTE. The President's budget freezes the agency at an identical, and insufficient, level for fiscal year 2002.

Under the President's budget, the Indian Health Service (IHS) is slated to receive $2.9 billion for its health services programs in fiscal year 2002. This budget request reflects a small increase of $151 million over the fiscal year 2001 level of $2.8 billion which NTEU believes fails to recognize and value the important work this agency does in improving health care for the millions of American Indians and Alaska Natives. A substantial increase is warranted here as well.

The fiscal year 2002 budget request for federal administration at the Administration for Children and Families (ACF) is $182 million, an $8 million increase over fiscal year 2001 funding. As the Chairman knows, ACF is one of the government's premiere agencies for promoting the health and welfare of America's children. Programs under its jurisdiction include Head Start as well as projects that promote and support child care, foster care and adoption efforts. The 2002 budget request would severely hamper ACF's ability to continue to provide quality services. It envisions permitting the agency to hire no more than 15 additional staff in the next fiscal year, a number that does not reflect the importance these employees play in overseeing the critical Head Start Program. Funding restrictions in past years have already hampered ACF's ability to fulfill its mission and I urge the Subcommittee to provide additional fiscal year 2002 funding over and above the President's request.

For fiscal year 2002, $18 million is requested for program administration at the Administration on Aging (AoA), a $1 million increase over the agency's fiscal year 2001 funding level. America's elderly population continues to grow and helping older Americans remain independent and productive is one of the key goals of AoA. The

employees of AoA operate nutrition programs and are active in the Alzheimer's programs. To continue and expand its work, the AoA, too, requires funding increases that reflect its critical mission.

NTEU also represents employees in the Office of the Secretary of HHS. The President's budget request for departmental management is $450 million for fiscal year 2002, an increase of $68 million over fiscal year 2001 funding levels that will allow the agency to hire an additional 107 FTE. As you know, the employees in the Office of the Secretary help support those activities associated with the overall operation of the department and NTEU hopes the Subcommittee will support this proposed increase.

The President's budget request for the Office for Civil Rights (OCR) for Fiscal 2002 is $32 million, an increase of $4 million over the fiscal year 2001 funding level. HHS's Office for Civil Rights enforces the Nation's civil rights statutes that prohibit discrimination in social service programs. Moreover, OCR plays a central role in efforts to prohibit discrimination against individuals with disabilities in programs under HHS's purview. In past years, the funding levels OCR has received have not reflected OCR's critical mission and NTEU urges the Subcommittee to provide the maximum possible increase to OCR in fiscal year 2002.

For the National Center for Health Statistics (NCHS), the Administration has requested $127 million for fiscal year 2002, an increase of $5 million over the fiscal year 2001 level. One of NCHS's primary responsibilities is to follow changes in health and health care, assess the effectiveness of health care programs and identify health and disease patterns and risk factors in our country. The NCHS deserves the maximum possible allocation for fiscal year 2002.

As the name implies, the Department's Program Support Center (PSC) provides support services to HHS and other agencies. These services include efforts in three areas, including human resources, financial management and administrative operations. For fiscal year 2002, the Administration has recommended a funding level of $308 million for PSC, a small increase over the division's fiscal year 2001 budget that NTEU hopes can be increased during Subcommittee deliberations.

NTEU also represents employees in the Office of Hearings and Appeals (OHA), and as I have brought to this Committee's attention in past years, OHA is again the subject of reorganization. The latest, the Hearing Process Improvement (HPI) plan, is not working.

As you know, disability claimants who have been found ineligible for disability benefits are entitled to a timely and fair hearing of their cases at the OHA level. In 1995, the Social Security Administration began an innovative program called the Senior Attorney Program, which, in every respect, was a resounding success. The agency's experienced staff attorneys were given the authority to decide and issue fully favorable decisions—without the time and expense of a full hearing—in those cases where the evidence clearly identified an individual as disabled. It materially improved both the quality and timeliness of service provided to the public. Despite the success of the Senior Attorney Program, the Hearing Process Improvement Plan eliminates it, largely due to opposition from Administrative Law Judges.

From 1995 until it was canceled in 2000, nearly 230,000 Senior Attorney decisions were issued. It is noteworthy that the SSA Appeals Council found no significant difference in the accuracy of Senior Attorney decisions vs. full, on the record decisions made by the agency's Administrative Law Judges. Moreover, these Senior Attorney decisions helped reduce the backlog of cases at OHA to 311,000 by September of 1999. That backlog is now on the rise.

The average processing time for a case favorably decided by a Senior Attorney was approximately 105 days. This was at a time when processing time for cases at OHA took approximately 386 days—more than a full year. Senior Attorney decisions helped deserving claimants receive their benefits in a more timely fashion while simultaneously not wasting valuable agency resources.

Since the Senior Attorney Program was terminated, the backlog of cases has risen at an alarming rate with almost 390,000 cases awaiting processing today. Without the Senior Attorney Program these cases will wait about 314 days to be processed. Even worse, the situation is expected to continue to deteriorate. There can be no significant reduction in the case backlog or case processing time without reviving this program. The Senior Attorney Program can help the agency address these problems with current resources and stem the decline in the quality of services nationwide. It does so without hiring new Administrative Law Judges and staff and it presents an immediate solution to a worsening problem. I urge you to question the agency concerning this matter as soon as possible.

Thank you again for permitting NTEU to share our views on the needs of the agencies within the jurisdiction of your Subcommittee.

PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) is the service organization representing the interests of the more than 2,000 municipal and other state and locally owned utilities throughout the United States. Collectively, public power utilities deliver electric energy to one of every eight U.S. electric consumers (about 40 million people) serving some of the nation's largest cities. The majority of APPA's member systems are located in small and medium-sized communities in every state except Hawaii. APPA member systems appreciate the opportunity to submit this statement in support of fiscal year 2002 appropriations for the Low-Income Home Energy Assistance Program (LIHEAP).

