DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of:

INTERAGENCY COMMITTEE ON SMOKING AND HEALTH

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P R O C E E D I N G S (9:05 a.m.)

DR. SATCHER: I'm David Satcher, Surgeon General and Assistant Secretary for Health. First, I want to welcome all of you to this agency Committee on Smoking and Health, a committee that actually has not met since 1994. A lot of things have happened in that interim.

But before I take a few minutes to discuss some of the developments since 1994, I do want to begin by going around the table and around the room and making sure that we know who is here.

Why don't we start with Jeff?

DR. KOPLAN: Jeff Koplan, Director of CDC in Atlanta.

MS. MAJESTIC: Elizabeth Majestic, Acting Director, Office on Smoking and Health in CDC.

DR. NOVOTNY: Tom Novotny, Assistant Secretary for International Refugee Health.

DR. EISS: Robert Eiss. I am Program and Planning Director at the Fogarty International Center for the National Institutes of Health.

MS. SUTTER: Kate Sutter. I am with OSHA Policy. OSHA has been charged with leading the effort for the Department of Labor.

DR. BACKINGER: I'm Cathy Backinger with Tobacco

Control Research Branch at the National Cancer Institute.

MS. SCHMIDT: I'm Christy Schmidt, Deputy to the Assistant Secretary of Health Policy in the Office of Planning and Evaluation in HHS.

MS. ROSSO: I'm Rosemary Rosso, and I am a senior at the Division of Advertising Practices at the Federal Trade Commission.

DR. GUST: I'm Steve Gust from the Office of the Director at the National Institute of Drug Abuse.

DR. CAPEHART: Tom Capehart from the Department of Agriculture Economic Research Service, an economist.

DR. HAVERKOSS: Lynne Haverkoss at the Child Development and Behavior Branch of the National Institute on Child Health and Human Development.

MS. WILLIAMS: I'm Chris Williams. I am the Director of the Office of Health Care Information at the Agency for Health Care Research and Quality.

DR. KAUFMAN: I'm Peter Kaufman, leader of the Behavioral Medicine Research Group, National Heart Lung and Blood Institute.

MS. DESHPANDE: Connie Deshpande, U.S. Department of Education, Safe and Drug Free Schools Program.

DR. WALTON: I'm Tracy Walton, Medical Director of the medical radiography program at the University of the District of Columbia.

MR. FORBES: I'm Ripley Forbes, Senior Advisor to Dr. Satcher.

MS. BAILEY: I'm Linda Bailey, Associate Director, Office on Smoking and Health.

(The remainder of the introductions were off mike.)

DR. SATCHER: Thank you very much. Once again, welcome to all of you. It is great to have this group together to have this very important discussion of where we are in terms of tobacco control and smoking.

I'm going to move to the podium. This is a little longer opening statement than usual, but I think it reflects the tremendous developments that have taken place since this agency committee last met in 1994.

This agency committee was established in 1984 under the authority of Public Law 98474, the Comprehensive Smoking Education Act. The committee is charged with helping to coordinate our Department of Health and Human Services and other federal research educational programs and other activities related to smoking and health.

This interagency committee provides a liaison function to appropriate private organizations and federal, state and local public health agencies regarding smoking and health activities. If you didn't already, I hope you have an opportunity to review the developments in this area since

1990. They have been outlined in a five or six page summary in the book. I believe it is under Tab E. But it really dramatizes how this working together under federal, state, local and the private sector and even the global sector has evolved.

This committee reports to the HHS Secretary through the Surgeon General, and is staffed by the CDC's Office of Smoking and Health. You will hear from Dr. Koplan in a short while.

Though we haven't met formally since 1994, the tobacco control field has certainly been busy in those past six years. In fact, while I won't go into great detail about our efforts and successes, I would like to mention just a few.

In this period of time since the last meeting of this interagency committee, we have released three Surgeon General's reports on smoking and health. In 1994, the report on preventing tobacco use among young people, and then when I came on board in 1998, we released a report entitled Tobacco Use Among U.S. Racial Ethnic Minority Groups, and most recently, Reducing Tobacco Use, a report that we released at the World Conference on Tobacco and Health in Chicago, I believe it was in July, in that meeting.

Early next year, a fourth report will be issued

which addresses the adverse health effects of tobacco for women. I think this will be the first report dealing with tobacco and women since 1980. We are very excited about that. That report is moving through the Department, beginning to move through as we speak.

CDC has done an outstanding job in all of these reports, and it has been really great working with that group while I was director there, and since I have been here in Washington.

CDC provides over $60 million in financial support and technical assistance for all 50 state health departments, the District of Columbia, seven territories, 11 national organizations, six tribal support centers and nine national networks. Since 1994, the budget for the CDC Office of Smoking and Health has grown fivefold. In 2001 we estimate that the budget for CDC's tobacco control program will exceed $100 million.

In 1996, the Agency for Health Care Policy and Research, which has had a name change and is now the Agency for Health Care Research and Quality, released smoking cessation guidelines. A few months ago we updated those guidelines, and we just updated the guidelines for smoking cessation.

This January with the release of Healthy People 2010, I think we took a major step forward. This is as you

know our national health promotion and disease prevention program which goes back to 1980. But in the release of the Healthy People 2010 document and the blueprint for action, there was a new development. For the first time, we actually listed the 10 leading health indicators that we would monitor over the next 10 years.

Now, when you get to the point where you have 300 and something objectives as we did for Healthy People 2000, it becomes increasingly difficult to communicate them. And of course, with Healthy People 2010 we have 467 objectives. I have come to understand that that is good, because it means we have more resources, more people with more interest from a lot of different areas that we didn't have before -- new focus areas, visual and hearing disorders, chronic renal disease, disability, things like that.

But we still are concerned. How do you really get a focused message to the American people about what this is all about? So working with the Institute of Medicine, we developed a list of 10 leading health indicators. Tobacco, reducing tobacco use, is one of our 10 leading health indicators for Healthy People 2010.

We have established the ambitious but I think very realistic goal of reducing tobacco consumption by 50 percent over the next 10 years. I think it is realistic, because given what we know, and given the guidelines that have been

developed and the best practices that have been published, we have the means to do this, given the tobacco settlements, which I will mention later. We believe the goal is achievable, especially because of the master settlement agreement.

The master settlement agreement between the states and the tobacco industry will over the next 25 years allocate over $200 billion in payments to states. All states, if they take advantage of this opportunity will have sufficient funds to support comprehensive tobacco control programs, programs that can certainly be modelled after the best practices document published by CDC earlier last year. But how these funds are used may represent the most important public health opportunity that we have had in a long time.

The Robert Wood Johnson Foundation launched the smokeless states grants programs to fund local initiatives for tobacco use prevention. With critical support from RWJ and the American Cancer Society, the Center for Tobacco Free Kids was started and gave a voice to tobacco control in Washington and in the states.

Our Department released a final rule on the Synar Amendment, which encouraged states to enforce laws prohibiting tobacco sale to minors. Today, all states are conducting compliance inspection to measure the level of

compliance with laws prohibiting tobacco sales to underage youth. Based on these inspections, illegal sales of tobacco to youth is definitely falling in this country. We have seen increases in federal and state excise taxes and many states are using increased excise taxes to deter smoking. There are some really great examples, which we talked about in a recent hearing with Senator McCain and Congress.

The President has issued an executive order banning smoking in federal worksites. As you know, the Department of Justice has initiated actions against the tobacco industry. This legal action is designed to hold the industry accountable for the harm they cause by efforts to deceive the American public about the dangers of tobacco. This is moving forward. We are hoping of course that in the budget that is coming out from Congress hopefully any hour now, it will include funds to support the action on the part of the Department of Justice.

In the international area, the President has instructed U.S. embassy staff to end support of tobacco industry efforts to promote the sale of tobacco products, and instead to encourage host countries to adopt science-based public health control of tobacco. This is a major step forward. Additionally, the President has encouraged the U.S. to take a leadership role in the World Health Organization's development of a Framework Convention on

tobacco control. We will hear from Tom Novotny a little later about the recent meeting in Geneva related to the Framework Convention.

Unfortunately, we have also had our setbacks. I think most recently the Supreme Court ruled that the FDA does not have regulatory authority over tobacco. That was certainly a major setback. This action has made it even more important that states fund comprehensive tobacco control programs, and certainly, more important and critical, that Congress approve legislation granting FDA the authority to protect children from tobacco.

As I'm sure you understand, that was the major point that the Supreme Court was making, but as it now stands the FDA has not been given that authority by Congress. So we are really focusing on getting Congress to give FDA that authority to regulate tobacco as a drug. On balance, I think it is fair to say that the news is good.

This morning we are going to devote our meeting to a discussion of one of the most exciting developments in tobacco control, the creation of a Framework Convention by the World Health Organization.

In May of 1999, the governing body of the World Health Organization unanimously approved the resolution calling for governments to negotiate an international treaty to stem the global epidemic of tobacco related death and

disease. In case you haven't been watching, you'll hear more about this later. It is certainly a growing epidemic.

U.S. and many other governments around the world are committed to the development of a strong convention that will have the ultimate effect of reducing the consumption of tobacco. Last week, as I mentioned, in the first meeting of the Framework Convention on tobacco control, the negotiating group concluded its work in Geneva, and several members of that U.S. delegation are with us today, which we will hear from Tom.

A Framework Convention can be a very important step in tobacco control, globally as well as in individual countries. Many problems related to tobacco cannot be resolved by nations working alone. Just as everybody now agrees that we live in a global community when you look at it from the standpoint of things like infectious diseases, it is just as clear when you look at it from the standpoint of things like environmental issues, violence and certainly tobacco.

Many problems related to tobacco just will not be resolved unless we take a global approach. I was very impressed by that when I was with the Public Health Association recently, at a meeting in China, in our discussion of tobacco, but also meeting with the Minister of Health in China and looking at the way the problem is

evolving in that country, but also hearing from other ministers of health.

We will spend a large part of this meeting talking about the importance of tobacco control to global health, and the specific role that participation in the Framework Convention can play. In addition, we will focus on three specific topics that are being discussed in the context of the framework convention. They include smuggling, health warning labels and advertising.

These are three issues that have no borders, and issues on which we need to work in collaboration with the global community. Let me emphasize that the Surgeon General and the U.S. government are committed to a really strong global treaty to curb premature deaths and preventable illness due to tobacco. That doesn't mean that we have solved all of our problems, that we don't have some struggles that still go on, but I think the commitment is real, and it continues to evolve in the right direction.

To be successful, a public health treaty must first curtail the rise in tobacco consumption internationally, and ultimately lead to a reduction in tobacco use around the world. But as you know, that curve as we see it now is going up, up, up in terms of tobacco use and deaths from tobacco. We have got to curtail that rise and reverse that trend.

At a minimum, we must seek ways to protect non-smokers from secondhand smoke, insure that illegal cigarette smoking is stopped, and prevent children from smoking.

At this point, I would ask if there are any concerns about the agenda, any additions, any concerns about anything on the agenda.

Now, I understand we have several members joining us by conference call? They didn't make it on? Okay, so we don't have.

We have a full agenda, so I am going to now turn the floor over to the Director of the CDC, Jeffrey Koplan. I don't need to introduce him to this audience, one of the great outstanding leaders in public health in this country and the world. Jeff will describe the magnitude of the global health problem created by tobacco in relation to infectious diseases and changes in the epidemic pattern as it moves into developing countries, and CDC's efforts in global tobacco control.

Jeff?

DR. KOPLAN: Thanks, Dr. Satcher. Good morning, everybody. As you have heard from Dr. Satcher, since the last time this group met, there have been significant changes both in this country and around the world regarding tobacco control, and indeed society's views toward tobacco, and the shift in emphasis around the world as to disease

burden and economic burdens are related to tobacco use.

While there have not been major declines over about the last eight years in this country among smoking in adults, it appears that smoking prevalence among youth in this country has peaked and could even be beginning to decline.

I think one thing, to summarize many of the points that Dr. Satcher made, we have learned over the last many years that a comprehensive approach to tobacco control is necessary to reduce tobacco use. That includes educational, clinical, regulatory, economic, environmental and social strategies.

This is an important issue to underline as we look at a more global issue of tobacco control. Although there are obvious cultural and economic and social and political, widespread differences between our country and particularly developing countries in the world, this multifactorial comprehensive approach is highly likely to be the one that is going to succeed in any country, whatever their economic, social and political situation.

In the past 10 years in the U.S., there have been some significant changes in individual states in this country. I just wanted to emphasize this, because there tends to be a view among some decision makers and some elected officials that we can't do much anymore about

tobacco, and that investment in tobacco control doesn't have a big payoff.

That is profoundly not true. If we look at a few states in this country, when we see the ones that have both invested more in tobacco control and then put in place more comprehensive programs, we see significant difference in those states.

In California, the per-pack excise tax on cigarettes was increased from 10 cents to 35 cents in January, 1989. It was used to fund a new tobacco control program. With only a slight change in the state excise tax between 1990 and 1998, a two-cent increase in 1994, the rates of tobacco use have continued to decline two to three times faster than the rest of the country.

Over the past 10 years, per capita consumption in California has declined by more than half. While the tax increase has had an initial major impact on consumption, the comprehensive program has insured more sustained and significant decline over time.

