bring up that point because this is so much case-specific. I know that you have to think about it in generalities because ultimately you have to do something with it and the generalities are characterized by the specifics.

The only way I'm comfortable thinking about this is across a continuum of claims and therefore across a continuum of qualifiers and disclaimers. And you may get to a point where you say no, that's just not it. That's not what's in the best interest and on a safety issue, you're taking a stand. And I think that, looking at the criticism for the agency in the Pearson, I think that was one of the pieces which was thought to have been left out. I think in terms of where you have your best way to put a barrier in that regard is in the context of safety.

But where it makes sense and where it is adding something overall and you're giving information to consumers so that they can do something with it, I think you will see that as a type of claim that should appropriately be put onto a dietary supplement. And to try and put the kind of language around that that describes what that was is our version of trying to have FDA focus on the truthfulness of the claim, as opposed to the validity of the relationship.

And I think if you make that paradigm shift over to the truthfulness of the claim, you then think about this in terms of the continuum of claim and where you then are in

the preapproval authorization seat of deciding from a safety standpoint and from a benefit standpoint where you're going to draw the line.

MR. LEVITT: Marsha?

MS. COHEN: You did mention benefit at the end but I think we need to focus on the fact that nothing is safe if it isn't efficacious. Even the slightest bit of risk is too much risk if it doesn't help, if it doesn't do anything, and I think that's--if we're in the medical world.

I mean if you take a lot of a water soluble vitamin and you know, it doesn't do all those things that you were sort of promised it would do and you just excrete it, you've wasted money. But if the promise is that it would mitigate or cure, treat a disease you have and you have wasted critical time, that's critical. You can't focus--and I think that's another flaw of Pearson, that it was so focussed on safety as a drug thing and safety's not a health claim thing. You have to focus on efficacy and not just marginal--oh, it may work but here's the disclaimer efficacy.

MR. SOLLER: I didn't mean to try and grab it from you.

MS. COHEN: But you did.

MR. SOLLER: We're agreeing. We were agreeing. I apologize.

But we're not disagreeing in the sense that I'm not going to put something into FDA if I think there's no benefit there. If I don't have a benefit that I can then express to the consumer to sell my product and it's in a preauthorization process, so benefit is part of this equation.

MS. COHEN: But the question is the standard by which that benefit is judged. The gold standard is what we use for drug approval. That is the gold standard and we occasionally have diverted.

In fact, over the last 15 years, and I live in San Francisco at ground zero of the AIDS movement, because of activism, we've moved back on sort of holding to the level of the gold standard because people were dying and you move back on that and even some advocates in that world realize that mistakes were made because we were approving things too quickly or weren't looking at such carefully controlled clinical studies. But at least we were doing that because people were dying and we had no other therapies.

But it was as mistake. If you're talking about products that are getting preapproval on the basis of some much lesser standard, that is not the equivalent of what's required of a drug. It's just not equivalent.

MR. SOLLER: Well, I agree. It's not a drug.

MS. COHEN: Except you're allowing it to be used

as a drug. That's the question, is how we maintain a line.

MR. SOLLER: It is the question of where you are drawing that particular line. It's not a question that you don't have benefit information that is available and is being reviewed by the agency, that is being put together by the companies. It's not a question that you're taking a small portion of that and you're ignoring all of it. It's the weight of the evidence and the preponderance of the evidence.

It's consistent with where the law is and what is expected in terms of the truthfulness of the claim. It's entirely consistent with the FTC guidance, which is an excellent document and one that I think should be built into the basis of this in terms of putting truthful information out to the consumer.

And we're not saying it's necessarily an absolutely open door but, by the same token, depending upon what that information would be and in the agency's particular consideration of the patient or patient subpopulation, the agency may determine that that is not an appropriate health claim for safety concerns. It's a pretty good standard.

MR. LEVITT: Okay, Dr. Holtgrewe, and then we'll draw this point to a close.

DR. HOLTGREWE: In the case of food supplements

marketed for lower urinary tract symptom relief, you're treating a disease and we do not have compelling evidence in the peer-reviewed literature of the world that there is safety or efficacy of these products, simply stated.

MR. LEVITT: We'll have one more question. Just before I do, after we finish with this we'll have a break and I have a feeling people will dart out of here.

Following the break, we have a number of people who have asked to speak in their own individual capacity. We'll provide for that. We have actually a section of the room up here which we'd ask you to sit in following the break. I believe you've been given numbers so we can get the flow through quickly for that.

So I say that now and we'll turn to Rachel Behrman for our final question for this panel.

MS. BEHRMAN: This is, to start with, for Dr. Soller but then for whomever else wants to address it.

You seem to be suggesting a paradigm where there are health claims that we could deny based on compelling safety issues and you use St. John's Wort and depression as an example. But you haven't spoken to the grayer areas. You talk about calcium which again, if you will, is more on the other extreme. There's a lot of information about calcium and a lot of acceptance about that.

But let's say, for example, you have a compound, a

supplement that had some effect on blood pressure or cholesterol, either one, but not a very great one and clearly there are therapies, drugs, that have been held to a higher standard and we have to accept that we're talking about two different standards--safety and efficacy and something else--we're not quite sure what that is.

So we a drug, a supplement, two different standards and one is more effective. How would you communicate that to the consumer? Do you believe that should be communicated to the consumer?

MR. SOLLER: I think if you thought it was important from a safety standpoint to communicate that, you might put that into the qualifier. I think that's possible. But it's very difficult--and I did say severe depression; I was walking about the extreme end of this--it's sort of difficult in the abstract to provide a generalized return on your particular question because in the specifics, just to hold the point, I might disagree with what I'm suggesting in the general here.

And I don't mean to be convoluted, with a pretzel argument, but what we're trying to convey is the concept that you're going to have a range of these types of claims and that the framework that should be developed should be developed in the context of the truthfulness of the claim but also keeping in mind that there should not be an

unreasonable risk, thinking back where you have your enforcement authority under the act. It's that kind of balance, I think, that is the paradigm shift in thinking from the validity of the relationship that we're trying to convey today.

MS. BEHRMAN: And if I could just follow that up with one other point, in terms of again an analogy with OTC, do you see areas that would not be acceptable for this simply because of either patient recognition, ability to self-diagnose, things like that, or do you really see the whole gamut as a possibility?

MR. SOLLER: The whole gamut?

MS. BEHRMAN: Of types of diseases, for example.

MR. SOLLER: Well, I think you could have a safety concern in the specifics of potential for a misdiagnosis. That's possible. You take the kind of safety considerations that you take on with any kind of product.

MR. LEVITT: Any other reactions to that question?

If not, let me thank this panel. It's been a very lively panel.

[Applause.]

MR. LEVITT: We will take a 15-minute break, which by my watch says we're back here at 10 minutes after 4. And again if the designated speakers could sit in front in your designated order. Thank you all.

[Recess.]

REGISTERED SPEAKERS

MR. LEVITT: Hello, if I could get people's attention, we're ready to begin the final phase of this meeting. We have a number of individuals--the number is a little less than 20--who have asked to speak. We have a podium that is set up right over here for your use. We have seats with your names on them, which hopefully are in the order in which you'll come out, to make it easier. And we have folks who'll bring people over toward the podium about three at a time in order to make it easier to get people up but also not cause too much disruption during the speeches.