APPA urges the Committee to support LIHEAP at its maximum funding level of $2 billion in fiscal year 2002. APPA also supports a minimum of $300 million in emergency funds in fiscal year 2002 and supports a funding level of at least $2 billion in advanced funding for fiscal year 2003. In addition, APPA supports the numerous amendments being considered in the Senate to increase the current $2 billion funding authorization level of LIHEAP. Because the majority of LIHEAP monies are needed during a short period of time in the winter months, advanced funding for LIHEAP is critical in enabling states to effectively plan for and administer the program. Moreover, a severe winter, escalating home heating oil prices in the Midwest and Northeast and higher than expected utility bills in California have depleted fiscal year 2001 emergency funds and highlight the important role LIHEAP plays for the elderly and working poor during winter months and for all consumers when energy prices are volatile.

Funding cuts since LIHEAP's reauthorization in fiscal year 1995 have forced a tightening of eligibility standards and, in some cases, significant reductions in benefit levels. According to the National Energy Assistance Directors' Association (NEADA), the primary educational and policy organization for state LIHEAP directors, the number of recipients has been cut by over one million households during the recent past and average benefits have declined by about 10 percent. Prior to the dramatic reduction in LIHEAP funding in fiscal year 1995, the program was serving 20 percent of the eligible population, with one-half of the recipients being elderly or disabled Americans living on fixed incomes. Without the assistance provided by LIHEAP, many would be forced to choose between paying their home energy bill or purchasing other necessities of life, such as food.

As the debate over restructuring of the electric utility industry and the issue of providing and funding "public benefits" programs continues, some have stated their belief that electric utilities should assume the entire burden of energy assistance for low income customers as a cost of doing business. As these restructuring efforts take place at both the federal and state levels, the risks become greater that bills for residential customers, especially those with low incomes, will increase as retail markets are opened to competition. This prophesy has come true for consumers across America this winter as we witness price spikes in all areas of fuel production, including natural gas, home heating oil and electricity. The need for full funding of LIHEAP remains critical in ensuring that all those in need of energy assistance receive help. APPA believes that any public benefits programs should not replace or supersede existing programs, such as LIHEAP, that are funded by federal appropriations.

APPA is proud of the commitment that its members have made to their low-income customers. Many public power systems have low-income energy assistance programs based on community resources and needs. APPA continues to remind its members of how important it is to have in place a well designed low-income customer assistance program, in tandem with energy efficiency and weatherization programs, that can help consumers hold down their energy bills and lower their requirements for assistance.

In addition, the impact of welfare reform on energy assistance is just beginning to be felt and LIHEAP is likely to play an important role in the transition. Persons leaving the public assistance rolls are entering lower paying jobs and continue to be confronted with large energy bills. These families remain at risk.

LIHEAP is one of the outstanding examples of a successful state-operated program. The requirements imposed by the federal government are minimal and most important decisions are left to grantees.

APPA urges this Subcommittee's favorable consideration of fiscal year 2002 funding for LIHEAP. Again, thank you for this opportunity to present our views.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICA'S PUBLIC TELEVISION STATIONS

The Association of America's Public Television Stations submits this testimony to the appropriations subcommittee on Labor Health and Human Services, Education and Related Agencies. APTS, on behalf of the nation's 354 local public television stations, urges the committee to support funding for the Corporation for Public Broadcasting and the Ready to Learn and TeacherLine projects within the Department of Education.

This year APTS is asking Congress to fund the Corporation for Public Broadcasting in fiscal year 2004 at $395 million. This modest $30 million increase will help pay for increases in system support such as royalties and copyright fees as well as funds to support projects to develop new content for our increased educational services and programming. Most significantly, this request would mean an average increase of $90,000 per station in the form of Community Service Grants. Eighty nine percent of CPB's funding goes to local public television and radio stations in the form of CSGs, which are the seed money for local operations. These federal funds are leveraged an average of six fold to raise non-federal funds to enable local stations to serve their local communities.

APTS thanks the committee for its generous past support and for acknowledging the special needs of public broadcasting in the form of advanced appropriations. The advance funding provision for CPB allows public broadcasting and local stations a predictable source of support that can be applied to research and development. It also provides the important lead time needed to leverage other funding sources necessary to bring programs to the air.

Public television also requests that the subcommittee provide funding for the Ready to Learn program at $24 million and the TeacherLine project at $8.5 million in fiscal year 2002. Both of these programs are administered through the Department of Education. The Ready to Learn program provides funding for the development and production of the highest quality children's educational programming. It also assists local stations in their outreach efforts to train teachers, parents and day care providers to effectively use these programs to teach young children. TeacherLine is an online professional development initiative that helps teachers improve their teaching skills in core subject areas.

Public broadcasting is also seeking equipment funds for the federally mandated conversion to digital through the Public Telecommunications Facilities Program (PTFP) within NTIA at the Department of Commerce.

COMMITMENT IN THE DIGITAL AGE

Public broadcasters historically have been the leaders in using new technologies for education and public service. The nation's public television stations stand ready to make an historic commitment to all Americans to provide near universal access to wireless, high-speed data for education. Specifically, public television stations will commit the equivalent of one multicast digital channel—a daily average of 4.5 megabits per second (Mbps), among the highest data rates available—for formal early childhood, K–12, and post-secondary education, as well as workforce training and professional development. This digital capacity is conservatively valued at $2.4 billion per year.