Massachusetts has also taken a leadership role in implementing comprehensive statewide tobacco control programs. It has substantially reduced tobacco use. The rates of smoking for both youth and adults have shown significant declines. Per capita consumption in Massachusetts has declined over 30 percent since 1992 when

the program started.

Oregon is another state that has had impressive declines. Between '96 and '98, per capita cigarette consumption declined 11 percent, or about 10 packs per capita. Florida has had a statewide anti-tobacco program that combines a counter-marketing media campaign, community based activities, education and training and an enforcement program, and it has been particularly effective in reducing teen tobacco use.

Tobacco use in Florida among middle school students declined from 18.5 percent in 1998 to 11.1 percent in the year 2000, an overall 40 percent reduction. For high school students, current cigarette use declined from 27.4 percent in '98 to 22.6 percent in 2000, overall reduction of 18 percent.

These successful programs should serve as a model for other states as they allocate the sums they have gained in the tobacco settlement. We hope that they will look at those models and apply them accordingly.

Many of the gains, as Dr. Satcher said, that we have made in the last decade in this country and beyond have been the result of collaborations among many of the government agencies assembled here. It is definitely a multifactorial program, and many of the non-governmental organizations that have played such a leadership role in

this country -- and it is always dangerous to mention any, but in that Dr. Satcher already mentioned a couple, I'll at least repeat those. Robert Wood Johnson Foundation has played a significant role. The Center for Tobacco Free Kids has played a major role, and certainly the large organizations, the American Cancer Society, American Lung, American Heart, have all played major roles.

These are lessons learned that we can now apply on a more global front. As Dr. Satcher said, on the global front, we tend to think of global threats. The international health community is largely focused on infectious diseases, and indeed, there are major issues in infectious diseases.

To use the other term of communicable diseases, I think we need to think about tobacco use as a communicable disease. We certainly communicate its use and desirability; we can also communicate the value of not using it and the powerful health effects that unfold from its use.

The global tobacco epidemic is in full force, and will only get worse, particularly affecting developing countries over the decades to come. At present, there are about 1.2 billion smokers over the age of 15 in the world, and approximately 80 percent of these smokers live in developing countries.

According to WHO in studies done by Richard Pedo,

more than four million people in the world die each year from diseases caused by tobacco use. Without effect comprehensive tobacco prevention and control efforts, by the year 2030, 30 years from now, this death toll will increase to as many as 10 million people per year. Seven million of these deaths will occur in the developing world.

It is estimated that by 2030, tobacco use will exceed HIV/AIDS and diarrheal diseases as the leading cause of disability adjusted life years, a mechanism for combining morbidity and mortality measurement, as the leading cause of this measure of global health.

Not only will health effects be devastating and unprecedented, but unfettered global tobacco use will result in dire economic circumstances and will be a threat to sustainable development in many of these countries, a point recently well made by the World Bank in their book, Curbing the Epidemic.

Now is the time for the global health community to increase its efforts and targets its efforts in the area of tobacco control. It is the right time to launch a global and coordinated effort to reduce the burden of tobacco use around the world.

We have a number of current activities that are underway. I'm going to mention a few. They largely revolve around three key areas, one surveillance, one information

management, and one capacity building. I'll briefly mention some progress in each of those three.

A cornerstone to public health control activities is successful disease surveillance and risk factor surveillance. This is nowhere more true than for tobacco control. Some of the major advances in societal influence we have been able to have in this country has been due to our data on children, and valid or reliable data is crucial in making progress in this area.

CDC was asked by WHO to support their global surveillance efforts, particularly in relation to a grant they received from the UN Foundation, which initially funded seven countries in approving tobacco surveillance. In response to that, we modified our own youth tobacco survey done in this country, and created a global youth tobacco survey. It is school based and tobacco specific, and it focuses on adolescents age 13 to 15.

In this coming year, this youth tobacco survey will have been conducted in more than 70 countries. This is an extraordinary increase in popularity for this, and seen as useful by the countries involved.

I'd like to recognize in particular the National Cancer Institute's financial support of this survey as a good example of the type of interagency cooperation and collaboration that I think will be necessary to continue to

address the problem of tobacco use globally.

In December, we're having a workshop for the countries that participated in this survey, to focus on the analysis of the information, the reporting of it, its dissemination, and then how you use information to affect public health programs. It will be a four-day meeting in San Francisco. There, experts will discuss a wide range of issues, including knowledge and attitudes, school based programs, counter marketing, enforcement, environmental tobacco smoke, and cessation. The participants will be trained in how to do the analysis of this complex survey, and report the data, and then disseminate it to their communities that need to know it in their own countries.

CDC has also provided technical assistance to WHO to develop a new survey for health professionals, collecting the information on knowledge and behavior. The design of the instrument was tested in the fall of '99, and a pilot study is currently underway to test the instruments further with sampling procedures in Bahrain, Oman, Kuwait, Korea, Lebanon and Cambodia. Our next step is to finalize this and then use it in many more countries, again with the purpose of converting the social norms in these countries in the way tobacco gets used.

You all remember -- some of you are too young to remember, but the first professional group, and a major one

that influenced the movement away from tobacco use in this country, was to switch physicians. It is a very difficult task to convince someone that a given health behavior is bad for their health or good for their health if their health practitioner doesn't practice it. This is a battle we have to fight under some other different committees. Dr. Satcher is leading this effort regarding both weight control and physical activity. But that is a model that tobacco has provided us.

The second key area is global use information management. Beyond surveillance, we know the data that is collected is only of limited value if it is not used and widely made available. In that regard, we are developing a global tobacco data warehouse, Web based, parallel to our domestic program called the STATE system.

It is going to make every country's tobacco specific data available on the Internet. It will not only include public health measures and prevalence information and youth tobacco survey results, but will also include information on national tobacco control laws, tax rates and other economic data. So countries can find information about themselves, and also compare themselves with neighbors and other places that may be doing better or worse, or have parallel problems to those that they face.

Then finally, capacity building. We never will

have, nor should have, the resources to provide full capability for all these countries that we are working in, but we feel the role we can play, both we at CDC, and I think the Public Health Service in general and the broader public health community, can play a role in assisting other countries in building their capacity to deal with this global health threat.

Currently, we are supporting a person to work exclusively on global tobacco control in the UN system stationed in New York, the WHO headquarters in Geneva and in the WHO regional office in Zimbabwe. Soon we will be sending a person to the WHO country office in Beijing, and we hope eventually to be able to place a tobacco control person in partnership with WHO in all of their regions.

So a wide range of activities are taking place today, this year, quite different from the last time this committee met in a meeting. We think a lot more will be going on in years to come. But as Dr. Satcher said, we view the global tobacco threat as a global transmissible illness that it behooves us for a wide variety of reasons to get involved in, and we are.

Thank you.

DR. SATCHER: Can I have you stay there, Jeff, for a moment?

DR. KOPLAN: Sure.

DR. SATCHER: We have a little time for questions and comments, but why don't we get the phone participants now? They include Nancy Kaufman and Nathanial Cobb. We'll have them mention them themselves.

(Recording interrupted.)

DR. SATCHER: Why don't we go on? Questions, comments? I want to make just one comment. Jeff's point about the role of physicians in this country really came home to me. As most of you know, when the first Surgeon General's report on smoking and health came out in this country in 1964, about 43 percent of the American people were smokers, and smoking among physicians was even higher.

Today, I think it is less than five percent of physicians smoke. So physicians have really provided leadership in terms of role models. We have not done as much as we could have done to help other people quit smoking, but we have certainly been good role models in that sense.

In China on the other hand, I remember having a meeting with the Minister of Health and his staff, that has not happened. I believe today, what, 58 percent of physicians in China are smokers. It is one of the biggest hurdles they are trying to get over. It really makes a big difference, and it makes you appreciate what is happening in this country.

Randy Smoke was with us. He is president of the AMA. He couldn't be here today, but he was with us in China. The AMA is going to be working with the China Medical Association on this issue of the role of physicians. So that point is a very good one.

DR. KOPLAN: Eight years ago, I visited Szechuan Medical College in China, and they presented information on the way the medical education curriculum went. They provided some smoking data. This was a five-year medical school, and students enter at about the age of 18, graduate at the age of 23. On entry, about 15 percent of the medical students who entered smoked, and on graduation about 75 percent of the medical students smoked.

So they asked me what I thought, and I said they should close the medical school.

DR. SATCHER: Other comments or questions? We'll move on. We will have other opportunities to interact.

Our next speaker is Dr. Novotny. Tom Novotny is Deputy Assistant Secretary for International Refugee Health. He is also Assistant Surgeon General and the leader of the U.S. delegation to the Framework Convention. Dr. Novotny is a member of the World Health Organization Executive Board, and a nationally recognized researcher on tobacco control.

As you will notice, he has some bronchitis. I have to take this opportunity to tell you that five of us --

probably more than five, but five that I know of in the division ran the Marine Corps marathon on Sunday. Tom had just gotten back from Geneva at 11:00 the night before, he was jet lagged, but he still ran. His voice sounds like it.

DR. NOVOTNY: It's not a smoker's cough.

DR. SATCHER: And he's not a smoker, that's right.

DR. NOVOTNY: I was exposed to a lot of secondhand smoke. Also, I only came in about an hour behind Dr. Satcher.

Thanks for the opportunity to come and present the background on the Framework Convention. I have to say, my voice was gone during the week in Geneva, too, so I didn't have a chance to give any of the interventions. That was greeted with relief in many quarters, but also it was the only time that the U.S. gets any sympathy in these international fora. So it was probably not a bad outcome.

The background on the Framework Convention I think is important for many of you to just briefly understand, because it is an unusual activity. This is not just a public health program, this is not an opportunity for public health people to get up and say, we think everything about tobacco is bad, and here are the things we can do to do it. It requires a far more complicated and more dedicated approach on the part of government in general, because this is a treaty process.

It is called the Framework Convention on Tobacco Control, but this is a treaty process that permitted to be engaged and negotiated by the World Health Organization under its bylaws. This is the first time that they have taken anything on like this. So by its nature, it is different from what we usually do in public health, which is a much more organized effort that involves only ourselves.

In this case, it involves first our State Department, because the State Department and ministries of foreign affairs of all of the member state -- and there are 191 member states of WHO -- usually have the responsibility to negotiate treaties. In this case, the State Department has graciously delegated that responsibility to HHS. That is why HHS leads the delegation to the Framework Convention, and we insist and expect to have health as the primary basis for this. As you know, there are many, many other components in negotiating something, a multilateral action on tobacco control.

What we have done in terms of our preparation has been very complex as well. It is actually guided by the Domestic Policy Council, from the White House, which gives this a much more broad involvement of our domestic agencies. Those have included the Department of Treasury, the U.S. Trade Representative. I understand Customs has not been in on this directly, but we are certainly interested in that.

The Bureau of Alcohol, Tobacco and Firearms, the State Department, several parts of HHS, CDC. FDA was involved for a large part of our activities, and Commerce, several other agencies.

This is important, because this is again a government activity. Our Administration, if it comes down to the point where we can sign this, -- and by the way, the projected time for the negotiation process is to be completed in 2003 -- if our Administration signs it, we have another part of this activity that has to occur, and that is ratification by the Senate.

The Senate is responsible for advice and consent, and within the Senate Foreign Relations Committee, the power to bring this treaty forward extends itself. I'll say more about that in a moment. But let me also say that our preparations have tried to be very, very complete and oriented towards both a public kind of involvement as well as, we have also broached this issue with the Congress. On four separate occasions, I think five now, we have met with representatives of Congress on the health issues as well as the Senate Foreign Relations Committee, who has taken a very great interest in this already.

As a result of that, one of the staff members from Senator Helms joined us during the negotiating sessions last week. I think this is good, because they need to know what

this is about, and I think it actually was a very positive outcome.

We have also had public commentary through a session that was held March 15. It is easy for me to remember, because that is the Ides of March. It was well attended by not only the NGOs -- non-government organizations, professional groups -- but also the tobacco industry presented their opinions.

WHO subsequently had one of these public commentary sessions prior to the negotiating session last week. That was also heavily attended and also a good opportunity for people to express themselves.

We have also at their invitation met with representatives of the tobacco industry and growers. They are of course interested in this, but at this point they are not a part of our delegation or thinking process in a direct way. But we certainly have heard some of their input.

The background to the World Health Organization's activities on this began actually a year and a half ago at the World Health Assembly, which is the governing body of the member states, where the decision was made to go forward with this Framework Convention. Through the efforts of their staff, the people led by Derek Yak, Neil Kolishaw, others within the WHO, this process has moved forward, and two working group meeting were held over the last year,

where issues were laid down for further discussion and actual negotiation.

So last week was the first real negotiating session, where the member states sit down and try to outline their positions, and from there go on to deciding what the content of the Framework Convention is.

It is really a two-part process. The Framework Convention itself is meant to be more of a broad document that can be signed by, we hope, many states. We have supported the ability for that document to be sufficiently general, so that many states can sign on to it. But then subsequently, protocols, which are more substantive and more detailed agreements that can be generated, would flow from the initial agreement reached in the Framework Convention.