We have allotted five minutes for each speaker. So when you get to the podium there is the timer over here, which is reasonably in front of you. Take a moment to look at it. Again, as before, when the yellow light goes on, that means there is one minute left. When the red minute goes on that means your time is out and in consideration of the other speakers we would ask that you stop at that time.

Finally, if there is anybody who has managed to sit here all day and did not sign up to speak but wishes to do so, if you could now go out into the lobby and talk to one of the women at the registration desk so we can get you signed up. There is a little time but not a lot of time for somebody who did not sign up in advance.

Finally, just one other matter of protocol. We do have one member of Congress who has asked to speak and if he is able to get here, we will ask him to move--if people wouldn't mind letting him move next in line and then we'll continue in the order that we have set out.

Finally, when you get up to the podium could you please introduce who you are and what organization you're representing.

With that, our first speaker is Mr. Norman Singleton.

MR. SINGLETON: Can everybody hear all right? Since I'm the first speaker, I'll do the requisite microphone check. There's no charge.

My name is Norman Singleton. I'm a legislative aide for education, work force and health care issues for Congressman Ron Paul of Texas and I will be reading a statement on behalf of Congressman Paul.

I appreciate the opportunity to express my support for immediate implementation of the Pearson v. Shalala decision. Every day the Food and Drug Administration delays implementing Pearson is another day when consumers are deprived of their First Amendment right to receive information regarding the health benefits of dietary supplements without interference from the federal government.

Such delays are especially hard to justify considering that the court in Pearson suggested a reasonable way for the FDA to implement the decision: allow the use of disclaimers for statement that, while not approved by the FDA, are not inherently misleading. Allowing manufacturers to make nonapproved statements with a disclaimer is a major step forward towards the creation of a true free market in information regarding dietary supplements.

I also encourage the FDA to continue its work in establishing clear scientific standards for reviewing health claims of foods and dietary supplements since the court in Pearson found that the FDA regulations relied on an impermissibly vague standard of significant scientific review. Of course, clear standards of conduct are the minimum citizens in a free society should expect from their government.

Finally, I urge the FDA to allow claims regarding the effect on existing diseases be made as health claims without subjecting the product in question to regulation as a drug.

Thanks to advances in nutritional science, there is a great deal of information available regarding how dietary supplements can help people with conditions such as diabetes, heart problems, and glaucoma.

However, regulating food supplements as drugs will

have the effect of depriving consumers of a great deal of this valuable information. This is because the manufacturers of foods and dietary supplements containing these benefits will simply refrain from informing consumers of the positive effects of their products on diseases in order to avoid having to go through the costly drug approval process. This, of course, bodes well for certain pharmaceutical companies who, some argue, exercise de facto control over the FDA's regulatory actions.

Liberalizing the regulations on truthful health claims is consistent with consumers' First Amendment interest in access to truthful information about the benefits of dietary supplements. Allowing participants to make health claims regarding existing diseases is also consistent with congressional intent, as most recently expressed in the Dietary Supplement Health and Education Act, popularly known as DSHEA.

In conclusion, I would like to reiterate my gratitude to the FDA for providing this forum and express my strong support for immediate implementation of the Pearson decision, as well as allowing product health claims without subjecting that product to regulation as a drug. Thank you very much.

MR. LEVITT: Thank you.

The next speaker, please?

MS. ZAWEL: Good afternoon and thank you for this opportunity to speak today. I am Stacey Zawel of the Grocery Manufacturers of America. We are one of the world's largest associations of food, beverage and consumer brand companies and, as such, our member companies have very deep interest in FDA implementation of the decision in Pearson versus Shalala, as well as the provisions that authorize disease claims for food products.

We commend the agency for providing this forum to address how the Pearson decision will be implemented and also to consider whether or not to permit health claims about an effect on an existing disease.

First of all, I would like to address the Pearson decision as we interpret it to apply to conventional foods. Although the Pearson decision involved four disease claims that arose in the context of dietary supplement, it applies to all food and not just dietary supplements. There is nothing in the Pearson decision that limits the impact of the court's analysis solely to dietary supplements.

In order to ensure a fair, balanced and efficient policy development process, it is incumbent upon FDA to consider directly conventional foods, along with dietary supplements. Indeed, the notice even acknowledges that the treatment of health claims with respect to dietary supplements is directly relevant to conventional foods.

The agency's apparent intent to consider these issues solely in the context of dietary supplements is ill conceived. FDA misses a very valuable opportunity to use its resources efficiently by considering a single set of issues once in connection with both dietary supplements and conventional foods.

This concurrent approach also facilitates timely development of policies. Ultimately these policies will be applied to conventional foods and it is therefore rational and prudent to directly consider conventional foods when such policies are developed.

We object to FDA's determination that it will not consider foods in connection with its implementation of Pearson due to purported limits on its statutory authority and because Pearson only involved dietary supplements. This viewpoint is incorrect as a matter of law, according to our lawyers--I'm a scientist--and represents unsound public policy.

FDA's continued preference to read the First Amendment protections narrowly to the facts of the Pearson case is short-sighted. FDA should not postpone consideration of these important issues in the context of conventional foods until ordered to do so by a federal court. And I think all of you probably saw a letter submitted to the Federal Register under which GMA requested

that this meeting, in fact, be expanded to include dietary supplements and foods, not just dietary supplements.

The second provision that I'd like to talk about today at the request of FDA is the disease claim provisions of the Food, Drug and Cosmetic Act that they applied to treatment, as well as prevention of disease. Claims in the labeling of a food that "characterizes the relationship of any nutrient to a disease" are authorized in the act. There is no limitation in this provision to the prevention of disease.

Some nutrient-disease relationships involve treatment, as well as prevention. For example, a person with hypertension is often put on a low sodium diet that is part of a treatment regimen. Similarly, patients with osteoporosis, as we've already talked about a few times today, are prescribed calcium for treatment. People with cardiovascular disease are prescribed a diet low in fat and dietary fiber as part of a treatment regimen, and the list goes on and on.

There is, in short, no bright line between prevention and treatment in the field of diet and disease.

In its Federal Register notice, FDA contends that the disease prevention or treatment characteristic of a food must be based upon its nutritional value. It is, moreover, directly contrary to judicial precedent. The court in

Nutralab versus Schweiker concluded that food is consumed "primarily for taste, aroma or nutritive value" but that "to hold, as did the District Court, that articles used as foods are articles used solely for taste, aroma or nutritive value is unduly restrictive." Thus, food may be comprised of nutritive and nonnutritive materials or completely from nonnutritive materials and there is no statutory requirement that the value of a food in preventing or treatment disease must be derived from those nutritive components.

In conclusion or in summary, FDA should proceed promptly to implement the Pearson decision for all forms of food and to recognize that the disease claims provisions in Section 403(r)(1)(b) of the act include the treatment, as well as the prevention of disease. Thank you.

MR. LEVITT: Thank you.

Next speaker, please?

MR. HAMMELL: I am John Hammell. I represent the International Advocates for Health Freedom, the largest group of anti-regulatory vitamin consumers in the world.

We are sovereign over our bodies. No regulatory body on earth has the right to tell us what we can or cannot ingest into our bodies, much less restrict our access to information about these substances.