HARNESSING DIGITAL TECHNOLOGY TO SERVE THE PUBLIC

With roots going back to the earliest days of radio and television, America's public broadcasters have played a unique role in a media industry that is otherwise built on consumer advertising and mass market entertainment. Since the 1960s, publicly funded noncommercial television has provided a clear alternative to commercial television, focusing on education and culture, public affairs and the performing arts.

While the proliferation of television channels has been driven by market demands, public television's core mission has not and will not change in a digital world. We will build on our track record of providing the best programming and services to educate and enlighten audiences. We also will continue to be leaders in using new technology for the public interest. From satellite delivery of broadcast signals, to the development of stereo broadcasting; from closed captioning and descriptive video services, to video streaming and cutting edge interactive television trials, public broadcasters have been inventors, innovators and blenders of technologies to serve the public.

Public television is committed to use digital technologies to transform the way we learn—by providing the American public with educational services anytime any-

where. That means how they want them, when they want them and where they want them—in homes, schools, childcare facilities, and workplaces across America.

MULTICAST DIGITAL SERVICES—UNLOCKING PUBLIC TELEVISION'S PUBLIC SERVICE MISSION

Since receiving their digital channels, public television stations have been engaged in systemwide and station level planning. In 1997, public broadcasting put forward a comprehensive plan for its digital conversion to the Administration and Congress. We set four broad systemwide goals for the use of digital technology—goals that are founded on fully utilizing the multicasting capability of the digital technology to expand and enhance services.

To make the full complement of Ready to Learn services available to every child, parent and caregiver in America.—The PBS Ready to Learn Service is currently meeting two national education goals: it teaches basic reading skills and it helps prepare more children for school success. Its 133 participating stations cover over 94 percent of the country. In the past three years, RTL public television stations have trained 370,000 parents and 250,000 teachers and caregivers, affecting approximately 6 million children.

To expand the reach of public television's K–12 educational programs and services by making them universally available to all schools and home schoolers.—70 percent of public television licensees provide K–12 programming in math, science, arts and humanities. These services are enhanced by:

—PBS TeacherSource, an online K–12 teacher resource with online lesson plans, teacher guides and activities, correlated to more than 90 national and state standards; and,

—PBS Teacherline, online modules to enhance the learning and teaching of K–12 mathematics and other core subjects.

To increase the reach of post secondary telecourses so that they are universally available to all adult learners.—Collectively, public television stations are the largest source of post-secondary telecourses in the nation. PBS Adult Learning Service (ALS) supports station-college partnerships that offer distance learning credit-bearing telecourses, enrolling more than 500,000 students in 1999–2000. GED on TV has enabled more than two million adults in five years to earn their high school equivalency from home. The estimated positive economic impact of these more productive workers exceeds $12 billion.

To expand our commitment to serving the unserved and underserved populations in our country, those who because of economic, geographic, physical, cultural or language barriers have been left behind by the commercial marketplace.—Public Broadcasting has pioneered the development of open and closed captioning for the deaf and descriptive video services and reading services for the blind or visually impaired. Stations like WYBE, Philadelphia and WNVC, Fairfax provide programming in multiple languages serving a variety of different ethnic cultures.

Local public television stations throughout the country have turned those systemwide goals into concrete and very bold and exciting service plans tailored to their local communities. APTS maintains an interactive clearinghouse of stations' plans for digital services. Our data show that virtually every public television station in the country has developed digital service plans to meet these and other goals. The centerpiece of virtually every plan is the delivery of multicast services with a strong focus on education.

—In exchange for federal financial support and favorable cable must carry regulations, the nation's public television stations stand ready to commit an average daily rate of 4.5 megabits per second (approximately one channel) of their digital spectrum to education. The value of this capacity is conservatively estimated at $2.4 billion per year

—Three out of every four PTV stations plan to carry at least two formal education multicast services.

—Approximately 85 percent of PTV stations plan to multicast a children's channel; 78 percent intend to broadcast university-level or post-secondary telecourses; and 66 percent plan to multicast an instructional programming channel for students in grades K–12.

—Others plan to multicast channels that focus on local public affairs, teacher training, foreign language programming, and programming aimed at minority and under-served audiences.

PTV DIGITAL SERVICE PLANS—CREATING LOCAL SOLUTIONS FOR NATIONAL PRIORITIES

REALIZING NATIONAL EDUCATIONAL GOALS ON A LOCAL LEVEL

While public television stations plan to deliver one or more formal educational multicast channel, the specific educational services are tailored to meet local community needs.

Florida public television stations have promised the state legislature that they will collectively devote a multicasting stream to the Florida Knowledge Network in return for digital funding. This statewide educational network will serve as a teacher training resource, linking Florida's classrooms with direct access to the highest quality programming, electronic field trips, and distance learning.

New York's public television stations plan to dedicate one of their multicast streams to an educational service called the Empire State Channel. Developed with the state Department of Education, the Empire State Channel will feature teacher training, vocational instruction and public affairs programming.

PROVIDING UNSERVED AND UNDERSERVED WITH ACCESS TO DIGITAL TECHNOLOGY

Today, public television stations, through their nationwide system of transmitters and translators, serve 99 percent of American households with an over-the-air analog signal. Public television stations that serve rural communities with a network of analog translators are ideally positioned to bring the benefits of broadband digital services to the most rural and remote areas of this country.

KAET in Phoenix plans to partner with KUAT in Tucson to dedicate one or two multicasting channels to feeding math, science, geography and other educational programming to 300 schools throughout the geographically diverse state. Directed by the stations and funded by the state Department of Education and Arizona State University, programming will relate directly to course materials, and teacher training will be accompanied by curriculum guides, instructional materials, and planning booklets that can be downloaded to computers in the classrooms. These services are intended to reach students in the farthest corners of Arizona, students who are unable to be linked via telephone and fiber optic lines.