Now, our discussions back here have been extensive. We have met weekly for practically a year and a half with the DPC group plus all these other consultations that I have mentioned to you. We have also heard from the NGOs. We have tried to take this information into our positions from all sides, actually, to shape the positions that have been generated.

What we have been able to do is get negotiating positions that have been signed off by all of the relevant departments. We now have a set of positions on issues that have been cleared through all of the departments. This is

no mean feat, and we really appreciate the involvement of people like the Treasury Department and the U.S. Trade Representative, because the reality of what we can do and what we can agree to is bound not just in HHS but certainly across government.

I'll briefly talk now a little bit about the organizational approach that WHO has taken on this, and our member states. It would have been easy to let the negotiating session fall into a procedural gobbledegook. Fortunately, that didn't happen. I think a couple of days were spent trying to decide on the procedural approach, and that was settled.

We lobbied hard to get ourselves on the bureau, which is basically the small management group that would help conduct the negotiations. So our representative is Ripley Forbes on the bureau, representing the group of the Americas. There are six regions of the WHO, so our region in the Americas, we are the representative on the bureau.

However, probably the more important position is that of the chairman of this whole process. It will go on, we hope, through the whole three years. His name is Celzo Amelin. He is a Brazilian, an ambassador to Geneva from the Brazilian government, and he provided a very steady hand in these negotiations, again keeping it from getting out of control, bringing humor to it, bringing a sense of

collegiality that I think was really appreciated by everyone.

We supported his selection. It was done by consensus. He is by the way a smoker. His leadership on this I think was appreciated by all.

The other big procedural issue that was considered was the more direct involvement of the non-governmental organizations. WHO has a bunch of rules about this. They have a set of official WHO affiliated NGOs. We supported maintaining the rules on this, so that that wouldn't be changed. It would take much more to settle on all of those rules and agreements than it would be to just allow things to proceed as they are as long as the NGOs were getting the input that they needed into this.

There is a coalition of NGOs, led by the Campaign for Tobacco Free Kids, called the Alliance. They have fairly strong opinions on this as well. We made an attempt, a successful attempt, I hope, to meet with the NGOs and anybody else who wanted to meet with their delegation every evening, to discuss what was the activities there. The NGOs gained access to the meetings through the larger groups like the International Union for Cancer Control and International Heart Association and Rural Division International. So there were many opportunities for them to become directly involved. They were certainly there in force, and we

appreciated that.

The delegation itself consisted of me as the lead delegate, Ripley Forbes from HHS, Michael -- not Michael Ericson, he was on it previously, but now it is Larry Green, and from the State Department, John Sanditch and Lynn Lambert, and from ATF, Tammy Light, who will be talking to you a little bit later. We also had a USDA person who is the attache in Geneva, and our attache there, Linda Vogel. I think that's it.

The other procedural thing I'll just mention briefly is that for the next session there are going to be three working groups. The next session will not occur until April 30 of next year. In the meantime, there will be other work to do. But the three working groups have been separated out so that we can detail our attention to specific issues, and those are grossly lumped as health issues, and then our economic issues, another lump takes place, then the third working group is a treaty making process. I won't go into the details on that; if I need to, I can answer some questions on it.

We came out with very strong statements about how the U.S. supports the Framework Convention. Dr. Satcher has made those statements. We actually issued a press release prior to going, that cited his comments, as well as other supportive comments to say that we are there to make this

treaty happen. A treaty that is broad enough to include a lot of countries will be a strong treaty. At the same time, we felt that including significant strong points in the treaty were important.

So the reference documents that have been developed by WHO were used as the basis for the discussions that then occurred during the meeting. These were basically a read-through. Each of the nations had a chance to say where they were on issues that were read through.

We supported some specific obligations within the Framework Convention itself. These included restricting sales to minors, reducing exposure to secondhand smoke, regulation of tobacco products, contents and disclosures, tobacco taxes. We offered additional language on secondhand smoke that would support prevention of exposure to children in particular, and public places in general, and that was a rather strong statement. We hope that it is something that we can support throughout; perhaps it will be moved to a protocol.

We also made a strong intervention on advertising. Even though we are going to have to stop short of supporting a complete and total ban on all advertising promotion and sponsorship, because the First Amendment guarantees free speech, we think would stop that complete ban language, we can and did support robust language on restricting

advertising, sponsorship and promotion permitted under domestic law, with special attention to that which appeals to children, not that which is targeted to children, but that which appeals to children, which is an important distinction, because it is a much broader concept.

We also supported an intervention on the elimination of smuggling, although we think that should go into a protocol, because you can really get down to some very significant detail, and Tammy will speak to that.

A few other things that we supported was a broad share in the scientific, technical and information throughout. That is a cross-border issue as well. We suggested however that support for this multinational stuff would be reliant on voluntary funding, that which Jeff Koplan has described. It showed the significant support that HHS has supplied now on a global level. I have to say this is much different from 10 years ago, when I was working in the office on smoking and health.

It is voluntary funding. That is not something that is required by WHO or any other outside body. In fact, we would be reluctant, and not support any outside regulatory agency or extra temporal body that regulates either the financing or the control of any sort of legal approaches that might be taken.

The key issue here is that whatever is agreed by

the states is reliant on domestic law, whether it is existing or whether it is something we want to go for. As you have heard, our FDA was thwarted in the attempt to exercise complete regulatory authority. That doesn't mean we can't go forward with that if there is a legislative effort to try to increase that regulatory authority.

The same with liability and compensation. One of the more successful control activities in this country has been losses, whether it was due to the exposure that has occurred as a result of the discovery process, but also now, with the state settlement master agreement, there has been funding available.

The litigation issue was brought up and discussed briefly, but what we support there is again domestic court actions, those lawsuits that have been brought in this country. Several of them have already been turned away as not being appropriate for our domestic legal system. Maybe we can get another comment from the Justice Department on that if we have time.

Finally, the whole treaty process requires that states somehow figure out what happens when people don't behave with respect to the treaty. Our position on this is that we do support reporting requirements on the activities that are agreed to. We don't think that there is a compulsory dispute resolution process or arbitration or

litigation, but rather, a diplomatic solution to disagreements that are based on the treaty.

One thing I'll just mention here, and I'll stop. I can go into more detail on the positions that we have taken. We cannot tell you everything about our negotiating positions that we haven't already said in public, because that is part of this treaty process; it is privileged information. But I can go into some more detail, if you are interested, on many of these points.

One of the things that came up that we didn't really get into, and we don't have as clear a position yet, is agriculture, and what can be done about removing either subsidies or dealing with the economic impact on farmers. Perhaps Frank will address some of this in his talk on the economic impact on the country of tobacco growing, and perhaps the reduction of tobacco consumption. But that will develop.

We have several meetings coming up now with a Presidentially appointed committee, who will deal specifically with agricultural impact here in this country on reduced tobacco consumption.

We did have an informal meeting where we invited many countries like Malawe, Zimbabwe, Brazil together, just to start talking about this. No negotiations, just what are the issues. So that I think is going to be important.

The future on this right now is that, as I mentioned, the next negotiating session will be in April. We will have an opportunity for now more public commentary. We plan to take this, a very brief presentation, to hear public commentary on the West Coast and North Carolina as a starter, perhaps in the Midwest as well. We invite the involvement of the growers and farmers and industry in those public commentary sessions, and just about any other time, we will talk to anybody who is interested in this thing on behalf of the domestic policy council group. That is where any negotiating positions will be modified or changed.

I think I'll stop there. Oh, the last thing is, the output of this last session will be a chairman's report which will outline all of the various nations' interests and activities that they presented. We will have that to work with in our further discussions, where we might want to come out. But at this point, we actually are in pretty good shape with already agreed-on negotiating positions. We are lacking on positions of sales of duty-free products, agriculture, we've still got some more work to do on trade, I think. Other than that, I think we are in pretty good shape in terms of the settled U.S. government position.

So I'll stop there. I ran a little bit over, sorry.

DR. SATCHER: Thank you very much. I think we can

allow about 10 minutes for questions. This is such an important presentation, to make sure that we are all together in terms of where we are headed, in terms of our position relative to the Framework Convention. Comments, questions? And I'm not going to limit it to people around the table; they seem to be pretty quiet today. Are there people beyond the table who have questions or comments?

DR. CHALOUPKA: I'll make one comment in response to something that you brought up about the agricultural issue. That is not actually something I'm going to talk about in my presentation; I was going to focus more on advertising issues. But I think the one thing that is important to keep in mind in all this is that right now, we are talking about 1.2 billion smokers in the world, and in 25, 30 years that is going to go up to 1.6 billion if we don't do anything. So even if we are successful, we are not talking about putting current tobacco farmers out of business. We are talking about maybe reducing their grandchildren smoking tobacco 50 or 60 or more years down the line.

So it is important to keep that in mind. It is important to keep in mind how farmers are going to be affected by these tobacco control policies that we are talking about, that we are not talking about putting tobacco farmers out of business in the short run.

DR. NOVOTNY: I think that is an extremely important point. The other point is that we have official policy already that says we are going to look out for the welfare of farmers in this country in some way, shape or form. Here in this country we probably will reduce consumption. Maryland for instance, permits the state government to buy out farmers' -- not buy them out, but give them a reimbursement for lost income over a period of five years, I think it is, $20,000 a year or something like that. So that is good, but I think your point is absolutely right, given the projection of consumption. It is very unlikely that agriculture is going to go away any time in this next century.

DR. SATCHER: When you ask a question, we are going to ask you to say your name just for the record. That was Frank Chaloupka who asked that question. Thank you.

Could I just continue a little bit on the broader economic issue, which I think has gotten to be a major challenge. You think about countries like China and Japan and Zimbabwe and Malawe, and the economic impact of tobacco. I think in China, is it 10 percent of the revenue to support the government comes from tobacco. In Japan, I understand that 80 percent of tobacco is actually owned by members of -- not the ministers of finance, but the Ministry of Finance, 80 percent of tobacco.

DR. NOVOTNY: It is more or less a monopoly.

DR. SATCHER: I don't know the figures in Zimbabwe and Malawe, but I know it is a major issue.

DR. NOVOTNY: Yes, some countries have far more investment in tobacco, either agriculture -- but in the case of China, they are the largest consumer and the largest producer, and the taxes and the revenue all come back to the Chinese government. Their delegation was led by their state planning council, and the tobacco monopoly within the government was part of the delegation as well. So they are obviously concerned about what they can sign on to, to the economic agreements.

MS. RODDY: I was wondering where the groundswell of support for FDA legislation is right now.

DR. NOVOTNY: I'm not sure I can answer that. Is there anybody here who would like to? From the NGO community or any others?

PARTICIPANT: I was just going to say, it certainly comes from the NGO community, the Campaign for Tobacco Free Kids, Heart Lung, Cancer, American Medical Association, physicians' groups.

DR. SATCHER: How is it going, Judy?

PARTICIPANT: Slowly. I think at this point we are all waiting for an event a couple of weeks from now.

DR. NOVOTNY: I think that within the

Administration there was tremendous support for the regulatory approach proposed by FDA, and some of which has now been implemented by states, anyway. So in that respect, there has been demonstrable support by implementing things from the FDA rule that weren't necessarily ratified by the Supreme Court.

But nevertheless, that doesn't mean -- depending on the Administration's wishes, if that is something we start to agree to in our negotiations to try to improve these things, that we would have to follow up with some address to domestic law. So these things are interrelated.

DR. SATCHER: Yes?

PARTICIPANT: On the support for FDA jurisdiction, over and above what was achieved in the master settlement agreement, the whole area of current regulation is still woefully inadequate, if not absent. That is critical before we see regulation in this country.

PARTICIPANT: Will the outcome of the Presidential election have any impact on your enthusiasm with which you continue with the WHO negotiations?

DR. NOVOTNY: I hope not.

DR. EISS: Tom, does the treaty contemplate any type of economic measures, taxation schemes, or is that considered a sovereign policy of national governments?

DR. NOVOTNY: It is considered sovereign policy of

national governments. That is not something we would ever agree to, having some external setting of tax policy. However, and this is already established government policy, we think that taxes are an important and effective way of reducing consumption, and also financing tobacco -- we also support language that would support dedicated taxes to tobacco control programs from taxes as a way of financing things.

So the support for increasing taxes is there, but we would not enter an agreement that would force us to raise it to any particular level of the law. There is language that describes things such as -- well, anyway, we will have I think a very strong position, but it is not something we can accept as an outside agreement that changes the way we may tax.

DR. SATCHER: Any other questions pending?

PARTICIPANT: I was wondering, have there ever been any discussions with the IMF about removing tobacco industries from their list of industries to be privatized? In relation to the growing awareness of what happens when you privatize the tobacco industry, increased competition leading to increased consumption, and how this fits in the Framework Convention. Did you have any discussion on that?

DR. NOVOTNY: Not that I know of. Frank, have you had any --

DR. CHALOUPKA: With IMF? No.

DR. NOVOTNY: Interesting thought.

DR. CHALOUPKA: Can I make a comment on that? That privatization automatically leads to increases in consumption, we have looked at governments that have privatized, and we have seen real positive effects as a result of privatization. Poland is probably the best example of that. Once the government gets out of the tobacco production business, they get much more interested in tobacco control. Generally, the World Bank in particular is drafting some guidelines to help countries think about how to best go about privatizing their tobacco industries.