The FDA has violated the Federal Advisory Committees Act, which provides that government meetings be

open by taking my camcorder at the start of this meeting.

In light of your security notice, I wish to publicly announce that although I consider the FDA to be in contempt of court for not abiding by the Pearson decision and that this entire meeting constitutes nothing more than on-going FDA foot-dragging, for which you are already being sued again by Pearson, I come in peace, unarmed, for the mere purpose of informing you in person, eyeball to eyeball, that I regard you to be the lowest pack of lawbreakers on the planet, bar none, and your actions repulse not only myself but vitamin consumers all over the world, many of whom already know I'm saying this to you because I e-mailed it out to them yesterday in advance of speaking here today.

The significant scientific agreement standard cannot be scientifically defined. It is a tautology. It means whatever you want it to mean. But in the Pearson case the judge ruled the law is not in your mouth. We recommend that you obey the law.

In the past, you dragged your feet before finally allowing the health claim that folic acid prevents neural tube defects. Through your violation of our First Amendment right to free speech, you condemned untold numbers of children to lives of ill health and many are currently permanently paralyzed from spina bifida as a result, unable to even walk or talk, because you have condemned them to a

hellish existence wherein they now require constant 24-hour nursing care due to your genocidal actions.

Today you want to cause heart attacks, strokes, cancer and other serious illnesses by dragging your feet on approving health claims on unpatentable nutrients for which there is equally great a body of evidence to support as that for folic acid but, due to the revolving door between you and the pharma cartel, you seek to do their bidding and not do the bidding of the American people or the Court of Appeals.

So you attempt to drive all the small vitamin companies out of business by creating a regulatory nightmare of red tape to enable the drug cartel to buy them out and my guess is that your next move will probably be to try to force the supplement industry to full HASAP GNPs or as far in that direction as you can, even though such a move would constitute gross regulatory overkill, which the American people will not stand for.

Since consumers never trust anything you say and generally ignore it anyway, I urge you to go ahead, put a skull and crossbones on the supplement that you want to condemn and give us the other half of the label. Let us say anything we can back up in a court of law, as Pearson has, and then honor the judge's decision after you lose.

It is my firm opinion that the founders of this

nation did not provide us with a Second Amendment so that we could engage in target practice or go squirrel hunting. It is my belief that this right was given to us as a check and balance against corrupt, unelected bureaucrats, as well as to balance the power of corrupt members of Congress and a corrupt President.

As a Christian, I pray to God that things never reach the point in this nation where we can't engage in honest, two-way dialogue, so I hope you are really listening to me today, not just going through the motions, as you have many times in the past.

Before the Revolutionary War against England broke out, many, many, many peaceful efforts, such as this, were made, but the king broke all his promises to the colonists, so they were forced to bear arms.

It saddens me deeply that you are so blatantly ignoring a judge who ruled against you in the Pearson decision, and for that reason another lawsuit had to be filed.

I will not dignify any of your specific questions with specific replies in my oral testimony, as all they represent is more of the same sort of foot-dragging that you have always engaged in in your zeal to violate the constitutional rights, as you seek to do the bidding of your pharmaceutical masters, the large companies that manipulate

you. But just to humor you, my written comments do address all of your questions.

Many of your corporate manipulators are well represented here today, such as Monsanto and Nabisco, Unilever and others who would love to dismantle our dietary supplement laws in order to ban consumer access to these safe and effective healing agents.

As you engage in your corrupt effort to block the making of truthful health claims on these natural products and as you seek to violate our civil right to free speech, please just know one thing. One day you must answer for these crimes to your creator, who gave us the vitamins for healing purposes.

And don't think you can get away with your effort to make an end-run around our laws via the U.N.'s Codex Salimantarius Commission, either. Do not think for one minute that Congress will allow this. Do not think for one minute that you are fooling anyone by trying to set us up for Codex harmonization via the National Academy of Science's so-called risk assessment paper, a risk assessment model for establishing upper levels for nutrients, which is on the IAHF website at IAHF.com.

On my website you will also find jif files with signatures of five congressmen, including Congressman Dan Burton, chairman of the House Government Reform and

Oversight Committee, Ron Paul, De Fazio, Cook and Stone.

MR. LEVITT: Excuse me. The five-minute timer has completed. If you could just quickly summarize.

MR. HAMMELL: Just to summarize, basically obey the law. You're not above the law.

MR. LEVITT: Thank you.

Next speaker, please?

MR. HANNEMAN: With respect, I'm Dick Hanneman. I'm president of the Salt Institute and we appreciate this opportunity to share with the agency our views on nutrition, health and disease information that can be provided with a dietary supplement or a food.

You've heard, I know, attempts to distinguish the two. We think, as GMA testified, that really they ought to be considered together and that the messages need to be consistent because consumers need that consistency.

Historically, we've supported, with caution, the FDA approach to resist health claims prior to NLEA but we are concerned that consumers are being confused and misled by information that they may receive about foods and supplements and that claims need to be sufficiently flexible and modified to reflect the new science that is coming about--we don't think that's happening.

Courts have now ruled in a variety of contexts with respect to different products that the FDA cannot

restrict information that's provided about a food if there is a less burdensome way that the information can be provided that's not false and misleading.

We're concerned about the implications on allowable health claims and particularly, of course, on sodium and hypertension when we have consistently stated that that health claim improperly simplifies the role of sodium in hypertension. By liberalizing allowable health claims, the Pearson decision offers FDA an opportunity to improve consumer understanding in this murky area of science.

Consumers do not properly understand the caveats included in the current sodium hypertension health claim and I'm sure that when FDA conducted its consumer polls before implementing the sodium-hypertension health claim, you found consumers may read the language crafted by your lawyers that some people may benefit by following low sodium diets, but actually consumers read this that most or all or probably they personally will benefit by a low sodium diet. And, of course, only the most zealous proponents of the sodium hypothesis would make such an extreme claim and your attorneys were careful not to make the language go that far.

There's no doubt that sodium reduction will confer health benefits for a small subpopulation of people and there's no doubt that sodium reduction increases health

risks for others. The current health claim conveys an incorrect impression of universal benefit to all and risk to no one. The Pearson decision points the way to rectifying consumer misunderstandings.

So given the Pearson decision, FDA should require or at least allow food companies to provide a more comprehensive, balanced presentation of the health effects of nutrients, including the debate that explains to consumers the significant qualifications to the asserted sodium-hypertension relationship, particularly if the health claim has meaning for only certain subpopulations. This will embrace the court's ruling that manufacturers have a First Amendment right to provide such information as long as it's presented accurately and in a balanced way.

Such an approach would also introduce flexibility into the process of providing health claims information and recognizing that significant advances in scientific understanding will eventually occur, as they have, for the sodium and hypertension health claim, since it was authorized in '93. The scientific literature suggests that there are significant health aspects for some small percentage of people resulting from the low salt diets but that most people do not benefit from sodium restriction, that obesity and other nutrients play a much larger role in the development of hypertension.

Today, for example, it would be much more accurate to tell consumers that they would derive blood pressure benefits by eating more fruits, more vegetables and more low fat dairy products than to reduce dietary salt.