KNME in Albuquerque is considering leasing part of its digital spectrum to the New Mexico Department of Education to facilitate the delivery of educational materials to the state's K–12 schools. The station will position itself as the state's virtual classroom, providing curricular support and teacher training opportunities for viewers separated by hundreds of miles. This arrangement would allow the Department of Education to help with the costs of digital conversion.

Public television stations also plan to use the multicast capability to serve populations under-served because of cultural, language or economic barriers.

KBDI in Denver plans to launch a Latino Initiative Channel. This channel would feature programming for Denver's Spanish-speaking and bilingual community and will emphasize news, public affairs, and social and cultural events. Potential partners include local community service organizations, schools, commercial Spanish-language broadcasters, and public service agencies.

WNYE in Brooklyn and WYBE in Philadelphia plan to provide multicast foreign language and international channels to serve the international residents in their respective cities. The WNYE multicast channel will feature programming in at least 12 different languages, including Japanese, Chinese, Italian, Greek, Polish, and Eastern European languages.

PARTNERING WITH LOCAL INSTITUTIONS TO SOLVE LOCAL COMMUNITY PROBLEMS

A key characteristic of public television's digital planning is localism. In an age of increasing media consolidation, public television stations remain the only locally owned, locally operated television service in many communities. Consequently, several PTV stations are planning "local" channels, focusing on specific community needs.

Vermont Public Television plans a Vermont Public Service Channel, which would provide regular coverage of the state legislature, important legislative committee hearings and other statehouse-related programs, as well as local government town meetings and debates. Additional programming might include call-in programs with the Vermont congressional delegation, travel and tourism information, and other local news and public affairs programming.

The federal government must play its historic leadership role in underwriting a portion of public broadcasting's digital transition. The government's failure to make this investment will have direct consequences. Millions of Americans may be deprived of the enormous educational promise of digital television. Many of the smaller and rural stations may be unable to make the transition at all.

The public broadcasting industry has updated its costs for the digital transition. Balancing reductions for the stations currently on the air against additions for increased costs, public broadcasters estimate the total costs of conversion for both television and radio at $1.8 billion.

CONCLUSION

For more than 30 years Congress has invested wisely in public broadcasting. We now have a strong system of public television stations that reaches 99 percent of American households, giving viewers tools to improve and enrich their lives. The public service promise of new digital technology is enormous:

—for children to provide a dedicated stream of nonviolent, educational and entertaining programs, commercial-free and free-of-charge;
—for parents and schools to better educate children;
—for colleges and universities to reach out beyond their campus walls;
—for students of all ages to have access to lifelong learning;
—for under-served audiences whose income, geography, culture or disability threatens to cut them off from the digital promise;
—for citizens who feel alienated from their local, state or federal governments; and
—for public service organizations seeking to build a sense of civic connection and commitment.

Realizing this potential and remaining a viable service provider in the digital age is fully dependent on a federal investment to ensure access to all digital services. Public television stands ready with service plans, matching state and local grants, and community-based content partners to fully utilize this technology for public service.

Funding for the Corporation for Public Broadcasting and through the Ready to Learn and TeacherLine programs at the Department of Education will provide essential financial assistance to stations in order to meet their digital service goals.

PREPARED STATEMENT OF THE MOTION PICTURE & TELEVISION FUND

Funding is requested by the Motion Picture & Television Fund (MPTF), Woodland Hills, California, in fiscal year 2002 appropriations, for an "Eden Alternative" demonstration project.

Nursing homes and assisted living facilities play a critical role in the delivery of care to older people with chronic needs. It is expected that over half of the people who turned 65 in 1990 will enter such a facility before they die. Too often the stay is characterized by feelings of helplessness, loneliness and boredom. It is presumed, but untested, that these ultimately add to the cost of care because of an increase in hospitalizations, medical problems, and the use of psychotropic drugs. Any program that can reduce the frequency of those problems would have major implications through a reduction of Federal expenditures for health programs, including Medicare and Medicaid.

The Eden Alternative is an innovative approach which was developed as a way to improve the quality of life of nursing home and assisted living residents. This approach seeks to overcome the problems of helplessness, loneliness, and boredom. It is intended to improve quality of life and decrease medical problems and expense through changes in the physical, psycho-social, and staffing environments. MPTF, by this proposed demonstration project, seeks to validate that improvement in both health outcomes and medical cost reductions can be achieved by implementing the "Eden Alternative" concept in its nursing home and assisted living community. A demonstration project of this type can serve as a model for other similar community based facilities nationwide.

The Federal Government and the Congress have a significant interest and responsibility in the quality of life and access to long term care by its older adults. This responsibility is particularly relevant when in the near future the aging baby-boom generation will substantially increase the number of United States citizens in retirement. By the year 2030, all baby-boomers will be over 65 years old, with the oldest nearing age 85. Twenty percent of the total United States population will be elderly in thirty years, compared with 13 percent today, 20 percent of all those over 85 years old will be residing in nursing homes. Since most, if not all, of these nursing home residents will be on Medicare, the nationwide impact of a program which significantly reduces medical costs should be a priority item of interest and responsibility.

The Eden Alternative offers a paradigm shift that seeks to transform the concept of institutional care. A central tenet is that the environment should help maximize

individual potential for personal growth by offering variety, vibrancy and spontaneity. This approach includes homelike furnishings, regular interaction with children and young adults, resident responsibility for the care of companion animals and plants, and flexibility in residents' daily activities to encourage spontaneity. Perhaps most important is staff development which facilitates the replacement of top down bureaucratic authority with decision making that is closest to the resident, whenever possible. Staff needs to be provided with the necessary training, skills and information, in order to assume responsibility for the improved social and medical outcomes. The change in surroundings results in an enhanced sense of self, a higher quality of life, and a relief from the problems that frequently affect nursing home and assisted living residents.