It is definitely true that there are a lot of negative consequences of it, but it is not automatically a bad thing, if privatization is done in the right way. There can be benefits that go along with it.

PARTICIPANT: So it would be controlled --

DR. CHALOUPKA: Privatization, not agreeing with the tobacco companies when they are sold off to multinationals, that there is not going to be testing and things like that.

DR. SATCHER: Thank you very much. I think we are going to break a little bit with the planned schedule and take a five-minute break here, and then come back and begin our special presentations.

(Brief recess.)

DR. SATCHER: As you already heard, there are some difficult issues facing the Framework Convention. What we are going to do now is to hear from several experts who will address some of these difficult issues. They are issues that will need to be implemented through national legislation, but I think more important, they will require multilateral cooperation.

It is our hope that the Framework Convention on Tobacco Control will provide the stimulus and motivation of national and multilateral cooperation. It is the FCTC that will provide the structure for collaboration and coordination of this global public health response to tobacco consumption, marketing, advertising and disclosure.

So our first topic this morning is smuggling. In the United States, it has been well established that smuggling takes place between high and low taxed states, yet smuggling is an even greater problem internationally, and the impact has far-reaching public health consequences.

The threat of smuggling between low and high taxed countries limits the ability of states to use tax policy as effectively to discourage consumption. Additionally, smuggling between countries can have the effect of actually denying government needed tax revenue, and circumventing local public health controls such as warning labels, content

disclosure and limitations on the sale to minors, so this is a very important issue.

We are very delighted to welcome Miss Tamara Light, who is a project officer with the Bureau of Alcohol, Tobacco and Firearms. Miss Light is also a member of the U.S. negotiating team for the Framework Convention, and an expert on the nature of smuggling and the unique challenges that face governments who seek to adopt smuggling controls.

Tamara?

MS. LIGHT: Good morning. I'd like to thank all of you for allowing me an opportunity to speak. As you can tell, I have Tom's cold. I promised him I would let you all know, he didn't touch me while we were there. It was very difficult though, because we were all huddled together many times, discussing strategies and plans. So I think several of us came home with the bug. Anyway, it is going to be hard for me to get through this, so I hope you will bear with me.

Tom did an excellent job of explaining why there is more than just public health people involved with this Framework Convention. I wanted to just expand on that and give you a guys a little of the background about ATF. Many of you may know that we are both a regulatory enforcement and criminal enforcement agency. We are responsible for the collection of excise taxes imposed on tobacco products

manufactured or imported into the United States. We are also responsible for monitoring contraband cigarette trafficking.

Under the contraband cigarette trafficking act, ATF is charged with assisting states in their efforts to also collect their revenues that they impose on cigarette products. So we typically find that tobacco trafficking occurs when foreign or state governments impose a higher excise tax on tobacco products than those tax rates found in surrounding jurisdictions.

For example, in Virginia the tax rate on a pack of cigarettes is two and a half cents per pack, but in New York the tax rate is $1.11 per pack, so there is a wide disparity of tax rates, and this leads to large-scale cigarette diversions from lawful destinations to unlawful destinations.

ATF is involved in efforts to curtail smuggling and trafficking, because such diversion ultimately defrauds the United States government, states and international governments of their revenues, and also because there has been increased criminal networks over the past 10 years; cigarette trafficking and smuggling is one of the top commodity crimes.

We also recognize though that besides being a revenue concern and a law enforcement concern, that it is a

public health concern. We know that smuggled cigarettes are frequently sold at low market prices which undermines increasing prices as a means to curtail consumption. As I mentioned, it denies governments tax revenues that they can use to support public health protection, and smuggled cigarettes often do not comply with the various health regulations, including labelling requirements and disclosure of actives.

So from the enforcement perspective, I would like to give you some examples of the types of smuggling scenarios that we deal with both domestically and internationally, by highlighting some recent cases and events.

In July of this year, ATF arrested 18 people involved in a cigarette trafficking and money laundering ring, of which some of the profits were used to support militant terrorism in the Middle East. In this particular situation, cigarettes were purchased in North Carolina, and they were transported to Michigan by small cars, vans, trucks, and they were sold on the black market in Michigan. So the Michigan state taxes were abated, and it enabled the smugglers to make huge profits, which they allegedly had gone to support some militant terrorism activities.

In another case this year, 31 people were arrested by ATF on an 102-count indictment for their involvement in

part of a networking scheme where there was trafficking in contraband cigarettes from New York to Michigan. The network involved a major U.S. wholesaler, Native American smoke shops, Michigan traffickers and retail source. This group moved over $70 million worth of cigarettes.

In another scheme where over 700 million cigarettes and alcohol were smuggled from the United States into Canada, the district attorney in New York indicted 22 defendants for money laundering, racketeering and wire fraud charges, and then in a secondary prosecution from this case -- a lot of you know about this -- there was a subsidiary of RJR Northern Brands International, who admitted to selling over eight billion cigarettes to U.S. companies that were smuggling cigarettes into Canada. So NBI paid $15 million in criminal fines, and an executive of this company pled guilty to aiding and abetting wire fraud. But it was an important investigation or victory, because it is the first time an actual tobacco company was implicated in smuggling issues.

We are also seeing a rise in cigarette highjackings, where semi-tractor trailers are pulled over and robbed on highways. We have seen other armed robberies occurring, too. There was one instance in California where a cigarette wholesaler's workers were shrinkwrapped together, and they made off with the cigarettes. I can't

imagine being shrinkwrapped with my co-workers. I like them, but they were shrinkwrapped together for about seven hours before anyone found them, and I just can't imagine.

Anyway, cigarettes may subsequently land in the black market here in the United States.

Also, this year in Italy two police officers were killed and two others were injured when cigarette smugglers rammed into their police vehicle in an attempt to get away. We also have intelligence information linking cigarette smuggling to Columbian drug cartels, the Italian Mafia, Russian organized crime, Asian organized crime and other worldwide organized criminal organizations. So it is a very widespread problem.

In view of this known criminal activity revolving around cigarette smuggling, the United States government is committed to supporting the development of a protocol in the Framework Convention with strong measures to curb smuggling. ATF being one of the lead agencies in this effort to eliminate smuggling, we are glad to be able to provide guidance to this process.

For example, from our experience, we feel that proposals to curtail smuggling should include a uniform distribution system regulating interstate commerce of tobacco. This would include a licensing system for tobacco products similar to the one that the federal government has

effectively used for the past 60 years to regulate alcoholic beverages. Such a system would require various entities in the distribution chain for tobacco products such as manufacturers, importers, wholesalers and exporters, to hold a license or a permit. The license would be issued based on certain clearly specified criteria, and it could also be revoked or suspended for specified violations.

These licensed entities would only be authorized to sell tobacco products to other licensed entities, or to purchase tobacco products from other licensed entities. The sale or distribution to any entity that is unlicensed would be unlawful, and those conducting business without a license would be subject to penalties.

In addition to a licensing system, we recommend effective marking, branding and identification of packages of tobacco products intended for either domestic distribution or for export. This would be necessary to prevent diversion or smuggling and circumvention of the legitimate channels of distribution. Any such regulatory system would necessarily have to include penalty and administrative provides that would deter would-be smugglers and would allow effective, efficient and uniform enforcement of controls over distribution. So simply stated, any regulatory system aimed at preventing smuggling would have to alert those contemplating entering the black market that

their chances are being caught are high, and that the costs of getting caught would exceed the profits from smuggling.

Right now, we hear from people that are on the fringe of this criminal activity that there are a lot of people that are getting involved in cigarette smuggling, because right now the sentencing guidelines and the penalties for it are much less than drug trafficking. So they are looking for another illegal means of gaining money, and cigarette smuggling is booming right now.

So under this system that we are planning to propose, the cigarettes would move through legitimate channels. Most importantly, these channels would not be open to America's youth. So it is evidenced through our current regulation of alcohol throughout the distribution chain, including the states, regulation of retailers, that a regulatory system that reaches through the distribution channels allows for commerce in alcoholic beverages, while effectively curtailing trafficking in illicit non-tax based products. So using that as our model, we are going to push forward with those types of recommendations.

During the opening statements at the Framework Convention, many countries mentioned that smuggling is a major problem for them. I think my counterpart counted -- I can't say I counted, I dosed a couple of times during the opening statements -- but he said about of 80 some-odd

countries that made remarks, that approximately 30 of them mentioned smuggling as being a major problem. It was really interesting for us to all hear that smuggling was a top priority issue for many people.

While I was there, I had the opportunity to meet with counterparts of several countries, including Canada, Russia and Mexico. Many of us attended the smuggling seminar presented by the Framework Convention Alliance. We felt that this seminar was helpful in illustrating the smuggling situation, and it helped to generate further discussion among countries that were interested in forcing consensus. So for those of you that were involved in putting that on, we thank you for that. It was a good icebreaker, so to speak, for those of us there to move forward and have some later discussions.

During some of these framework discussions with each other, we talked about the unique challenges that all our governments face in detecting and prosecuting cigarette smuggling violations. My Canadian counterpart, he couldn't be here, so I told him that I would try to incorporate some of the things that he shared with us there.

He was telling us that in order for Canada to tackle their smuggling problems of the early 1990s, that they devised a national action plan to combat smuggling. It was a comprehensive plan with health, tobacco tax and

enforcement initiatives. Their anti-smuggling initiative which was the enforcement component, increased their enforcement resources for the RCMP, Canada customs and the revenue agency and Department of Justice, while the health component saw the introduction of a major anti-smoking campaign. He graciously admitted that Canada knows that they have an opportunity for improvement, but they have experienced some decline in the overall contraband tobacco market, partially attributed to the implementation of a number of strategies that they implemented under the national action plan which are similar to those that we are proposing.

So Canada has seen success in their increased penalties, application of export taxes, improved stamping and marking, improved security features on tobacco markings, creating proceeds of crime offenses, increased enforcement and auditing, increased use of electronic surveillance and increased cooperation between domestic and foreign agencies.

Despite developments in our government's efforts to combat smuggling, we continue to have serious concerns. Research conducted by the United States Department of Agriculture leads one to conclude that up to a third of world tobacco exports are diverted to the black market. So we know that the worldwide growth in large-scale organized cigarette smuggling is largely aided by the lack of control

on the movement of tax-free tobacco products by international criminal organizations with sophisticated distribution efforts.

Recently ATF and NRC&P and I think Customs as well participated in a meeting that was sponsored by the G8 group on organized cigarette smuggling. The meeting was composed of police and customs official from the G8 and the European Union.

What we heard there is that cigarette smuggling is intensifying globally. Organized crime is increasingly involved. Cigarette smuggling is linked to secondary criminal activity and increased disrespect for the rule of law. Counterfeit cigarette seizures are on the rise, and cigarette smuggling is highly profitable.

The G8 member states identified a number of obstacles in the fight against organized cigarette smuggling, which not surprisingly include many of the same types of obstacles that were enumerated last week in Geneva. They included the inability to trace confiscated cigarette shipments, the lack of cooperation and information sharing between member states, and the inability to effect controlled deliveries in some countries. So what was apparent is that the national responses are inadequate, and that there is a need for broader international cooperation to tackle cigarette smuggling.

So in conclusion, it is evident that a country cannot effectively tackle organized cigarette smuggling in isolation. A successfully negotiated Framework Convention on tobacco control with a comprehensive anti-smuggling component will assist countries in meeting their domestic tobacco control policies and goals by reducing the threat of international tobacco smuggling.

I'll look forward to continuing working with the U.S. delegation and others in this ongoing effect. Do you have any questions?

DR. SATCHER: Thank you. Questions, comments?

DR. BACKINGER: Just curious, what are the current sanctions for tobacco smuggling, and then what is proposed under the Framework Convention, which is one question.

The other question I have was, what percent of ATF's effort is devoted to finding tobacco smugglers and prosecuting them?

MS. LIGHT: Your first question, I believe it is five years imprisonment and up to a $10,000 fine, I'm not sure. John, can you add to that?

PARTICIPANT: The basic penalty is five years and a quarter of a million dollars fine. A smuggling activity is a specified and unallowable activity for money laundering. The money laundering laws carry much more stringent penalties, 10 years, and the sentencing guidelines

are higher. That is where in the United States the issue of cigarette smuggling loses some of its oomph. But in Europe, most of the smuggling offenses only carry a two to three year penalty, with time served hovering somewhere around one year. The offenses do not trigger those nations' money laundering laws.

One of the issues brought up at the G8 conference was to harmonize the money laundering laws in an effort to bring up the sentencing guidelines, particularly in Europe where the smuggling problem is very profitable.

MS. LIGHT: And the second question, we have developed a national diversion enforcement program to put more and more resources into finding, prosecuting, developing our cigarette smuggling cases. We are working with Customs and some other agencies to try to come together and form a task force to tackle the problem.

It is an issue that I know my bureau takes very seriously. We are a small agency, and we are responsible for a lot of things that people don't even realize. We have 435 inspectors and 2,000 agents. So resources are tight, and Customs probably would agree that we could all use more resources to attack the problem.