Science is the process of creative destruction, of testing and replacing facts when new evidence proves them inaccurate or incomplete. Scientific developments demand more flexibility in health claims generation and evaluation.

The current rules, for example, make no direct provision for modifying or deleting a health claim when science shows it to be inaccurate or ineffective. No health claims have been modified or discarded in the history of FDA health claims regulation. If not today, eventually such a system becomes unacceptably rigid in ignoring the advances of science. However, an approach along the lines of Pearson, where information is presented in a balanced, accurate, and nonmisleading manner, can significantly assist in enhancing consumer understanding.

In addition, FDA suggests that different standards should apply to health claims on dietary supplements as on food products. Unfortunately, consumers do not distinguish between the information they read based on whether it's on a supplement or a box of cereal.

Therefore, FDA should assess the acceptability of health claims based on the same criteria--whether the

information is false and misleading. If not, the claim ought to be allowed to stand.

In summary, the Salt Institute encourages FDA to use the impetus of the Pearson decision to modify its rules for both foods and dietary supplements to allow food manufacturers the right to offer additional diet health information in a balanced and accurate manner. The public misunderstanding of the sodium and hypertension health claim, in light of scientific advances, makes it an instructive guide to fashioning these new FDA rules. Thank you.

MR. LEVITT: Thank you.

Our next speaker, please.

MR. LIEBERMAN: My name is Ben Lieberman. I'm substituting for Sam Kazman. I'm a policy analyst with the Competitive Enterprise Institute, a promarket public policy group committed to advancing the principles of free markets and limited government.

My organization has followed the dietary supplement health claim debate, as well as other commercial speech controversies, for many years. We are encouraged by the growing body of recent case law, such as Pearson versus Shalala, that has expanded the First Amendment protections afforded information on product labels and advertisements and we urge EPA--excuse me; we urge FDA; EPA can do a few

things, too--we urge FDA to quickly brings its labeling policies into compliance with the First Amendment.

MR. LEVITT: We'll send them a note.

MR. LIEBERMAN: Okay. Today I'd like to briefly add a few points to the issues addressed in the first two panels, which centered around the significant scientific agreement standard, as well as the nature and extent of any required disclaimers. These issues really boil down to the larger question of what information dietary supplement producers will and will not be allowed to say and, more importantly, what consumers will and will not be allowed to read on product labels.

I believe that the Constitution and the public interest is best served if FDA's role as information gatekeeper is kept to a minimum, that of forbidding dietary supplement health claims that lack scientific support. But beyond restricting unsupported health claims, the agency has no legitimate role in limiting truthful and nonmisleading information on dietary supplement labels.

With regard to the significant scientific agreement standard, the problem with this standard, especially given FDA's tendency to interpret it fairly strictly thus far, is that it has served to keep a good deal of accurate and potentially beneficial information away from consumers. Initially, FDA interpreted the NLEA and the

Dietary Supplement Act in such a manner as to prove only those very few health claims that are an evidentiary slam-dunk while completely suppressing all others that fall short of its tough significant scientific agreement standard.

I hope that Pearson versus Shalala will put an end to this interpretation but I'm somewhat concerned by FDA's December 22, 1999 guidelines, which once again set the bar very high.

In contrast to FDA's restrictive approach, I believe that more truthful information is better than less. If a dietary supplement probably has a health benefit, it's better to inform consumers that it probably has this benefit than to use any lingering uncertainty as a reason to tell them nothing.

The preference for greater disclosure is particularly acute in the absence of any real evidence that dietary supplement health claims not meeting the significant scientific agreement standard will cause any harm to consumers. The Supreme Court has repeatedly held that the party seeking to uphold a restriction on speech carries the burden of justifying it. In the words of Justice Kennedy, "This burden is not satisfied by mere speculation or conjecture. Rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will, in

fact, alleviate them to a material degree."

FDA has yet to demonstrate that any such benefits would be derived from banning dietary supplement health claims that are accurate but do not meet the significant scientific agreement standard.

Rather than setting a high standard that no more than a handful of claims will ever meet and either forbidding or requiring disclaimers for the rest, I would suggest an alternative approach. I believe that FDA should not place restrictions on any health claim so long as it is worded so as to accurately reflect the state of the science. Only those claims that misrepresent the degree of scientific support or lack any support should be banned. Indeed, it's hard to imagine any other standard that would not run into future First Amendment problems.

With regard to disclaimers, I applaud the U.S. Court of Appeals' clear preference in Pearson versus Shalala for disclosure with disclaimers, if necessary, over a policy of suppression, but since the court has given FDA wide discretion in fashioning these disclaimer requirements, I believe that a few words of caution are in order.

Keep in mind that the truth is a two-way street. FDA can be just as wrong understating the benefits of a dietary supplement as can the manufacturer by overstating them. Unfortunately, thus far the agency has shown only

concern for the latter but not the former. However, a required disclaimer that serves to make a dietary supplement health claim sound less true than it actually is is also misleading and must be avoided.

I'd add one last word of caution before FDA promulgates its policy on disclaimers. The Bureau of Alcohol, Tobacco and Firearms, which also regulates products, including alcoholic beverage labels, is facing similar constitutional questions regarding its refusal to allow winemakers to say anything on their labels about the evidence that moderate consumption of alcoholic beverages confers cardiovascular and overall health benefits.

Though not officially banning such health statements, ATF has responded with the tactic of imposing disclaimer requirements so onerous that it would be nearly impossible for producers to meet them. This is particularly easy in the context of product labels, where there simply is no room for more than a few sentences of text.

In fact, ATF has gone so far as to boast that any disclaimer meeting its standards would be extremely unlikely to fit on a typical label and has thus far successfully stopped industry members from using health claims. My organization is now challenging this policy in federal court.

Here any similar attempt by FDA to create

disclaimer requirements so burdensome so as to create a de facto ban on any health claim would subvert the purpose of the constitutional preference for more speech, rather than less.

In summary, there's a growing body of evidence that a number of dietary supplements have health benefits, yet very little of this information has thus far been communicated to consumers on product labels, where it can have the greatest impact. I hope that the FDA uses the Pearson versus Shalala decision as an opportunity to substantially modify its dietary supplement health claims policy so as to comply with the First Amendment and comport with the best interests of the American people. Thank you.

MR. LEVITT: Thank you.

The next speaker, please?

MR. ULLMAN: Good afternoon. My name is Mark Ullman. I'm a partner in the New York City law firm of Ullman, Shapiro & Ullman. I appear here today on behalf of Traco Labs, Incorporated, a manufacturer and supplier of dietary supplements based in Champagne, Illinois and, I might also note, a defendant in one of FDA's black currant oil cases that we like to think paved the way for DSHEA.

Over the past 10 years Traco has consistently urged FDA to permit the free flow of all truthful, nonmisleading information concerning the important health

benefits of dietary supplements. This position has been grounded in the notion that only with this complete information may American consumers take full control over matters related to their health and make fully informed, intelligent decisions on this all-important issue.

Once again today, Traco appears here to urge FDA to allow the free flow of all truthful and nonmisleading information to consumers by taking all necessary steps to implement the D.C. Circuit Court's decision in Pearson v. Shalala and by acknowledging that health claims which discuss the effects of dietary supplements on existing disease conditions are permissible under the federal Food, Drug and Cosmetic Act.