In addition to a plethora of environmental changes, the Eden Alternative also promotes substantive changes in management philosophy and style and organizational culture. Management principles include:

—Replacing top down bureaucratic authority with decision making that is closest to the consumer whenever possible. This includes empowering residents and those who provide the most direct care and transforming the roles of staff to family-like companions rather than medical care providers.

—Encouraging leadership that embraces change which is focused on improving residents' quality of life. To support necessary changes in the physical and work environment, leaders assume the role of coaches. Leaders and staff are encouraged to reward appropriate risk-taking, promote fundamental fairness, and recognize that mistakes are part of change.

—Organizing work through self-directed work teams in contrast to hierarchy and strict departmental lines. To ensure informed decision making, team members are provided with necessary information, resources, training and skills, knowledge, and a supportive environment. Thus empowered, teams are responsible for making decisions about how to meet their goals including scheduling and organizing their work.

These innovations are believed to create a more desirable environment for residents and staff and to result in improved health status for residents. In addition to the relief of boredom and helplessness that afflicts residents, preliminary work suggests that such an enriched habitat improves residents' quality of life and leads to such related benefits as reducing prescription mediation use; reduced incidence of infections, skin breakdowns, and falls; less depression; and improved sense of well being and control. Studies have also suggested that an enriched environment positively affects staff, resulting in less absenteeism, reduced turnover, and higher levels of job satisfaction.

MPTF goals for this project are two-fold: (1) Implement the environmental and staff changes necessary to achieve the life style envisioned by the Eden Alternative (including programmatic changes and staff training); and (2) Measure and report on specific parameters related to quality of life and decreased medical resource consumption. These parameters would include the use of psychotropic drugs, the presence of skin ulcers, falls, and hospitalizations. In addition, national data on specific outcomes in nursing homes has been collected for several years. Our experience will be compared to these national benchmarks. We believe that this demonstration project will confirm significant financial savings for our residents and that these savings will be applicable to Medicare and Medicaid if this effort is adopted nationally. Once confirmed, we would share our experience and teach other organizations how to effectively implement the operating principles of the Eden Alternative.

MPTF is an 80-year old non-profit health and social service organization which serves the Southern California entertainment community. Among our services are a 195 bed long-term care facility and a retirement community (independent and assisted living) of 120. In the first quarter of 2002, we will be opening additional retirement housing with a capacity of 95. Our residents are admitted regardless of their ability to pay. It is because of our history of providing the highest quality of life in the most cost-effective way possible that we seek support for this transition in our care model.

PREPARED STATEMENT OF THE NATIONAL FEDERATION OF COMMUNITY BROADCASTERS

Thank you for the opportunity to submit testimony to this Subcommittee regarding the appropriation for the Corporation for Public Broadcasting (CPB). As the President and CEO of the National Federation of Community Broadcasters I speak on behalf of 150 community radio stations across the country. NFCB is the sole national organization representing this group of stations which provide service in the smallest communities of this country as well as the largest metropolitan areas.

Nearly half of our members are rural stations and half are minority controlled stations.

In summary, the points we wish to make to this Subcommittee are that NFCB:

—Requests $395 million CPB for fiscal year 2004, a $30 million increase over fiscal year 2004 funding;

—Requests that advance funding for CPB is maintained to preserve journalistic integrity and facilitate planning and local fundraising by public broadcasters;

—Requests report language to ensure that CPB utilizes digital funds it receives for radio as well as television needs;

—Supports CPB activities in facilitating programming services to Latino and Native American radio stations;

—Supports CPB's efforts to help public radio stations utilize new distribution technologies and requests that the Subcommittee ensure that these technologies are available to all public radio services and not just the ones with the greatest resources.

Community radio fully supports $365 million for the Corporation for Public Broadcasting in fiscal year 2004.—Federal support distributed through the CPB is an essential resource for rural stations and for those stations serving minority communities. These stations provide critical, life-saving information to their listeners. Yet they are often in communities with very small populations and limited economic bases so that the ability of the community to financially support the station is insufficient without federal funds.

In larger towns and cities, sustaining grants from CPB enable community radio stations to provide a reliable source of noncommercial programming about the communities themselves. Local programming is an increasingly rare commodity in a nation that is dominated by national program services and concentrated ownership of the media.

For the past 25 years, CPB appropriations have been enacted two years in advance. We are grateful for Senators Spector and Steven's comments in support of continuing the advance appropriations. This insulation has allowed pubic broadcasting to grow into a respected, independent, national resource that leverages its federal support with significant local funds. Knowing what funding will be available in advance has allowed local stations to plan for programming and community service and to explore additional non-governmental support to augment the federal funds. Most importantly, the insulation that forward-funding provides "go[es] a long way toward eliminating both the risk of and the appearance of undue interference with and control of public broadcasting."—House Report 94–245.

In the last two years, CPB has increased support to rural stations and committed resources to helping public radio take advantage of new technologies such as the internet and satellite radio. We commend these activities which we feel provide better service to the American people, but want to be sure that the smaller stations with more limited resources are not left out of this technological transition. We ask that the Subcommittee include language in the appropriation that will ensure that funds are available to help the entire public radio system utilize the new technologies, particularly rural and minority stations.

NFCB commends CPB for the leadership it has shown in supporting and fostering the programming services to Latino stations and to Native American stations. Satélite Radio Bilingüe provides 24 hours of programming to stations across the United States and Puerto Rico addressing issues of particular interest to the Latino population. In the same way, American Indian Radio on Satellite (AIROS) is distributing programming for the Native American stations, arguably the fastest growing groups of stations. There are now over 30 stations controlled by and serving Native Americans, primarily on Indian reservations.