PARTICIPANT: (Comments off mike.)

MS. LIGHT: I don't know statistics on those numbers, but I would say yes, definitely we need more

resources on it. I'm sorry, I just don't have the breakdown available at the bureau. We get huddled in our office back there and focused on what we are working on, and I really don't know in the overall scheme of things. I can find out, though.

PARTICIPANT: It is a pretty small division that works on the tobacco --

MS. LIGHT: We have come such a long way in the past few years, I can tell you that.

DR. NOVOTNY: It is clear that the smuggling issue is a very much law enforcement issue. Tammy has a great badge, by the way.

MS. LIGHT: But no gun.

DR. NOVOTNY: No gun. At least she didn't bring it with her, anyway. But the issue here is a health one also, because if prices are depressed by smuggling and cigarettes are cheap, kids and everybody else can buy them more easily. So the health consequence of this is that if we can maintain and sustain prices at the high levels as a result of taxation, less consumption will occur. So the health link is very, very clear on this.

PARTICIPANT: (Comments off mike.)

MS. LIGHT: I'm not aware of this report. I do know that they have been out in the marketplace looking and doing inspections, where foreign cigarettes have come back

into the country. I know that we have got our first case moving forward, where we have utilized the new penalty provisions, I think it is five times the tax that would have been due on the cigarettes when they came back in. So not only were they penalized for re-importing these cigarettes, but they also had to pay an additional amount of five times the tax.

I don't know where that is in the whole assessment process right now, but I know that was an encouraging first case for one of our inspectors down in Miami.

As far as statistically in the report, I'm not aware of where that stands.

PARTICIPANT: Do I understand that in the United States there is considerably less smuggling of alcohol and that you saw the alcohol distribution scheme as a model for --

MS. LIGHT: Right now, that is what we are seeing. We do have alcohol smuggling problems; that is a whole other speech. Recently -- this is interesting -- recently one of our distillers pled guilty and fined because they were shipping alcohol to Russia, and this alcohol, they said, was specially denatured spirits, but it really wasn't. They just put some dye into it. It was going over to Russia, and they were cleaning it up and selling it.

So the distillery was fined for recordkeeping

violations and a bunch of stuff as well, criminal violations. They had to pay Ukraine a million dollars. They had their permit suspended for seven days.

So we do have an alcohol problem, but we don't have as big of a problem with the interstate smuggling of it as we do with the cigarettes. So it is one measure that we think that we can use that model as a regulatory scheme.

PARTICIPANT: I just wonder if you can tell us briefly, why is alcohol so much lower? What is the difference? What do they do right that tobacco is doing wrong?

MS. LIGHT: We don't have the federal regulatory scheme for cigarettes and tobacco products like we do for alcohol. At ATF we only license manufacture, and that is where we collect our taxes from, from the manufacturer. We don't have any control over the wholesaler or the retailer right now. So that is the reason why we are proposing a more comprehensive regulatory scheme.

PARTICIPANT: You alluded to the predominant problem internationally, which seems to be the large scale smuggling in transit in the international shipment of cigarettes, tax-free cigarettes. One thing that that does is make smuggling of the low tax countries more profitable and easy. In fact, the data suggests that certainly in Europe, the predominant problem is in the low tax countries

like Spain and Portugal, not the high tax countries.

Do you have any thoughts -- is there any movement towards a proposal or position from the U.S. on how to deal with and reform that in-transit system of shipping cigarettes?

MS. LIGHT: That is part of what we are starting some of these task forces, and the meeting that was held in Ireland, where all countries could come together and give some ideas of how they think we should tackle some of this international movement.

I think a big problem is that we don't have good communication with other countries, nor they with us, to where we can share information, share our best practices, share intelligence. So those are the types of things I think the countries internationally are going to be working on together.

Also, ATF has been involved recently in doing some training for some of the developing countries to help them devise the regulatory tax system for their tobacco products.

DR. SATCHER: Let's go with one last question.

PARTICIPANT: A brief followup. Are there other products with a high liability for in-transit diversion, like small arms or pharmaceuticals -- are any of them treated as liberally as cigarettes are in international trade?

MS. LIGHT: It doesn't appear that they are.

DR. SATCHER: So there is a real opportunity and challenge here.

PARTICIPANT: Smuggling in high tax countries in Europe is a dramatic problem, about a billion and a half U.S. dollars a year. British Customs increased their staff by one thousand positions this year, and that included criminal investigators, intelligence specialists, inspectors. The European Union is also losing more than one billion a year in their revenues, which would be smuggling into all of the member countries because the European Union collects 45 percent of the duties on cigarettes in their countries. So there is a significant problem in the high tax countries.

DR. SATCHER: Thank you very much, Tamara. We are going to move on to our next topic, which is warning labels and packaging. We have a panel here. These speakers have been asked to talk about issues involving changes in tobacco health warnings and packaging of tobacco products, one of my favorite topics.

Rosemary Rosso is a senior attorney for the Federal Trade Commission. She was deeply involved in FTC's recent action requiring health warnings on packaging and advertising of cigars. The FTC is also reviewing the regulations that apply to health warnings on spit tobacco to

determine if we need changes there also. We look forward to hearing about the nature of FTC's work in these areas, as well as on health warnings on cigarette advertising and packaging.

Following Miss Rosso, we will hear from our neighbors to the north. Norman Brown as you have heard is Director of Regulations and Compliance with the tobacco control program of Health Canada. Mr. Brown is playing an important role in the administration and evaluation of requirements for new tobacco health warnings that utilize graphics and text. We look forward to learning about these new labelling requirements and steps that will be taken to assess their effectiveness.

So welcome.

MS. ROSSO: Thank you, Dr. Satcher and everyone else, for the opportunity to present here.

The Federal Trade Commission has been involved in the area of tobacco marketing since the late 1930. Under Section 5 of the FTC Act, we have authority for unfair or deceptive acts or practices for a whole variety of consumer products, including tobacco products. In addition, we have certain authority under the smokeless tobacco and under the cigarette act, and I'll talk about that today.

What I would like to do is set out what the existing system of requirements offer health warnings in the

United States, and then talk a little bit on what we have learned and where do we go from here.

As a federal agency that is composed primarily of attorneys and economists, we like disclosures a lot. I'm going to start out with a disclosure. I am here speaking on behalf of Rosemary Rosso, an attorney in the Bureau of Consumer Protection. I am not representing -- the views that I speak here are not necessarily the views of the Commission or any individual Commissioner.

Having said that, let me start. In the United States, we currently have health warning requirements for three types of tobacco products, cigarettes, smokeless tobacco, which HHS usually calls spit tobacco, and cigars. Each of the systems for requirements are different, primarily as a result of historical happenstance.

Cigarettes have required health warnings for the longest period. The first warning requirements for cigarettes came about in 1964 when the Federal Trade Commission issued a trade regulation rule that required health warnings in the cigarette packages and in advertising. That regulation rule was issued shortly after the Surgeon General issued its landmark report in 1964.

That trade regulation rule never went into effect. It was superseded in 1965 by the first cigarette act, which required a single warning on cigarette packages. There was

no requirement at that time for warnings in cigarette advertising.

The warning for cigarettes changed at various times during the 1960s and early 1970s. In 1981, the staff of the Federal Trade Commission wrote a report that concluded that the then-existing warning for cigarette packages was ineffective. Staff had done considerable consumer research, and it found two problems with the existing warning.

The first was a problem of wearout of the warning. The warning had been in effect for a long period of time, and after a certain period of time, people just no longer even see it, even if they are aware that there is in fact a warning on the package.

The other problem is, the consumer research indicated that the existing warning was vague and general, and that shorter and more specific warnings were more effective than long general warnings.

After publication of the report, various groups went up to the Hill, and in 1984 Congress passed amendments to the cigarette act requiring four rotational warnings for cigarettes. I have an overhead that just shows what the four warnings are. The warnings that were required in 1984 continue to be the current warnings required on cigarette packages.

There really is no guidance or regulations governing the format or display of the label warnings, other than a provision in the cigarette act which essentially grandfathers in the warnings that were in effect in 1984 at the time of enactment of the statute, and essentially codified those warnings. They are the warnings that you see that are very familiar on the side of the pack.

This is one of the better warnings you can see, it is usually right here, and there is an attribution from the Surgeon General and then the warning statement.

Enforcement of the labelling requirements for cigarettes is with the U.S. Department of Justice. The Federal Trade Commission does have responsibilities under the cigarette act to review and approve rotational warning plans. All cigarette manufacturers, importers or distributors are required to file a rotational warning plan that specifies how the company intends to comply with and insure that the packages are going to bear the four different warnings, and that the warnings are going to rotate.

In terms of language regulation and enforcement that is really it for cigarettes.

For smokeless tobacco, smokeless tobacco first require health warnings in 1986. There are three rotational warnings that are required for smokeless tobacco. For

smokeless tobacco, Congress required the warning statements. For advertising, Congress did specify and circle and arrow format. For people who might not have ever seen the circle and arrow, it is essentially -- that is what it looks like.

Congress when it passed the smokeless tobacco act gave the Federal Trade Commission -- or directed the Federal Trade Commission to issue regulations governing the format and display of the warnings. Our regulations which are in the CFR set out provisions that govern things such as the size of the warnings, the color of the wording and things such as that.

For enforcement of the health warnings on smokeless tobacco, that enforcement authority is shared by both the FTC and the Department of Justice.

The third product that has a warning requirement are cigars. Cigars are the most recent addition to the package of tobacco products that require warnings. This year the Federal Trade Commission in close collaboration with the Office of the Surgeon General and the Office on Smoking and Health at CDC came up with a set of five warning requirements that are required to be placed on both cigar packages and in advertising.

These are not regulations. We obtained these warning requirements through consent orders, which are -- we issued orders against seven cigar companies together, so

approximately 92 percent of the cigars that are sold here in the United States. So while the orders only apply to those seven companies, they do cover by far most of the cigars that are being sold in the United States right now.

The orders were finalized this summer, and we anticipate that people will start seeing packages bearing the warnings sometime early next year. Obviously, enforcement of the orders is vested with the Federal Trade Commission. The cigar companies under order are required to file rotational warning plans which would specify how they plan to distribute the packages bearing the different warnings. In addition, if a company violated one of the consent orders we could bring a law enforcement action for violating the order, and the company would be subject to civil penalties.

So that is pretty much what the system in place right now is. Before we talk about where do we go from here, I think it is important to think a little bit about what the purpose of the warnings are, because it really shapes what we think needs to be done. It is easy to say the purpose of the warnings is for informed decision making. It is informed decision making if there can be informed decision making, but it applies for both new smokers and existing smokers. The hope is for new smokers by seeing the warning, it might trigger at least a cue to think about

this product is really dangerous, it does bring real health risks with it. For existing smokers, the hope is that for some of those existing smokers, they might decide they are at least going to start quitting, or at least reduce the amount of cigarettes that they are smoking.

I was talking about cigarettes, but obviously the same applies to both smokeless and to cigars.

It is also a good way to reach the smokers. In 1998, our cigarette report reported that 558 billion cigarettes alone were distributed in the United States. That is a huge number. If you think that means that if everyone had to pick up the pack, that there were 558 billion opportunities at least for smokers to at least see some message. So even if the warnings -- and obviously by themselves they are not going to have a huge impact, but even a small impact here can translate into a large impact in terms of numbers of people, even if it is small.

Everybody does know in any survey that tobacco is dangerous. Still, we do see gaps. If you look at various demographic groups, you still see real gaps in peoples' knowledge about the health effects of smoking.

In 1998, the monitoring the future survey indicated that only 55 percent of eighth graders think that there is a great risk of smoking a pack of cigarettes a day. The science also is always evolving. If you think from 1984

to 1986, when the cigarette and smokeless tobacco warnings were designed, we have learned a lot of additional knowledge about the health effects. We have learned a lot about the effects of ETS, we have learned a lot about addiction. So the science is always evolving, and the warnings do give us a real opportunity to get information about those risks out.

Finally, all of the surveys that are conducted always show that smokers underestimate the risk. Surveys that we do, surveys that the tobacco industry does. They all show that yes, if you ask the question, does smoking cause serious disease, people will answer yes, but if you divide it up and you look at the responses that smokers give relative to non-smokers, there is a very significant, 10 to 20 points normally, difference between the risk that smokers report to the risks that non-smokers report.

What have we learned and where do we go from here? I think that everybody would agree that the existing system can have some improvement to it. In the letter that the chairman of the Federal Trade Commission wrote to General Satcher requesting assistance on cigars, Chairman Patovski indicated acknowledgement of the need for comprehensive work in this area.

The language has been the same since the mid-1980s. The effects of wearout and changed science merit examination.

Now, under the system, the only way that the language of the warnings for both cigarettes and smokeless tobacco can occur is through legislation. No agency can even require an additional warning. The pre-emption provisions of the cigarette and smokeless tobacco act prevent any other party other than Congress from requiring any different warnings. But we do need to think about updating the warnings, shortening the warnings, changing the science for things such as ETS. The cigar warnings have the first ETS warnings on them.

The question comes up on whether or not it might perhaps make sense to switch from a legislative to administrative requirement for warnings, just to add more flexibility, and if an agency with scientific expertise were involved, they could keep up with the changing science more easily. So that is something that people need to think about.