In the Federal Register notice announcing this meeting, FDA requested that comments address a series of questions the agency posed pertaining to these issues. I will attempt to address the most pertinent of these in the brief amount of time allotted for this presentation.

On implementation of Pearson, what is the best approach for public health? Traco firmly believes that the answer to this question is one which allows for the free flow of truthful and nonmisleading information. The public health is best served when consumers are provided with truthful information relating to the broad range of health benefits that can be provided by dietary supplements.

Our First Amendment jurisprudence has repeatedly expressed a preference for disclosure rather than suppression of information. In its 1977 ruling in Bates v. the State Bar of Arizona, the Supreme Court noted, "We view as dubious any justification that is based on the benefits of public ignorance."

Similarly in 44 Liquor Mart v. Rhode Island, Justice Stevens recognized that, quoting, "The First Amendment directs us to be skeptical, especially skeptical of regulations that seek to keep people in the dark for their own good."

Of equal import, however, Traco believes that there is no place in the market for false, misleading information. Such information is entitled to no First Amendment protection and the full array of FDA's enforcement powers are properly utilized against those individuals and companies marketing products on the basis of such misinformation.

On qualifying language and disclaimers, Traco believes that the answer is an unqualified yes, such disclaimers can be utilized to convey information in a manner understandable to consumers. Several examples of these disclaimers were cited by the D.C. Circuit in the Pearson decision.

To the extent that FDA has expressed concern that

disclaimers and qualifying language may be so broad as to justify even the most outrageous claims, Traco submits that the Pearson decision does not require the agency to validate any and all claims so long as they are accompanied by a disclaimer. It is well established in our case that that false promotional claims may not be protected by overarching disclaimers. What Pearson does require, however, is that FDA explain the basis for its decision in rejecting a claim rather than simply announcing that it's failed to pass some unarticulated standard.

To the extent that the agency has sought information from the industry demonstrating that disclaimers and qualifying language can be used in conjunction with claims without causing consumer confusion, Traco notes that the Pearson court expressly recognized that the burden is on FDA to justify any restriction it may seek to place on speech and that it's not the industry's burden to justify that speech.

Specifically, the court stated that although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where products affect public health, it must still meet its burden of justifying a restriction on speech.

On health claims on existing disease conditions, Traco believes that the answer again here is an unqualified

yes, those claims should be allowed under the FDCA. I'm going to rely basically on my written speech--I see my time is running out--because I do want to address two questions that were raised repeatedly to the last panel.

On the question of what standard to apply when a health claim is submitted that is directed at treating or mitigating diseases, we believe that the Pearson decision allows FDA to adopt a sliding scale. The decision does address FDA's public health concerns and the FDA can impose a higher standard on that type of claim.

And, in conclusion, I'd like to suggest a disclaimer FDA might be able to use to draw the distinction--the agency has asked about how do we distinguish between OTC products with claims and supplements with health claims. The disclaimer we'd like to suggest is, "This product has not undergone the FDA drug approval process. You may want to consult your physician." Thank you.

MR. LEVITT: Thank you very much.

The next speaker, please?

MS. CAMPBELL: My name is Candace Campbell. I'm the executive director of the American Preventive Medical Association. We were one of the plaintiffs in the Pearson case, so I think you know what I'm going to say.

For the past nine years APMA has asked FDA to

approve four dietary supplement health claims. FDA denied the claims and refused to permit them even with disclaimers, despite our successful arguments that the First Amendment prohibited outright suppression of the claims and required their authorization with disclaimers.

On January 15, 1999, the U.S. Court of Appeals for the D.C. Circuit agreed with us and held FDA's four rules suppressing the claims invalid under the First Amendment. The court ruled that FDA may not suppress health claims if it can render them nonmisleading through the addition of disclaimers. The court ordered FDA to favor disclosure over suppression and found almost frivolous FDA's arguments to the contrary.

The court gave the agency precise disclaimer language that the court found acceptable for use with each of the four claims FDA suppressed. In other words, the court gave FDA a precise road map to follow to assure full compliance with the First Amendment.

Despite the court's orders, in over one year after the court's decision FDA continues to enforce the four rules the court held invalid. My attorney has been told by Director Levitt that FDA will prosecute anyone who uses the claims the court found wrongfully suppressed, even if those claims are used with the court's preferred disclaimers.

In short, FDA is continuing to violate the First

Amendment and it is resisting compliance with the Pearson court constitutional order. Where I come from that's called contempt of court.

The Pearson court's decision is extraordinary in many respects. First, the court not only ruled that the FDA violated the First Amendment by suppressing the four health claims rather than disclosing them; it also spelled out in detail the kinds of disclaimers it found sufficient to eliminate the potentially misleading connotations FDA identified.

In other words, the court not only told FDA why its actions were unconstitutional; it also told FDA precisely how to comply with the Constitution--by authorizing the claims in a nonmisleading way.

After the court's clear explanation to the agency, one would have thought FDA would act immediately to authorize the claims with those disclaimers, but FDA did not. Instead, the agency has spent over 14 months enforcing the very rules the court invalidated and struggling to find some legal argument for not complying with the court's order. FDA has refused to set a date certain by which it will authorize the claims with disclaimers, despite five letters from our attorney requesting a date.

FDA has refused to allow APMA members to use the claims with disclaimers, threatening enforcement action

against them if they do so.

In today's meeting, FDA does not identify a date by which it will authorize the claims. Rather, you ask questions which reveal that it seeks yet another scientific validity test to prevent authorization of the claims.

Moreover, FDA is now trying to redefine the term "health claim" to exclude treatment claims from those permitted without drug preapproval.

To be blunt, we would like to see this nonsense come to an end. Rather than follow the law faithfully, the FDA is doing everything it can to evade, circumvent and disobey the law. These actions are reprehensible.

I realize from communications with the agency that you believe you are responding with all due haste. Let me assure you you are alone in this perception. FDA's duty to comply with Pearson is clear and immediate. We have suffered at least nine years of speech suppression and should not be made to suffer an additional moment.

The court ordered this agency to authorize the claims with disclaimers. The court told this agency what disclaimers it found acceptable. We ask that you do what is required of you and stop these obvious evasive tactics.

It's mind-boggling to me that we spent six years, hundreds of thousands of dollars--not tax dollars--and won a landmark lawsuit and the agency has yet to comply. If an

individual acted with such impunity, he would be in jail by now.

Please authorize all four of the health claims with the disclaimers the court has given you and do so immediately.

I came here today to ask you, to urge you to stop playing games with the Constitution. Stop running roughshod over our free speech rights. FDA is not above the law.

MR. LEVITT: Thank you.

Our next speaker, please?

MR. McCURRY: My name is Steve McCurry. I'm here representing the Research-based Dietary Ingredient Association, commonly written as RDIA. I'd like to thank you for this opportunity to make a few comments. We're submitting written comments, as well. These will be as brief as I can make them. It has been a very interesting day with lots of interesting points made.

Certainly the First Amendment applies to commercial speech. I don't think I heard anybody today disagree with that notion. But problems do crop up in the way it's implemented. Statements that do not meet the standard of truthful and not misleading are of no help to anyone. Claims that are not understood by the consumers are inherently misleading and, at best, can do no harm; at worst, they can do something much more difficult--claims

that are not understood.