CPB plays a very important role for the public and community radio system. They are the convener of discussions on critical issues facing us as a system. They support research so that we have a better understanding of how we are serving listeners. And they provide funding to programming, new ventures, expansion to new listeners, and projects that improve the efficiency of the system. This is particularly important at a time when there are so many changes in the radio and media environment with new distribution technologies and media consolidation.

Finally, community radio supports funding for conversion to digital broadcasting by public radio and television.—While public television's needs are more immediate, the Federal Communications Commission is now in the process of identifying a standard for digital radio transmission. We expect that there will be funds available for radio conversion as well as television conversion. More immediately, the television conversion process is already having an impact on public radio stations. As television stations increase the space they need on their towers to accommodate both analog and digital signals, radio stations that rent space on TV towers are los-

ing their leases and being forced to move to other towers—sometimes with very short notice. This situation will only get worse over the next year as we approach the FCC deadline for television conversion. We would like to see emergency funding to help public radio stations who lose their tower space do the necessary engineering studies and move to new tower locations.

We appreciate Congress' direction to CPB that it utilize its digital conversion fund for both radio and television and ask that you ensure that the funds are used for both media. Congress stated, with regard to fiscal year 2001 digital conversion funds:

"The required (digital) conversion will impose enormous costs on both individual stations and the public broadcasting system as a whole. Because television and radio infrastructures are closely linked, the conversion of television to digital will create immediate costs not only for television, but also for public radio stations (emphasis added). Therefore, the Committee has included $15,000,000 to assist radio stations and television stations in the conversion to digitalization . . ." (S. Rpt. 105–300)

This is a period of tremendous change. Digital is transforming the way we do things; new distribution avenues like digital satellite broadcasting and the Internet are changing how we define the business we are in; the concentration of ownership in commercial radio makes public radio and particularly community radio, more unique and more important as a local voice than we have ever been. During this time, the role of CPB as a convener of the system becomes even more important. And the funding that it provides will allow the smaller stations to participate along with the larger stations who have more resources, as we move into a new era of communications.

Thank you for your consideration of our testimony.

PREPARED STATEMENT OF THE NATIONAL MINORITY PUBLIC BROADCASTING CONSORTIA

The National Minority Public Broadcasting Consortia (Minority Consortia) submits this statement on the fiscal year 2004 appropriation for the Corporation for Public Broadcasting (CPB). Our primary missions are to bring a significant amount of programming from our communities into the mainstream of PBS and public broadcasting. In summary, we ask the Committee to:

—Reject the Administration's proposal to end forward funding of the Corporation for Public Broadcasting

—Recommend at least $395 million for CPB for fiscal year 2004, a $30 million increase over fiscal year 2003

—Encourage CPB to increase its efforts for diverse programming with commensurate increases for minority programming and the Minority Consortia

—Support the Administration's request of $20 million for digital conversion

The National Minority Public Broadcasting Consortia consists of the National Asian American Telecommunications Association, the National Black Programming Consortium, Native American Public Telecommunications, Pacific Islanders in Communications and the Latino Public Broadcasting Project

Forward Funding.—We strongly oppose the Administration's proposal that the advance funding for CPB be eliminated, a proposal that would stop CPB funding for two years. We were pleased to see the colloquy on the Senate floor April 6 between Senators Stevens and Specter concerning this issue, and we support any efforts to continue the practice of two years forward funding for CPB. Reasons to continue forward funding for CPB include:

—The production of programming for public broadcasting usually takes several years and substantial lead time is needed for planning.

—Public broadcasting programs are supported by multiple funding sources, and two years advance knowledge of the amount of federal funding allows CPB to better leverage its federal funds to bring in other sources of revenue.

—The Minority Consortia administers a significant amount of CPB programming monies, and elimination of forward funding would negatively affect our organizations' planning and fundraising activities.

CPB Appropriation.—We support a fiscal year 2004 federal appropriation for CPB of at least $395 million. This would be a reasonable, albeit modest, contribution toward our national treasure of public broadcasting. The debate of the past several years regarding public television and public radio has highlighted the great esteem in which they are held.

Public broadcasting, including PBS and NPR, is particularly important for minority and ethnic communities. While there is a niche in the commercial broadcast and

cable world for quality programming about our communities and our concerns, it is in the public broadcasting industry where minority communities and producers are more able to bring quality programming for national audiences. Additionally, public television and radio is universally available.

Digital Conversion Assistance.—We support the Administration's request for $20 million for digital conversion funding for CPB. We also urge Congress to enact the necessary authorizing legislation so that these funds can be distributed.

With stations able to broadcast on multiple channels, there will be a need for a tremendous amount of new, quality public broadcasting programming. There are costs involved in the conversion which go beyond the significant equipment and hardware needs of stations. It will also take additional money to produce programming for digital broadcast. All producers will face these new, higher costs.

Part of the equation in bringing more high quality diverse programming to public broadcasting is that independent producers be able to transition to digital production. Federal funding for digital conversion should include assistance for independent producers.

The Minority Consortia works closely with CPB. We value our relationship with President Coonrod and the CPB staff and appreciate the financial and technical assistance provided to us by that organization. We do not doubt CPB's commitment to increasing the diversity of programming on public television and radio but also believe they can do more with the resources at hand. The oft-stated commitment of CPB and Congress for increased multicultural programming combined with four years of funding increases make this an ideal time for significant progress.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and thank you for your long time support of our work on behalf of our communities.