For the display of the warnings also, the conspicuousness or prominence of the warnings need to be considered. Size matters, placement and location matters, color matters, and they all merit attention.

Again, the limiting principle here is that under the current system, legislation is needed for cigarettes. For smokeless tobacco, last spring the Federal Trade Commission began a regulatory review of the Commission's

regulations on smokeless tobacco. We routinely try to do regulatory reviews of all of our rules. On this one here, we opened it up to more than just the standard cost-benefit analysis, but also just opened up questions generally on the effectiveness of the smokeless tobacco warnings themselves.

The public comment period closed the end of July with a brief re-opening of the comment period a few weeks ago. We have received approximately 35 to 40 comments from both CDC, the Massachusetts Department of Health, public health organizations, consumes, and we also received comments from industry.

At this point in time, those comments that were received are being reviewed by staff, and staff will issue recommendations to the Commission, and then the Commission will decide what amendments if any merit the Commission's attention. Should the Commission decide that amendments are appropriate, we would begin a rulemaking proceeding to amend the regulations, and there would be a public comment period again at that point in time.

There are issues that have been raised that merit consideration there, too. Again, the size of the warnings, the colors of the warnings. Language will not be an issue for us, again because we can't change the language of the warning. So I would expect that you probably will be seeing something on announcements from the Federal Trade

Commission, again probably sometime early next year on the results of the regulatory review process.

Beyond health warnings, there are also other issues in the area of packaging that merit consideration. You will hear from my counterpart in Canada about their warnings, where it is both text and pictures. There is also the issue of ingredient disclosure, to what extent should ingredient disclosure be required on packages, or package inserts or even tombstone advertising for packaging.

There are issues that haven't really garnered a lot of serious attention at this point. Through the Framework Convention perhaps there is an opportunity for people to start talking about them. I can't make any promises on what would happen on it, but at least the time seems right for at least a debate on the issues.

Limiting principles in the United States. As always, our First Amendment, which does protect commercial speech. There have been some court decisions that have been both favorable and unfavorable on size of warnings. The First Circuit recently issued a very good decision on giving the state of Massachusetts a fair amount of discretion when it came to their cigar warnings, even though it ultimately struck those warning requirements under the Constitution's commerce clause, but the First Amendment language is actually quite good.

Statutory authority is also an issue. Any federal agency can only act to the extent of their authority.

Finally, to the extent that you are going to be doing things regarding trademark or copyrighted materials, intellectual property issues will be raised as well that need to be considered.

So that in a nutshell is where we are, at least what the issues are to go forward on. So thank you.

DR. SATCHER: Thank you very much. We are going to hold questions and hear from the other member of the panel, Mr. Norman Brown from Canada.

MR. BROWN: Never travel without my props. Thank you very much for extending to Canada the opportunity to participate in the discussions today. I have been asked to speak specifically on Canada's new health warning labels, but I thought it would be important just to quickly describe the Canadian context.

The Canadian Tobacco Act of 1997 gives the government of Canada the authority to place requirements on the tobacco industry in response to conclusive evidence linking tobacco use and fatal diseases. The new health warning messages and the interior health information messages form an effective combination designed to enhance public awareness of the health hazards of tobacco use, and to help smokers find out more information to help them quit.

I see that the mockup packages I have brought are being passed around. I would also encourage you to open them up, look at the teaser flap and also look at the health information message on the inside.

Tobacco use is a leading cause of preventable deaths and disease in Canada. In 1999, just over six million people smoked, of whom approximately one half will die prematurely as a result of their tobacco use.

The new health warning messages could prevent more than 30,000 premature deaths over the next 26 years. Ideally, the health warning messages should be the first thing the smoker sees when buying a package, and the last thing seen before lighting up the cigarette.

Health warning messages in Canada have undergone great chances. Prior to 1989, they consisted of a single message on the side of the pack. In 1989, manufacturers were required to print one of four messages simultaneously and equally at the bottom 20 percent of the package.

In 1994, the requirements were changed so that the health warning message was moved to the top 25 percent of the package. This is what we currently have in place voluntarily by the tobacco industry.

Between 1990 and 1999, Health Canada conducted a number of studies on consumers' knowledge, actions and behavior towards health warning messages, looking at the

impact of size, picture, color and legibility. What we found was that warning messages with pictures were approximately 60 times more encouraging to stop people from smoking or from starting to smoke than messages without pictures. The impact of a message occupying a size of 50 percent of the principal display surface of the package was significant in stopping youth from smoking. Over two-thirds of adults and 80 percent of youths felt that health warnings showing blackened lungs and text was more effective than a message using text only.

Warnings with color pictures were more effective than black and white. The new designs were two times as legible and 3.5 times as effective as those in current use.

The new regulations require that manufacturers and importers of tobacco products insure that every package of cigarettes, tobacco sticks, cigarette tobacco, leaf tobacco, cretex, BD's, pipe tobacco, cigars and smokeless tobacco sold in Canada display a health warning. We have developed 16 different health warnings for cigarettes, four health warnings for pipe tobacco and cigars, and four health warnings for chewing tobacco and BD's. With one exception relating to cigars and pipe tobacco, this health warning message will occupy 50 percent of the principle display of the package.

Here are a few examples of our health warning

messages. As you can see, we have tried to include messages that focus by range of issues including disease and children, secondhand smoke and addiction. With a few exceptions in addition to the health warning messages, every manufacturer and importer must also include in their tobacco packaging one of 16 health information messages. Nine of these messages deal with tips on how to quit smoking and seven messages provide additional information on diseases caused by tobacco use.

In Canada, we are governed by the federal regulatory policy that provides a primary policy framework for making regulations. We also have to follow the regulatory process which is governed by the statutory instruments act. This process requires a number of steps be followed, including obtaining the approval of Cabinet prior to the regulations becoming law.

As part of the regulatory policy, we must first engage in extensive consultations with the tobacco industry as well as other stakeholders and interested parties. To do this, Health Canada began its consultations almost two years ago with the release of a consultation document. In January of 2000, the draft regulations were published as a notice of intent in the Canada Gazette, and stakeholders were invited to comment during the 30-day period. The regulations were then redrafted based on comments received, and published for

the second time in the Canada Gazette. For a second time, we solicited comments from stakeholders and again redrafted the regulation.

All in all, the Department held over 40 separate meetings with the tobacco industry and received over 2,000 submissions, of which more than 400 separate recommendations were received and analyzed. On May 12 of this year, our new regulations were tabled in the House of Commons, and were referred to the standing committee on health for their recommendation. The standing committee held six days of public hearings and reported back to the House of Commons that the regulations should be passed without amendments.

Members of the House of Commons voted unanimously -- this was a first in the history of Canadian Parliament -- to pass the regulations without amendments. On June 26 of this year, the regulations were registered and became law. Official versions of the two regulations were published in the Canada Gazette on July 19.

During the regulatory process, we faced many challenges, both internal and external. Working within a very tight time frame with a small but dedicated team, we had to insure that the health warning messages were both scientifically accurate and legally sound. To achieve this, re revalidated some of the research studies and put together a scientific panel of medical professionals to sign off on

all the messages.

In addition, because Canada is a bilingual country, drafters when preparing the regulations had to prepare both the English and the French simultaneously, and had to insure that there were no discrepancies between the two.

Externally, we found we had to find a balance between the health community who shared our concerns on public health and the tobacco industry, who were concerned with lost jobs and trademark infringements. We believe that as a result of all the consultations and meetings, that we successfully struck a balance of maintaining the health objectives of the tobacco act while trying to insure that an undue financial or administrative burden was not placed on the tobacco industry.

As well, we had to take into consideration trade issues, as our regulations would have far-reaching effects on companies overseas wishing to export tobacco products into Canada.

Looking back through the process, I can recall numerous times when we did not think we would be able to achieve our goals. There was a grueling time for all involved, but during that time, we did celebrate a number of significant successes. Three events in particular stand out in my memory.

When the standing committee on health tabled the report to Parliament without any recommendations for amendments, and when on the same day we received the unanimous Parliamentary consensus, we celebrated. The week after the regulations became law, the big three tobacco manufacturers in Canada simultaneously filed a motion to amend their current litigation action against the tobacco act to include both the two new regulations, the recording regulation and the two new labelling regulations, and filed for a motion for an injunction against the labelling regulations. This potentially could have meant that the warnings would not have been seen on packages in Canada for as long as five years. However, we did win the injunction and had another reason to celebrate.

The reasons for our success are many. Our research team laid the groundwork for the development of the messages. We conducted extensive focused group testing to insure that these messages would be effective, and we insured that all the messages were scientifically accurate and valid.

We put together a task group that was dedicated to seeing the regulations through to the end, no matter what the obstacles. We had the political support from our minster as well as the support of senior developmental officials, legal services and Canadian health groups. We

built strong partnerships with the Privy Council office, the central agency responsible for seeing regulations through the Parliamentary process.

By publishing a notice of intent at the beginning of the process, we accomplished a number of things that also helped us succeed in the end. Notices of intent are not necessarily part of the federal regulatory process. However, we did feel that it was necessary to provide stakeholders with as much opportunity to comment on the regulations as possible. As a result, we made most of our changes to the regulations during that first phase.

I spoke earlier about the support we received from the health groups. I would like to point out that in addition to their ongoing support and encouragement, during the standing committee on health hearings, they were often the voice that we could not use in counting the tobacco industry claims.

I have mentioned the obstacles and the successes we experienced, but I think nothing captures it better than the tobacco regulations task group model. Better we found out about it now, but it is what we don't know about that worries us.

I won't even attempt to share some of the horror stories that formed the basis for this model. You just have to experience it for yourself. But maybe just to give you a

taste of what we went through. One example was, two days before our minister was to table the regulations in Parliament, our original labels had, two of them, pictures of Debby and Antonio. These were very well-known faces in Canada, because they were part of our national media campaign in 1999.

What we discovered was, neither of them had signed off authority to use them on every cigarette package in Canada, and we found out that Antonio actually was suddenly becoming cigarette package shy. So again, we found out about it with great support and diligence by one of our health group allies. Needless to say, we had to scramble in two days to find scientifically valid and legally accurate replacements.

What you will now see when you look at our new health warning messages is that Antonio and Debby have been replaced by a picture of an overflowing ashtray full of butts. In the end, we actually had coffee mugs made up with our motto emblazoned on both sides as a persistent reminder of the realities of regulatory life.

The new regulations became law on June 26 of this year. The law requires that brands of cigarettes that have sales of more than two percent of the Canadian market share display our health warnings by December 23 of this year, a very nice Christmas present for the Canadian public. All

other products will have to have the messages displayed by June 26 of next year, which means that our health warning messages can be expected to be appearing on retail shelves as early as January 2001. I actually know that a lot of the smaller manufacturers and importers are already putting the labels on, and some of them are probably on shelves across the country as we speak.

While most of the large manufacturers and importers are fully aware of the laws, there are several hundred -- actually, I think it is more like several thousand -- small companies who have not played an active part in the process, and as a result, may not be fully aware of their responsibilities under the law. Even though it is not up to Health Canada to seek out and inform all affected parties, this is exactly what we are attempting to do.

The labelling regulation is so important to us that we want to insure that all manufacturers and importers in Canada of tobacco products sold in Canada comply with the new laws. On Tuesday of this week, for example, we had a fairly large meeting in Montreal, with over 300 people attending, small importers, small manufacturers, to explain and introduce them to the new regulations.

We expect to spend the next few months meeting with all affected parties to explain the new regulations and inform them of their responsibilities under the law.

In addition, the health information messages which you can see on the inside of the packages distributed, provide a Web address that will lead to a specially developed Health Canada website that provides smokers with additional information on how to quit smoking. We believe that this combination of health warnings and health information is an important part of a comprehensive messaging system.

Again, I'd like to thank you all for this opportunity to share this experience with you today. Thank you.

DR. SATCHER: We have a few minutes for questions and comments.

MS. RODDY: Has there ever been any attempt in the United States to regulate or to put labels on pipe tobacco?

MS. ROSSO: There have not been. Congress has not required warnings on pipe tobacco. In the '60s because prevalence was so high relative to other tobacco products, when we started looking at cigars, the reason we did it was because after years of significant decline in cigar consumption, we saw cigar consumption going up.

If you look at pipe tobacco usage, it really is still declining. I'm not sure, it may have leveled off at this point, but I think that it is primarily the result of decline. Though I should say that when we had the press

conference to announce the consent orders on cigars, the chairman did indicate that we would at least look at the question of pipe tobacco and decide whether or not warnings were merited there as well. That is really as far as we have gotten at this point.

DR. SATCHER: But it is a very important point. There is a dramatic difference in what is happening with cigar smoking sine 1990 as compared to especially pipe tobacco, dramatic increase, especially among young adults in cigar smoking between 1990 and '96 or so?

MS. ROSSO: It is a dramatic increase in cigars. Even from the data that CDC just released, I think it was last week, you see that among youth and young adults, cigar smoking is the second leading form of tobacco use, and really significant.

DR. KAUFMAN: Can you tell me what proportion of tobacco products sold in Canada are produced or grown in Canada?