Any disclaimer has to be worded to match the health claim desired based on the totality of the scientific information that's actually available for it. Especially given that the scientist who tries to evaluate the study has spent years going to school, has spent years gaining experience and is still having trouble understanding what the science actually concludes about it, it's sort of difficult to imagine a way to communicate that information to the public in a simple form so that it can be easily understood, notwithstanding the fact that the public is entitled to see the information.

What or how much information constitutes useful disclaimers, given that the explanation over a certain length, as we heard earlier today, isn't read, anyway? So this is another rather large problem as far as implementing meaningful disclaimers.

The last point I'd like to make is that a solid, independent, third-party review system by experts, such as has been suggested as an option in the SSA guidance document by FDA, as well as during the first panel this morning, would be one way to help implement such claims.

We've heard many concerns about safety and the need for data substantiating the claims. Our organization believes that the GRAS standard or the GRAS principles are

the same, should be the same for dietary supplements and functional foods--a reasonable certainty of no harm. In other words, the public is entitled to safe products.

We believe the claims, no matter what regulatory category, have to be adequately substantiated with appropriate, adequate and rigorous scientific data, and I think that's all we have to say now. And the written comments I hope will be a little more clear, rather than some that were assembled sort of the spur of the moment in response to a lot of talks today. Thank you.

MR. LEVITT: Thank you.

Our next speaker, please?

DR. BAER: Good afternoon. My name's Dr. Andrew Baer. I'm an internist and I practice integrative medicine and I'm also here representing the Life Extension Foundation.

What are the real core issues here? I think what we're really talking about is safety and efficacy as it applies to dietary supplements, and that's what everybody was talking about this morning ad infinitum.

The will of Congress was really that we not treat dietary supplements in the same way we treat drugs. They shouldn't be run through the same sort of process that we use to approve drugs.

Pearson has really opened up this Pandora's box

yet again. I know Pearson and although he's used the First Amendment, I think the First Amendment really is a cop-out and that's not really what's at issue. What we're really talking about is whether or not we really want dietary supplements to be handled in the same fashion that we handle drugs.

The drug approval process is unnecessarily expensive--we all know that. The companies that manufacture and sell and distribute dietary supplements can't really afford to do this kind of research. And really safety and efficacy has been demonstrated in most of these things in other countries and many of them have been used for a long time without any kind of untoward effects.

Some years ago I remember when--just a couple of years ago, really, when acupuncture needs were finally taken out of the investigational class and approved by the FDA. I remember thinking to myself that this was really unmitigated hubris. I mean acupuncture has been practiced in China for thousands of years; so has eight-principle medicine, which is sort of their internal medicine, and eight-principle medicine is how physicians there prescribe the herbal preparations that they mix together to treat disease.

Certainly they've been doing this for a long time--thousands of years, again--without any kind of a regulatory oversight. And God knows there are still

billions of Chinese on the planet. They're not dropping like flies from ingesting herbs.

Medicine is actually a dynamic process. We know that things change. Everybody knows the thalidomide story and what we went through about that and yet thalidomide is back in the news again. We now find that there are some uses for thalidomide.

We also know about H2 blockers and the fact that we now know the etiology of peptic ulcer disease is from a biological agent and not from aberrant excursions of stomach acid. And yet we still have H2 blockers on the market, despite the fact that having the pH of the stomach altered in such a way that it's raised probably interferes with digestion, leaving digestive remnants in patients that have a leaky bowel. This can result in T-cell-mediated allergies.

I'm bringing this up because really it's very difficult to regulate everything. We can't control the whole world.

When we were talking this morning I was listening to what was going on and I started thinking to myself, do we really want a bottle of supplement, whatever it happens to be, to look like a page from the PDR? When you think about it, why is it that a prescription bottle doesn't look like a page from the PDR? The reason is because we give informed

consent dispositions and that's what we're really talking about here when we're trying to get into this whole issue of the dissemination of information and disclaimers. I mean there's pros, there's cons. How much of this can you put on a label of anything?

And I think really the same sort of thing obtains here that obtains with drugs. You know we've gotten so crazy with informed consent that it's difficult to do this without scaring off patients. I mean if we were to give true informed consent about surgery, we'd tell the patients, you know, you have a 1 in 10,000 risk of just dying from the anesthesia alone. Do we really want to tell people everything?

Well, yeah, that's fine. Yeah, that's fine. That may be, but you have to make some sort of decisions about how much you can tell them. Do you want to be read the whole PDR page? You can go read it yourself. That's great if you want me to read it to you but that's something I think the American public can read themselves. They don't need me to read them from the PDR just to give them the details of every little possible thing that can happen, especially because that's absurd. You include every untoward drug reaction, whether it happens 1 in a billion. That's not informed consent. That's diarrhea facts.

MR. LEVITT: Excuse me. The time is up. If you

could find a way to summarize briefly, please, and conclude.

DR. BAER: Anyway, the public isn't stupid. They can make these decisions themselves. They don't need the FDA to do that for them.

And the important thing is that many of the supplements are now within the provision of the standard of care in the community of physicians and if you prevent us from being able to prescribe or disseminate information, we're going to be liable to be sued and so are you. I mean I can think of a lot of cardiologists that prescribe anti-oxidants, so it's now within the province of the standard of care. Thanks.

MR. LEVITT: Thank you. I do apologize for the interruption from the cell phone. Does anybody else that does have a cell phone or a pager here--again, I asked earlier if you could please turn them off. It is distracting to the speakers who, like others, have waited all day for their turn. Thank you.

Next speaker, please?

MS. PELETIER: Thank you. My name is Joy Peletier. I'm a biochemist and nutrition scientist for Pure Encapsulations, Incorporated of Sudbury, Massachusetts. I advise the company on product formulations, on the scientific evidence of product ingredients and on permissible claims. I spend a great deal of my time

reviewing peer-reviewed scientific journals in biochemistry and nutrition science.

Nutrient disease information need not be proven conclusively true to be accurately represented to the public. The Pearson court understood that First Amendment lesson; this agency still does not.

In the course of my work, I frequently encounter nutrition science which although not conclusive, strongly associates a nutrient with reduction in the risk of a particular disease or reduction in disease symptoms. That accurate information is not of the kind FDA approves under its health claims review standard. In other words, although a nutrient-disease association can be accurately stated, the FDA prohibits it until it can be proven conclusively.

To follow the law, companies such as the one I represent deprive consumers of truthful answers to nutrient-disease questions every day. We know that truthful answers on the nutrient-disease association will violate FDA's health claim ban, which judges speech on conclusiveness, not on truth.

FDA's health claim rule has blocked from consumers a wealth of accurate scientific information contained in the peer-reviewed literature that indicates certain nutrients may affect certain diseases. The nation's leading scientists and even the Surgeon General may rely on that

information and accurately inform patients of the possibility that Vitamin E may reduce the risk of heart disease, that Saw Palmetto may relieve the symptoms of benign prostatic hyperplasia, that Vitamin B6, B12 and folic acid may reduce the risk of vascular disease, that ginger may eliminate nausea or that prune juice may relieve the symptoms of chronic constipation, but that same information cannot appear on the label or the labeling of a dietary supplement.