PREPARED STATEMENT OF THE NATIONAL PUBLIC RADIO

INTRODUCTION

Thank you for the opportunity to submit a statement for the hearing record on behalf of National Public Radio (NPR) and the hundreds of public radio stations that air NPR programming across the country. Public radio offers diverse perspectives by airing a combination of local and national public affairs and cultural programming, funded by local and national sources, both public and private. Public broadcasting raises nearly 85 percent of its funding from non-federal sources, yet it requires help from federal sources to fully achieve its programming mission.

Public broadcasters seek a $395 million appropriation for CPB in fiscal year 2004 (for the past quarter century, CPB has received appropriations two years in advance).—The CPB was established in 1967 to provide federal support to stations. A $395 million funding level for the annual CPB appropriation would provide an additional $6.7 million for radio over last year. Of that $6.7 million, $5.2 million would be available for local public radio stations to keep pace with technological changes and to produce and to acquire content for a number of technological platforms and, $1.5 million would allow CPB to fund 10–15 new radio production projects in fiscal year 2004.

Public broadcasters urge the Subcommittee to maintain advance appropriations for CPB.—The Administration and the House and Senate budget resolutions have proposed to eliminate this long-standing practice that preserves freedom of expression, affords program managers more lead time to plan and organize activities, and provides seed money for raising non-federal money.

Public broadcasters support the Bush Administration's request for $20 million in fiscal year 2002 for local stations' transition to digital technology.—The estimated cost for digital radio is $116 million for transmission only, excluding production equipment.

Thank you for your commitment to our nation's public broadcasters, and the citizens and communities they serve.

A COMMITMENT TO LOCAL AND NATIONAL SERVICE

Public radio stations are committed to serving their local communities for philosophical, geographical and financial reasons.

Philosophically, non-profit public radio stations' missions are to serve their local communities with a variety of programs and perspectives. For instance, the mission of WDUQ–FM in Pittsburgh, PA states, "WDUQ is a noncommercial, educational public radio station licensed to Duquesne University. As a steward of this license,

WDUQ serves Duquesne, listeners and the community with high quality programming and services to inform, educate, enlighten and entertain."

As a result of these guiding missions, many public radio stations provide listeners with more than headlines and traffic reports by building local news departments that produce in-depth reports on community issues. Moreover, stations air national and international programming that connects listeners to broader sources of ideas, cultures and events.

Geographically, stations are licensed locally and make all significant operational and programming decisions. In fact, stations are often the only locally owned media outlets in their communities. NPR Members include stations licensed to communities, local school boards and other local institutions, and private and public colleges and universities. Specifically, 78 of NPR's Member licensees are local communities (including several Native American tribes). In addition, 8 are school boards, 11 are state entities, 27 are private universities, and 146 are state universities.

Public broadcasting has been a grassroots movement, joining diverse regions and viewpoints around a common purpose of community service and education. Because public radio's foundation was built by and is maintained by local decision-makers and listeners, this local nature preserves accountability to the people in the listening community.

This support is also reflected in the personal support dedicated by listeners and viewers to their local stations. For instance, according to CPB, replacing the work that volunteers contribute to public television stations would require nearly an eight percent increase in full-time staff, and for public radio more than a 14 percent increase.

Financially, public broadcasters are part of a successful public-private partnership. Nearly 85 percent of public radio's funding comes from non-federal sources. Stations are supported by a variety of sources, including government, foundations, businesses and listeners. Currently, local stations' listeners generally provide the largest percentage of funding (approximately one third) for local stations.

Nevertheless, federal money is crucial because it helps public radio stations plan, produce, acquire and air programs that attract these non-federal funding sources. CPB funding acts as "seed money", raising $6 of non-federal money for every $1 of federal funding.

A statutory formula governs all federal appropriations distributed through CPB. Public television receives 75 percent of the CPB appropriation while radio receives 25 percent. 93 percent of the radio designated federal money goes directly to local communities. The other 7 percent of radio funds remain at CPB to support national radio programming, which is awarded on a competitive basis. This money is essential to support the unrivaled services public radio stations bring to their communities.

ADVANCE APPROPRIATION FOR CPB

President Bush's budget document calls for a series of reforms to the federal budget process, one of which is targeted on the "abusive" use of advance appropriations for short-term budgeting purposes rather than for "advanced appropriations enacted for programmatic . . ." The President's policy of limiting advance appropriations is reflected in the House and Senate budget resolutions. This cap will effectively preclude any advance appropriation to CPB for fiscal year 2004.

During the April 6, 2001 Senate debate of the budget resolution, however, Senate Appropriations Committee Chairman Ted Stevens (R-AK) and Senate Labor/HHS Appropriations Subcommittee Chairman Arlen Specter (R-PA) expressed their concerns regarding the elimination of CPB's advance appropriations. NPR and its Member stations sincerely thank these two Senators and strongly support this effort to maintain advance funding for CPB.

Advance funding preserves journalistic integrity by insulating CPB from reactions to programming decisions. Advance appropriations also afford program managers more lead-time to plan and organize their activities. Moreover, advance appropriations provide seed money for raising non-federal funding. Ordinarily, the decision to advance fund a program is driven by a desire to insulate that program from the uncertainties surrounding the annual appropriations process, such as delays in enacting appropriations. Legislative history shows that it was this reasoning that led Congress—backed by the recommendations of three presidents—to place CPB on an advance appropriation basis beginning in 1976. In fact, in 1975, President Ford sent a five-year reauthorization to Congress with a five-year advance funding provision. Subsequently in 1976, the Congress, in a bipartisan vote, established a three-year funding practice with two-year advance appropriations that has supported CPB ever since (Public Law 94–439).

DIGITAL RADIO CONVERSION

Like our friends in public television, NPR and its member stations are excited about the possibilities of digital service and "new media." Public radio supports President Bush's budget proposal that earmarks $20 million in fiscal year 2002 for CPB to help facilitate public radio and television's transition to digital broadcasting. The estimated cost for digital radio is $116 million for transmission only, excluding production equipment.