MR. BROWN: I think it is quite a high figure, probably in the mid-90s. Sorry, produced and grown?

DR. KAUFMAN: Yes. In other words, what is the balance between imports and locally produced tobacco products?

MR. BROWN: Still, it is in the mid-90s, 95 percent versus five percent, four percent that are imported.

PARTICIPANT: (Comments off mike.)

MR. BROWN: Yes, it is a different tobacco than apparently. The constituency and the processes are different, although there is a concept of a Canadian tobacco versus an American tobacco.

MS. ROSSO: Even in the United States, the tobacco that is in U.S. product is both -- consists of both product that is locally grown in the United States and tobacco that is actually imported from other countries.

DR. SATCHER: Do we know the percentage?

MS. ROSSO: I don't have the percentages off the top of my head.

DR. GUST: We do calculate those percentages, and it is 44 and a half percent foreign grown tobacco in U.S. produced cigarettes.

DR. SATCHER: Thank you.

PARTICIPANT: What was the rationale for putting BD's in with pipe tobacco for labelling purposes?

MR. BROWN: BD's, it was mainly because of the smaller package, and we went with text only. The same with smokeless because of the sizing of the package. It wouldn't be feasible or realistic to have a graphic and text message on those.

MS. ROSSO: In the United States, we don't have a specific statute that requires warning for BD's. However,

BD's under cigarette ads in the definition of cigarettes, BD's are cigarettes. We take the position that as a result, the BD's are required to bear the warnings just like regular cigarettes.

PARTICIPANT: I understand the size question on BD's, but wouldn't the health warning be closer to the cigarette warnings than they would be to the smokeless warnings because of the health risks involved? I know the difference in the U.S. between the health warnings on cigarettes, they talk about lung cancer and emphysema, et cetera, and all the health risks that come from smoke, and those that come from smokeless tobacco we talk about oral disease, are radically different. Are those differences not evident in Canadian warnings?

MR. BROWN: Again, our warnings on cigarettes were grouped into four categories, and the four messages for BD's capture the same four categories of addiction, use, disease and secondary smoke.

PARTICIPANT: (Comments off mike.)

MS. ROSSO: I know that General Satcher has come out and spoken quite eloquently about the need for ETS warnings on tobacco products. We have a warning for cigars. In order to change and require an ETS warning for cigarettes or smokeless tobacco, you would need to have new legislation.

DR. SATCHER: Yes, that is a very important point. I think most of the American people really think that the Surgeon General has complete control over -- I remember one day walking in an airport in New Orleans, and I passed this couple and this young lady said, oh, I know who you are. So I stopped and had her tell me. She said, you're the guy who is in charge of smoking. I said, I'm against smoking. She says, yes, but I see your name on cigarette packages. So there is a lot of confusion here.

But it is a very complex process, in terms of getting warnings. But the cigar warnings are the first to include the environmental tobacco smoke. We have known about that for quite a few years; it is clearly documented. So there is a lack here, a Rosemary pointed out, between the science and getting it to the warnings.

DR. BACKINGER: Following up on what you just said, have you thought about being proactive versus reactive? You couldn't have predicted that kids were going to be using cigars 15 years ago, just like we couldn't predict the increase in smokeless tobacco use back in the early 80s. We don't know what the next tobacco product is that kids are going to use, although we know about the BD's.

It makes intuitive sense to me to look at putting warning labels on all tobacco products, not just as things occur, deciding now we need to catch up with the science,

because now we have a problem. In one sense, tobacco is tobacco is tobacco, even though there are different forms and different uses and differences between inhaled versus smokeless and others.

MS. ROSSO: I think the McCain bill would have required warnings on all tobacco products. The Commission did support that. It makes conceptual sense.

As I said in the beginning, the system that we have in place right now is largely a function of historical happenstance. We took it as it occurred. We can only act within our existing statutory and Constitutional authority, so we are limited. But certainly, should all tobacco products require warnings? Sure.

DR. SATCHER: But I think even beyond that now, it would be great if all children received the kind of education that CDC guidelines recommend in elementary and middle school about the dangers of smoking. I believe right now, only about five percent of schools in the country are providing that education.

That's what we did in talking to a reporter on reducing tobacco use. We pointed out that in those cases where this has been done, there has been a 20 to 40 percent decrease in the initiation of smoking by teenagers who have gone through those programs. So both in terms of warnings, but also just making sure that every child gets the

information that he or she needs about the dangers of smoking. We still have a long ways to go, but hopefully we will be able to implement many more studies.

MS. SUTTER: I think you set a wonderful example for us to emulate here in the United States. I would just like to suggest that in the United States, manufacturers often put packaging on their products that are much larger than the product to deter shoplifting. Maybe as your next steps, on those products where you can't put everything on there that you would like, you might have legislation that would require manufacturers to use larger packaging.

MR. BROWN: I wanted to just address the other point that was made. Even though I focused today on our labeling regulations, we are equally proud of our reporting regulations, which require information on literally everything short of the color of socks being worn by the executives of the tobacco industry. I'm not even sure we won't get that.

But just to respond to your comment earlier, one of the things we are getting are all the ingredients and the recipes and formulae for all the tobacco products, as well as all the research that is being done. So we will be able to monitor trends in development of products.

We have already seen a fairly huge increase among youth on the smokeless area in our prairie areas. They are

coming out with mint flavored and bubble gum flavored smokeless, and that has become the trend of tobacco use out there. So as they develop and do research on more of these innovative directions, we will be seeing that in the research, so we will have an opportunity to offset it with our own work.

MS. MAJESTIC: Are you getting the ingredients disclosed by brand and by weight?

MR. BROWN: Yes.

DR. SATCHER: Last question.

PARTICIPANT: If the packages were required to be considerably bigger than what is needed just to have 20 cigarettes, then the messages will be bigger, and smokeless will require much larger vehicles.

Everybody I think is familiar with the smuggling issue back in the early '90s, when the Canadian taxes had raised the prices so high as against the United States. I read that Canada at the federal level is considering raising taxes again. confident that they will be able to control any smuggling efforts this time around.

MR. BROWN: I'm not prepared to comment on that. I don't know the answer to that.

DR. SATCHER: Thank you very much, both panel members, a very interesting discussion. Now we are moving into our last area of discussion, in terms of advertising.

I want to try to help set the stage for this. As you know, cigarette advertising on television has been prohibited in this country since 1971. In many developing nations, however, tobacco companies continue to promote cigarette use. We have a very interesting example of that in the tobacco conference in Chicago, from a presentation from the Philippines. We decided that we would share this with you.

Nancy Kaufman, who was supposed to be with us --

DR. KAUFMAN: (Inaudible.)

DR. SATCHER: Oh my goodness, Nancy, welcome. We didn't know you were on the line. Welcome, from the Robert Wood Johnson Foundation, which we have talked about before in this meeting, that played such a great role. Do you want to say anything about the videotapes, about the show?

DR. KAUFMAN: I would just say that they were brought to the Chicago meeting and shown by a report from the Philippines. To me, they were quite a shock in terms of what is currently airing in different places around the world in terms of televised advertising and tobacco products.

DR. SATCHER: Great. Thank you very much for making them available and distributing them. Let's show them.

(Whereupon, videotapes are shown.)

DR. SATCHER: You see what we are missing. It is really amazing and quite disturbing. You can also understand why some of the developing countries have a lot of trouble understanding our commitment to global tobacco control. So I thought that was a good way to introduce this segment, since it is such an important one.

We are going to change the orders of presenters, I understand, is that right? We're okay now? Okay. Our first presenter is Frank Chaloupka. He is professor of economics at the University of Illinois, and a contributing author for the recent Surgeon General's report on reducing tobacco use. Again, he will help us understand the extent to which tobacco advertising and promotion plays a role, especially for young people.

DR. CHALOUPKA: Thank you. I'd like to thank everyone for inviting me to participate in today's meeting and giving me the opportunity to talk about this important issue that transcends national boundaries.

I tried to break the mold of economists this morning and go with some high-tech color presentation, Power Point, and I ended up back in the standard mode that we use, which is black and white overheads. So I'll apologize in advance if some of the colors don't show up very well.

If you are interested in the full presentation, the slides I am presenting are going to be up on my websites

by the end of the weekend. So will the papers I will refer to and several of the studies I will refer to here are also posted on the websites.

The next couple of slides are what the U.S. experience has been with regards to cigarette advertising and promotion over the last 20 or so years. But the story that these slides tell is consistent with what is going on around the world.

Cigarettes are one of the most heavily marketed produces in the U.S. and around the world. Cigarette companies are among the leading advertisers in most of the developing world, if we look at the numbers where the data are available.

This chart shows what was going on in 1998 in the U.S. Total advertising and promotional advertising for cigarettes in 1998 were $6.7 billion. That is up 19 percent from what they were in 1997 and up nearly 32 percent from what they were in 1996.

One of the interesting things to note about this chart is the breakdown on how these dollars are being spent. As this chart illustrates, much of the expenditures are on promotional allowances. These are the payments that retailers receive for the placement of tobacco products in their stores. This accounts for about 43 percent of total expenditures currently.

The second largest category is retail value added and coupons. These both lead to lower cigarette prices. There is a huge amount of evidence documenting he relationship between cigarette prices and demand, and these account for nearly one-third of overall advertising and promotional expenditures in the U.S.

When it comes to the more traditional print, outdoors, transit type of advertising, traditional image advertising, this accounts for about 16 percent of total market activities, and the remaining activities include things like sponsorship of public events, special item distribution and other sorts of advertising and promotions.

The nature of cigarette marketing has really changed dramatically over time. This slide illustrates in the left-hand bars is the situation in 1978, and the right-hand bars are the situation in 1998. It is all in inflation adjusted 1998 dollars. This slide really illustrates clearly the shift over time in cigarette companies' marketing strategies, away from the more traditional image oriented advertising towards promotional efforts that are often concentrated at the point of sale.

If we look since 1978 at inflation adjusted spending on more image oriented advertising, that has been cut almost in half. That is the other advertising bar there, the second set of numbers. Point of sale, the other

image advertising that is out there, has more than doubled. More importantly, overall promotional spending has risen nearly tenfold, with huge increases in promotional allowances, huge increases in coupons from retail value-added, which were almost non-existent in 1978, significant increases in the sponsorship of public events, and more. Overall, image oriented advertising has gone from about three-quarters of the total tobacco companies' marketing effort in 1978 to less than one-sixth by 1998.

Conceptually, tobacco advertising and promotion can have several direct effects on tobacco use. These direct effects include attracting new users to the market, which is increasing initiation among teens, reducing current users' willingness to leave the market, or reducing cessation among adults, simulating use among current users, which is raising cigarette consumption by existing smokers, and finally, inducing former smokers to resume use or raising re-initiation among former smokers. All of these have the effect of increasing the prevalence of tobacco use, increasing the overall demand for tobacco products, and ultimately increasing the health, economic and social consequences associated with tobacco use.

In addition to the direct effects of advertising, several commentators have suggested that there are several indirect channels by which advertising and promotion can

raise tobacco use. These include the discouragement of a full discussion of the health consequences of tobacco use in the print and other media receiving tobacco advertising dollars. There have been several studies that have documented this over the last 10 years.

In addition, advertising and promotion can lead to the normalization of tobacco use by contributing to an environment where use is perceived as socially acceptable and less hazardous than it actually is.

In addition, advertising and promotion have the potential to create political opposition to strong tobacco control policies among the advertisers, retailers and other institutions that are receiving tobacco industry marketing dollars, and finally, the increased brand proliferation and market segmentation that results from advertising can also attract new users to the market and discourage users from leaving the market. All of these will raise smoking prevalence consumption and the consequences of tobacco use.

There have been numerous studies that have looked at the links between advertising and tobacco use. Several have used logical arguments that are based on the size of tobacco company marketing expenditures and the industry's opposition to advertising restrictions, to conclude that there must be a strong link between advertising and demand. Other studies that are largely based on cross-sectional

survey and other data conclude that cigarette ads capture attention, are recalled particularly among youth, and that the strength of interest in these ads is correlated with current smoking behavior, with intentions to smoke in the future, as well as youth smoking initiation.

Similarly, there have been several other studies that are based on longitudinal data that look at youth ownership of tobacco company promotional items and later smoking initiative. These conclude that youth ownership of these promotional items does predict smoking initiation in later years.

Similarly, consistent with the observation that 86 percent of teen smoking the three most heavily advertised cigarette brands compared to only 30 percent of adults, there is other research that finds that youth smoking is three times more receptive to cigarette advertising than is adult smoking.

But the one area where there is more mixed stuff, and this has been produced from the empirical studies, is from the econometric literature, that tries to relate overall cigarette advertising expenditures to overall cigarette sales.

This literature tends to produce either small or negligible effects of cigarette advertising on cigarette sales, but there have been several recent critical reviews

that point out the limitations of the econometric methods in trying to look at the relationship between cigarette advertising and demand. Nonetheless, most of these studies do conclude that there is some small positive effect of advertising on consumption.