The ones hurt most by FDA's health claims rule are consumers. Consumers buy dietary supplements for health reasons. They perform a basic risk-benefit analysis before making a purchase. If the product is safe and it may help reduce a disease risk or disease symptoms, even if the jury is still out, they may still want to give it a try. Consumers are far more independent and sophisticated than the FDA believes. They appreciate that very little in science is proven conclusively true, yet much in science not proven conclusively is still of great potential use.

Thus, most oncologists in the U.S. use anti-oxidant vitamins. They know well that the scientific evidence that anti-oxidants reduce the risk of cancer is very strong but may not yet be conclusive. Most cardiololgists in the U.S. consume Vitamin E. They know well that the scientific evidence that Vitamin E reduces the

risk of heart disease is very strong but may not yet be conclusive.

Yet the risks of consuming these products is zero while the potential benefits are great. In short, it is a safe bet.

Consumers are entitled to make these safe bets, too, but they can only do so if they are accurately informed. They can only be accurately informed if the FDA embraces the Pearson decision and discloses this information rather than suppresses it.

The Pearson court has ordered FDA to get out of the business of suppression and into the business of disclosure. This agency has to do a 180-degree turnaround and start fostering the distribution of accurate health claims, rather than blocking all health claims it deems inconclusive.

Consider the consequences of FDA's prohibition on the dissemination of inconclusive yet accurately stated science. First, the absence of accurate science at the point of sale deprives consumers of information they need to make informed choices. When deprived of accurate nutrient-disease information at the point of sale, consumers are bound to be misled by erroneous assumptions derived from secondary sources, such as television, radio, magazines or newspapers.

Second, the absence of accurate science at the point of sale increases the chance that consumers will harm themselves by taking too much of a product or by avoiding a needed medical treatment.

Third, the absence of accurate science at the point of sale increases the chance that consumers will be defrauded. Without accurate information, consumers are less likely to be skeptical about false claims.

Fourth, by prohibiting all but those claims that are proven to a near conclusive degree, FDA has created a huge black market in unapproved claims. By implementing the Pearson decision and allowing inconclusive claims with disclaimers, FDA will lower the bar and cause many who now avoid health claim submissions to file claims. That way more accurate information will reach consumers than ever before.

In sum, FDA's effective ban on all but conclusive nutrient-disease information at the point of sale not only violates the First Amendment right for people like me but also endangers public health. It leaves fraud and misinformation in the market unchecked by accurate information. Remember, nutrient-disease information need not be proven conclusively true to be accurately presented to the public. The Pearson court understood that First Amendment lesson. This agency still does not. Thank you.

MR. LEVITT: Thank you.

We have several more speakers left. The next speaker, please?

DR. WHITAKER: Good afternoon. I'm Julian Whitaker. I'm a medical doctor. I'm in private practice in Newport Beach, California. I've written eight books on health and unconventional methods of treatment. I write a monthly newsletter, "Health and Healing," which is received by 500,000 people. I consult with a nutritional supplement company on matters of use and formulation.

I am the founder and past president of the American Preventive Medical Association and was the president when the American Preventive Medical Association joined Pearson and Shaw as plaintiffs in the successful suit brought against the Food and Drug Administration. The ramifications of that suit are the reason for this hearing.

I am one of the petitioners to the FDA to approve a claim for the use of Saw Palmetto that alleviates the symptoms of benign prostatic hypertrophy.

Ladies and gentlemen, truthful, nonmisleading information has not been on nutrition supplements for the past 25 years. For instance, the labels on bottles of Vitamin C should tell you that this vitamin may help in the prevention of cancer and heart disease. On bottles of Vitamin E it should clearly state that the supplement of

Vitamin E may be helpful, along with diet and exercise, in preventing cardiovascular disease.

On bottles of B complex vitamins, it should state that these nutrients may be helpful in preventing heart disease, several types of cancer, neural tube birth defects.

These are truthful. These are nonmisleading claims that are substantiated by a wealth of scientific data and could be used to the treat benefit of the citizens of this country.

You haven't seen such information as this on supplement labels because the FDA has not allowed it. However, the court has ruled that the FDA's censorship of this kind of information on nutritional supplement bottles is not only illegal but is unconstitutional. That ruling by the D.C. Court of Appeals, three to zero, was handed down January 1999. The court ruled that the FDA's requirement that a health claim must meet FDA's standard of significant scientific agreement was not only a bad idea but it was illegal. That standard was undefined and thus that standard was arbitrary and capricious. That is illegal for it violated the Administrative Procedure Act.

The court also held that its prior restraint of speech forbidding manufacturers and retailers from saying anything good about a nutrition supplement until the FDA approves such was a violation of their First Amendment

rights guaranteed by the Constitution.

The FDA appealed these rulings to the Fourth Circuit D.C. court. They lost again, 13 to zero.

The FDA did not appeal this decision to the Supreme Court for more obvious reasons. Thus, the court mandate of the D.C. Circuit in Pearson and Shaw versus Shalala became the law of the land in January of 1999.

So what has the FDA done to create its illegal and unconstitutional ruling to abide by the court order? Absolutely nothing. They have procrastinated, rolled out excuses and dragged their feet.

In fact, this hearing is a fraudulent sham. We are gathered here as if on a fact-finding mission to answer compelling FDA questions. The first question is should health claims be allowed on dietary supplements other than those that meet the FDA standard, whatever it may be, of significant scientific agreement?

Ladies and gentlemen, pardon my mirth. We need not answer that question for it has already been a court order and a resounding unequivocal answer of yes. The answer to that question is a court-ordered yes.

The court ruling did not provide for the FDA to have a hearing just for input as to how they should abide by a court ruling.

Ladies and gentlemen, if a government regulatory

agency, such as the FDA, were engaged in a regime of censorship and deprived an ethnic minority--let us say African-Americans--of their constitutionally guaranteed rights of speech and if the court found that the regulatory agency had violated statutory law by using an arbitrary and capricious ruling and that the court had ordered the agency to immediately remedy their actions, do you think that over a year following that decision they would be calling for a hearing seeking input to see if free speech should be given to the minority group? I think not.

Ladies and gentlemen, the FDA's illegal and unconstitutional censorship of truthful and nonmisleading labels on nutritional supplements has been dealt a fatal blow and I am proud to be a part of those who orchestrated such. Like a female lion on a hunt who has struck, we have this illegal repression of speech by the throat.

If it has not been swept from our political landscape within the next year, then we all had best worry because that will mean that our system of checks and balances, put in place to protect us, the citizens, from overriding governmental action, not to protect us from ourselves but to protect us from government, the system of checks and balances to guarantee the freedom that we have in this country has failed. Thank you.

MR. LEVITT: Thank you. Next?

MS. ORTUZAR: My name is Alyce Ortuzar. I'm a medical, legal and social science researcher and I run the Well-Mind Association of Greater Washington, a holistic medicine information clearinghouse.

In 1949 Dr. Frederick Klenner published that he had cured polio with intravenous Vitamin C. He published for 40 more years and documented his success with intravenous Vitamin C, often in very high dosages of over 200 grams in a 24-hour period with measles, chicken pox, third-degree burns and pneumonia, which he said he never lost a case of, no matter how close to death the patient was. I personally used it to reverse my Lyme's Disease.