Digital radio transmission technology is poised to deliver near compact-disc-quality sound free of interference to listeners. Digital production and transmission conversion will enable public radio stations to produce and deliver programming using a far more efficient process than currently exists. It may allow listeners and users to experience a variety of new services such as the ability to search program formats, scan selective programs and read music lyrics and song titles.

U.S. broadcasters are developing a digital technology that works in the existing AM and FM radio bands named In-Band, On-Channel or "IBOC." The Federal Communications Commission (FCC) initiated a digital audio broadcasting, or "DAB," rulemaking in November 1999, placing a high priority on preserving spectrum. IBOC DAB achieves spectrum preservation by combining digital and analog signals within the same AM or FM radio channel, thereby avoiding the need for additional spectrum.

The National Radio Systems Committee (NRSC) will independently test IBOC DAB in the Summer 2001. At some point after evaluation of the additional testing, the NRSC is expected to make a recommendation to the FCC on the selection of a standard. The FCC is awaiting this industry recommendation before it endorses a digital transmission standard.

NATIONAL SUPPORT FOR LOCAL EFFORTS: CPB FUNDED PROGRAMS

The majority of CPB dollars go to local stations to help sponsor community outreach activities, create local programming and purchase national programming from a diverse set of content producers. The following are a few of the many examples of the local and national programming that are supported in part by CPB funding:

KSKA–FM in Anchorage, AK.—Produces Community Forum. Host Robert Howk and his guests discuss community issues and take listener calls during this live, call-in broadcast. The station also partners with other Alaskan public radio stations to produce and broadcast Alaska Edition, an award-winning daily radio magazine. It is an hour-long mix of news, interviews, music and commentaries written, produced and hosted by Alaskans for Alaskans.

KPBS in San Diego, CA.—Partnered with the California League of Women in the last election season to offer voters personalized election information. Along with locally produced news stories, the feature contained a sample ballot with candidate profiles, proposition information, links to voter registration and polling place information. Users could create their own portfolio of election information and stories that interested them.

WOI Radio in Ames, IA.—Partners with St. John's Lutheran Church Foundation, Essman/Associates to produce St. John's Forum, a series devoted to promoting civil discourse on ethical questions and other issues facing Iowans. Beginning its third season on WOI Radio, The Forum is recorded before a live audience at WOI's studios in the Iowa State University Learning Connection in downtown Des Moines.

WFPL–FM in Louisville, KY.—Broadcasts Louisville Forums, programming that helps Louisville citizens learn about local issues and ideas from people in the community. WFPL–FM broadcasts presentations at the Downtown Rotary Club, the Louisville Forum, the University of Louisville, the Louisville Free Public Library and other local venues. The station also produces State of Affairs, a program offering substantive discussion with an inquisitive host, informed guests and thoughtful callers covering topics as diverse as politics and economic development, to social issues, religion and arts.

New Hampshire Public Radio.—Produces Front Porch with John Walters, a program dedicated to hearing from the Granite State's most interesting people with a unique, creative approach to their work or their life.

KNPR–FM in Las Vegas, NV.—Produces The Las Vegas I Remember, a series devoted to the history of Las Vegas and Nevada told by those who lived it. For instance, the program featured members of three of Las Vegas' founding families. Another program examined the history of Las Vegas after the building of the Hoover Dam.

WVIA–FM in Scranton, PA.—Broadcasts performances of artists who perform and record in the magnificent space of St. Stephen's Pro-Cathedral in Wilkes-Barre. Past performances have included organists, choral groups and chamber music. The sta-

tion also produces Art Scene, a unique program bringing attention to the area's cultural events through interviews, reviews and commentaries on films, books, jazz, and classical music.

KERA–FM in Dallas, TX.—Airs The People's Agenda, a call-in show exploring issues of public concern such as work, family, transportation and crime. The show defines problems from the public's perspective, examining how citizens are addressing local matters.

WXPR–FM in Rhinelander, WI.—Produces nearly a dozen programs such as Northwoods Café, a mix of music from traditional, new and ethnic folk music, as well as world music to some blues, cajun and zydeco music.

NPR's.—Morning Edition is the premier national/local program on public radio, with 10 million weekly listeners. The program is designed to encourage local stations' news departments to report on community news and events by inserting these stories into the national feed.

NPR's.—Lost & Found Sound is a collection of stories that chronicles, reflects, and celebrates the changing sounds of this century. Stories explore American life through sound—endangered sounds, shifting accents, vanishing voices, the merging of languages, the music of new technologies, and the soundscape of the streets.

NPR.—Distributes Latino USA, a national, English-language news and culture program produced from a Latino perspective. It is a production partnership of KUT Radio and the Center for Mexican American Studies at The University of Texas at Austin.

CONCLUSION

Survey after survey finds that public broadcasting is valued and supported enthusiastically by leaders of both political parties and by Americans from all regions and walks of life. According to Roper Starch Worldwide, a leading global marketing research and consulting firm, public television and public radio are among the top five choices for government services that provide excellent or good value for the tax dollar.

Please support a $395 million appropriation for CPB for fiscal year 2004 and maintain advance appropriations for CPB. Moreover, please support $20 million for public radio and television's digital transition that is contained in the President's budget.

NPR is a private, nonprofit corporation that produces and distributes award-winning programming such as Morning Edition, All Things Considered, Performance Today, and Car Talk. NPR is also a membership organization. NPR Member stations are independent entities, licensed to a variety of non-profit organizations, local communities, colleges, universities and other institutions. Public radio stations independently select and produce community-appropriate programming that best serve their listening areas rather than having these decisions made by a centralized conglomerate.

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

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ERGONOMICS

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