He recommended it as the treatment of choice in the emergency room, called it the safest, most effective antibiotic and was critical of the AMA and the FDA for either recommending to lower the dose or for discrediting the treatment outright.

In the 1950s Drs. Osmond and Hoffer documented their ability to reverse certain schizophrenias with high doses of Vitamin C, B3 and B6. Also in the 1950s the Chute brothers documented their ability to treat and reverse heart disease with Vitamin E. Intravenous magnesium was also documented as a life-saving treatment in the case of heart attacks.

In 1962 Bill W., cofounder of Alcoholics

Anonymous, documented his success with a high protein, low carbohydrate diet and niacin.

In 1966 in the National Medical Journal the title of an article was "Hypoglycemia as a cause of neuropsychiatric disorders," implying that with most mental illnesses there was really an underlying physical cause and focussing on the brain or focussing on just drugs is not going to resolve the patient's problems.

In 1968 Dr. John Tintera published his data where he used adrenal cortical extract and the high protein, low carbohydrate to successfully reverse alcoholism, hypoglycemia, certain schizophrenias and certain arthritis cases. He was very critical of prednisone, documenting it as being very toxic and the only time he ever experienced failure in his patients was if people had had prednisone first.

In 1970, Dr. Ben Feingold documented his ability to reverse learning and behavior disorders by taking children off of all but organic foods, eliminating sugars and eliminating artificial chemicals, dyes and additives, all approved by the FDA, USDA and EPA, including pesticides.

Studies claiming to refute these doctors were paid for often by the chemical or sugar industries and were shown to have serious design flaws.

Dr. Linus Pauling, who won the Nobel Prize for his

chemistry, was also critical of claims that high dose Vitamin C caused harm and said chemically it just was not possible.

In 1978, the FDA submitted false information characterized by then-Congressman Barry Goldwater, Jr. as sloppy and suspect to take adrenal cortical extract off the market and make the public a captive audience for prednisone. In mainstream medical literature today prednisone is identified as one of the most toxic drugs, and yet the FDA was promoting it as safe. Even in the Physician's Desk Reference, over 40 years of use of adrenal cortical extract documented no incidence of adverse reactions.

In 1988, the FDA consumer publication stated that intravenous vitamin treatments were useless. In 1989 the FDA released a health fraud kit where they also misinformed the public about the safety and efficacy of vitamins.

The FDA also evidence about folic acid until 1993 and '94, which could have saved we'll never know how many birth defects in babies.

And in the 1990s when the FDA took the L-Tryptophan off the market, they never really told the public that what caused the harm was the genetically modified L-Tryptophan.

The FDA recall rate in a 10-year period is 52

percent. In November 1994 Newsweek documented that because something is FDA approved it does not mean it is either safe or effective. In June 1998 JAMA revealed hundreds of thousands of deaths from FDA-approved drugs taken as directed. This is the gold standard. This is good science.

People are dying as a result of FDA's betrayal of its mandate for safety, which has been subsumed by the more ambitious and ambiguous standard for efficacy in the FDA's power grab on behalf of the chemical, food and drug industries, well documented in the 1993 expose "Raqueteering and Medicine" by Tulane Medical School professor Dr. James Carter.

My suggestions to the FDA are that they become a clearinghouse of information submitted by practitioners, by scientists, by patients documenting the research and outcome data for these nutritional supplements and natural treatments and that they release that information and the label should reflect that information and the FDA should really care more about the hundreds of thousands of people dying from the drugs for which there are, in just about every case, a nontoxic natural alternative. Thank you.

MR. LEVITT: Thank you.

We have, on my list, one more speaker.

DR. SIMONE: Good afternoon. My name is Charles Simone. I'm an internist trained at the Cleveland Clinic, a

medical oncologist trained at the National Cancer Institute, immunologist and also a radiation oncologist trained at the University of Pennsylvania.

I've written a number of books, "Cancer and Nutrition," "Breast Health," and I've authored over 50 peer-reviewed papers.

In 1993 I was called upon to help frame the language that led to the ultimate DSHEA Act and then I was called upon again to help with the work that led to Pearson.

I have a written testimony that you have there and I'm going to skip over some of the things to address a few other things.

As a director of a nonprofit cancer institute, I've devoted my entire life to teaching professionals and lay people about diseases and disease prevention through lifestyle modification. We know that since 1930 we've made little progress in the treatment of cancers--adult cancers, not children's cancers--despite a number of things you may have heard.

I translate scientific information into a language that is understandable by most people. Treating thousands of patients and speaking with tens of thousands of people, I'm convinced that when people are given accurate information, they can comprehend it and make good decisions accordingly. We all have a right to this accurate

information. Since food supplement products are already in the marketplace, people should be given accurate information so that they can choose wisely as to which products they should have.

People make choices all the time but armed with accurate information, they can make informed choices.

The FDA really can't continue to be paternalistic about these issues. They must change their mind-set and allow people to trust and make the right decisions once they have information. Disclosure over suppression of information allows people to become better educated. The FDA can no longer suppress information that is truthful, nonmisleading and substantiated. The FDA cannot mislead people by restricting information or being arbitrary and capricious in defining terms.

I learned that people realize that their lifestyle is a major factor for their good health. People generally modify their lifestyle and incorporate proper food supplements as an overall strategy for good health. I have found that people do not rely on the food supplement solely and with accurate information, instances of harm can decrease.

I'm also convinced that once people have information that is truthful, nonmisleading and substantiated, they will integrate this information by

modifying their lifestyles accordingly and properly choosing products that fit their needs. The American public deserves this information and the American public is guaranteed this information by the Constitution.

I would also point out that our mission as physicians is to provide information to people--informed consent. I've written extensively about that. In fact, the American Urological Association has told people in their journals and in their throw-away papers that Saw Palmetto, for instance, is as effective as prescription medications. We must, as physicians, inform people. We must provide information. There's enough information to give good information to people, accurate, nonmisleading information. So we need to change all of our mindsets and provide people with information.

We have not made tremendous strides in the treatment of cancer since 1930 for adults. We need to do something else. We need to look at other avenues, other issues, and help people get information to help prevent these problems. Thank you.

MR. LEVITT: Thank you very much.

I'm just checking with our staff to be sure there are no other registered speakers that are here.

Okay, with that, that will bring our meeting to a close. I want to thank all of the staff that worked to put

on this meeting. These things don't happen magically. People work hard and put those together and I thank all of you, as well as the--is there anybody here from this building?--for letting us use the facility here for this purpose.

I thank the panelists from the FDA and all the speakers and the audience that maintained wonderful decorum through a day with a lot of strong views being expressed.

VOICE: Could you explain when and how the transcripts will be made available?

MR. LEVITT: The question is if I could explain when and how the transcripts of this meeting will be made available.

The general process is it takes usually a couple of weeks and then we put it up on our website. Is that right? Do we have an exact date for that? No. But I would say usually two to three weeks--within three weeks is what's a safe bet.

Okay, again I thank everybody here. This concludes our meeting.

[Whereupon, at 5:26 p.m. the meeting was adjourned.]

CERTIFICATE

I, **SUSAN A. HARRIS,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

Susan A. Harris

SUSAN A. HARRIS