One area where econometric methods are much better at detecting the impact of advertising on demand is when it comes to looking at the effects of advertising restrictions on demand. In those cases, the best of the recent studies conclude that the most comprehensive restrictions on advertising and promotion can significantly reduce overall cigarette consumption. Estimates from my recent study, for example, with Henry Safer, that uses data from OECD countries over the last three decades concludes that comprehensive advertising and promotion bans can reduce cigarette consumption by more than six percent.

In general however, these studies find that partial advertising bans really have little or no effect on overall cigarette consumption. The main reason that this takes place is because partial bans, bans on advertising in one media or a couple of medias lead to substitution of resources away from the media that are banned into other types of advertising and promotional activities that aren't restricted.

Some of our recent work, for example, concludes

that the elimination of tobacco company billboard advertising led to moving resources from billboard advertising into more advertising and promotional activity at the point of sale. Similarly, there is other recent evidence from the Massachusetts tobacco control program that found that cigarette advertising in magazines also rose after the master settlement agreement, particularly in magazines with high youth readership.

This next slide is based on a study of 102 countries from 1981 to 1991, including a mix of high income, middle income and low income countries. It was done for the recent World Bank and WHO reports.

This graph illustrates this point, that you need to have comprehensive advertising bans to successfully reduce consumption. The two lines there show that countries that have had comprehensive bans in advertising and promotion have significantly reduced cigarette smoking, while those countries that have relatively limited bans or no bans on consumption have seen much slower reductions in overall cigarette consumption.

No discussion of this issue would be complete without including at least a few comments on the impact of counter marketing on demand. Based on the U.S. experience of the late 1960s under the fairness doctrine anti-smoking campaign, when cigarette ads were matched by anti-smoking

advertisements on TV, as well as the stuff that we heard about this morning from Dr. Koplan on the effects of the state campaigns that included large mass media components, in California, Massachusetts, Florida and several other states, as well as a large amount of international evidence from countries like Australia, New Zealand, Turkey, Spain, Canada and several others, it is really clear that tobacco counter-marketing efforts lead to significant reduction in overall cigarette smoking as well as in youth smoking.

The magnitude of the effects of these reductions depends on public components. It depends on the reach of the campaigns, the frequently with which those messages are being broadcast, and he duration of the counter marketing campaign. If it is sustained over time at high levels, these do lead to significant reductions in smoking.

Finally, these campaigns appear to be the most effective when they are one element of a broad overall comprehensive tobacco control program that also includes a variety of other approaches to reducing tobacco use, like tax increases, strong tobacco control policies, increased access to cessation, and a variety of other activities.

So to sum up, tobacco advertising and promotion in the U.S. and almost certainly around the world is substantial and is increasing, and is an issue that transcends national boundaries. This issue requires

international action, given the growing evidence that tobacco advertising increases tobacco consumption, particularly among the most vulnerable populations like youth, and almost certainly among the least educated folks in developing countries.

Comprehensive bans on tobacco advertising and promotion will lead to significant reductions in overall tobacco use, limited restrictions on the other hand are not likely to have much of an impact given the potential for substitution.

Finally, counter marketing is effective in reducing tobacco use, and should be considered one component of a comprehensive tobacco control program.

Thank you.

DR. SATCHER: Thank you very much, Frank. We are going to go on to the next presenter on this panel, who is Tom Perrelli, who is Deputy Assistant Attorney General in the Justice Department, to look at some of the legal issues, including the FDA rule and its impact, as well as the recent master settlement agreement.

MR. PERRELLI: Thank you very much, Dr. Satcher. I should probably give the same kind of disclaimer that Rosemary gave at the beginning, although I imagine you have figured out by now I'm not Janet Reno.

I do want to talk a little bit about the history

of restrictions on tobacco advertising as well as some of the legal issues raised. One of the things that has become clear to me just from listening to the discussion today, or a lot of the questions focusing on, did you ever think about doing this, why not do that, and then Dr. Chaloupka's demonstration of how the advertising dollars shift over time, I think re-emphasizes the need once again for a comprehensive regulatory authority, somebody who can adjust to it in a way that realistically Congress can't do, setting aside any set of political concerns, so that the case for enhanced FDA authority with respect to labels and disclosures, and also comprehensive regulatory in the FDA is made by watching the way that dollars can shift over time, and the need to be able to respond to that in the regulatory setting is really the way to do that.

I think one of the things with respect to tobacco advertising and the legal issues today that is interesting is the number of people in the different processes that are involved. You have state and locals now engaged after many years of not being involved in regulating tobacco advertising, at least in the particular context in the placement of billboards. You have the FTC's longstanding efforts with respect to misleading advertising, and their role in the warning labels. You have the master settlement agreement in effect. I think we are far from understanding

what the ultimate impact of that is going to be. Again, I think the last presentation showed you that one effect may be simply to shift advertising dollars from one place to another.

With respect to all of these different areas of activity in tobacco advertising, I think essentially the legal issues remain the same. Those legal issues informed the Framework Convention negotiations. Whatever we might agree to in an international treaty in implementing legislation, it has got to be consistent with the Constitution, particularly the First Amendment.

Since the beginning of this Administration's tobacco control efforts, our focus has been in the area of advertising and marketing, the most restrictive advertising requirements that we could impose, with a particular focus on protecting minors from images that might encourage smoking within Constitutional bounds. It was from there that the FDA began with their starting point and with an enormous record about the impact of advertising on children particularly, and led to the promulgation of their regulation.

But that wasn't in any sense the first time that tobacco advertising has been a big issue. The Supreme Court considered tobacco advertising as far back as 1932 in upholding billboard and streetcar restrictions in Utah. The

FTC in the 1950s and '60s did a great deal of work in building our knowledge on tobacco advertising and its impact, as well as examining some of the explicit and implicit health claims being made by the tobacco companies in that era.

Congress gets involved principally starting in the 1960s with eventually culminating in 1969 the Federal Cigarette Labeling and Advertising Act, which requires -- the second effort at requiring warning labels.

Among other things, and this impacted the history of regulation in this area, it pre-empted a lot of state and local regulation of advertising in the pre-emption provision, which has been litigated in the context of both particular local regulation as well as in the various litigations that led to the state settlements, particularly the provision, no requirement or prohibition based on smoking and health shall be imposed under state law with respect to the advertising or promotion of cigarettes.

At the same time that Congress imposed the warning labels again in 1969 as well as that pre-emption provision, they also prohibited tobacco advertising on any medium of electronic communications, subject to the jurisdiction of the FCC. That led to -- is the reason why you do not see those advertisements on television in the United States. That statute was eventually upheld by the Supreme Court in

1971.

In the years following that, other than the activity before the FTC, you had state and local governments not being particularly involved. The momentum for regulation for tobacco advertising grew up from two different sources -- one, the various state litigations. As one of their goals in addition to recovering health care costs were to change the way the industry does business to attempt to address marketing, and particularly marketing to kids.

Then the effort at the FDA to build the record, particularly the case on addiction and to try to address in a comprehensive way marketing and promotion, particularly to children, again.

The FDA rule which came out in 1996 focused on protecting children, and among the advertising restrictions that were included there were requirement of tombstone advertising, where you had in publications and outdoor advertising that was acceptable to children, requirements saying no outdoor advertising within a thousand feet of schools and playgrounds, restrictions on brand name sponsorship, among other restrictions.

I know that it is popular to believe that those restrictions were struck down, but they weren't on First Amendment grounds. The Supreme Court determined the FDA to

not have jurisdiction. But the underlying question of whether those restrictions would be permissible under the First Amendment was never actually decided by a court. We have taken the position of the Justice Department that we believe the restrictions under current law as well as the FDA rules restrictions would be fully Constitutional.

In the context of subsequent legislation we have at different times taken positions, particularly in the context of the McCain bill, which had some additional direct restrictions on tobacco companies that we also believe were fully Constitutional.

At the same time that the FDA rule was being litigated, you had eventually in July of 1997 the first state settlement, the so-called July 20 resolution, which had a series of marketing restrictions that went beyond in many respects what was in the FDA rule. But that resolution could only come into force and effect with Congressional legislation, particularly Congressional legislation that would give some level of protection from future liability for the tobacco companies.

That led in 1998 to the Congressional debate and particularly consideration of the McCain bill, which really incorporated both of the two models that were presented by the FDA rule and state litigations. In its final form, the McCain bill proposed a set of restrictions similar to the

FDA rule, but a little bit beyond the FDA rule on all companies directly, and then had a separate portion of the legislation which was essentially consensual, the idea being that tobacco companies who voluntarily restricted their advertising to a greater extent would obtain certain benefits, including a limited form of liability protection.

Ultimately, that was not successful, and the states went back to the drawing board, and ended up with the master settlement agreement in 1998, which does a number of things. I think people have characterized it as broader and narrower than the FDA rule.

Again, I think the last presentation demonstrated, it leaves open quite a number of avenues for tobacco advertising, particularly in the print medium. That is why you still see tobacco advertising in the same form that you have seen for years in Sports Illustrated and other magazines. Also, while the agreement has a general provision against targeting of youth, it remains to be seen what that provision will turn out to mean over time. I suspect that it is likely that the state attorneys general and the tobacco companies may have different views as to what that provision will ultimately mean.

Somewhat in conjunction, but really following the settlement, we have had a couple of other areas that have grown up where tobacco advertising regulation may become an

issue again.

First, after the demise of the McCain bill, we at the Justice Department, working with a number of agencies, went back to consider the liability of federal tobacco litigation that eventually culminated in the lawsuit that we brought in September of last year, that has among the types of relief that we are seeking, additional market restrictions.

The second area, which is the area where we are likely to see further illumination of the legal principles in this area, comes in the area of state and local ordinances related to placement of certain kinds of advertising.

For many years, state and local governments shied away from that kind of regulation of advertising, perhaps because of the view of the pre-emption provisions. We now have five circuit court decisions that are somewhat in conflict, that deal with whether or not states and localities can regulate the placement of advertising, not necessarily the content of advertising, which the courts have generally not allowed them to do.

It is basically four to one allowing the local governments to do that. We now have two cases, one out of Baltimore and one out of Massachusetts, which look at once again the First Amendment issues related to tobacco

advertising restrictions. In both of those cases, the courts upheld on First Amendment grounds the restrictions, including one in Massachusetts which in effect would have removed tobacco advertising from about 90 percent of the land area of the three major cities, because it was targeted to no advertising within a thousand feet of schools and playgrounds. That had a significant practical effect on where you could place tobacco advertising.

To give you a quick overview of the legal principles that are at issue here, tobacco advertising restrictions are going to be analyzed under the commercial speech doctrine, as a couple of people have indicated before. Generally, the shortest version of the test is from a case called Central Hudson, which focuses on four issues, one of which is the key one for the purposes of tobacco advertising regulation. It first asks whether the regulated speech is related to an unlawful activity or is misleading, and if it is in that box it will get less protection, if any. Is the government interest asserted to regulate the speech substantial; I think obviously in this context we have spent years building the case that restricting tobacco advertising to protect youth is a compelling government interest.

Third, does the regulation directly advance the government interests asserted. This is an area over which

there was a lot of litigation in these various local cases, but has turned out to date to have been not that difficult for states and localities to meet, given the broad record that demonstrates that to the extent that you can keep tobacco advertising away from children, you are going to make a difference in whether or not they begin or continue to smoke.

Then the final aspect of the Central Hudson test, which is, is the regulation more extensive than necessary to serve that interest, the government interest. This is essentially what is called a fit requirement, is the relationship between your ends and your means reasonable. Something that bans substantially more speech than is necessary is more likely to prevail. Something that provides alternative channels of communication is more likely to succeed in that test. That has been the controlling test under which the courts have examined that there is billboard advertising and outdoor and indoor advertising efforts restrictions that have been attempted in states. I think you will see a new wave of these kinds of ordinances as people adjust to what the master settlement agreement, how that has changed the playing field.

I would say that we are going to get a lot more guidance in this area in the next couple of years, because I think there is at least a reasonable chance that the Supreme

Court will consider one of these cases. I believe the First Circuit case is now -- they have filed a petition to have the Supreme Court hear it.

A couple of things jump out from those opinions that are of relevance. First, I think the courts found it of great significance that this was not a run of the mill restriction on commercial speech. This was an area where there is significant interest in the regulation where the sale of a product is banned to children. The idea of restricting speech, this was not an anti-democratic measure, but is actually a democratic measure intended to support a ban on sales to minors, so they very much looked at it in light of how it supports the underlying regulating regime, which doesn't implicate any First Amendment interest.

I think second, the courts did manifest a concern about children who might be victimized by the highly addictive nature of the product, and focused among other things on their inability to understand the impact of starting or continuing to smoke. That too is an aspect of this that may suggest that the court would be willing to accept greater restrictions of advertising in the tobacco area and in other areas.

Last, the practical effect of the Massachusetts ban being so broad, the fact that it would have banned -- I think the record suggests about 90 percent of the land area

of the three major cities in Massachusetts. The court was not in the end troubled -- at least, the First Circuit was not in the end troubled by that, saying that there were other avenues for tobacco advertising. There they focused among other things on the print media.

I think the simple lessons from all this background is a few things. One, we should know a lot more in a couple of years about what the legal principles are. I think there is a reasonable chance that we will.

Second, the First Amendment does leave room for a significant number of restrictions in this area, such as those in current in the FDA rule.

Finally, I think the experience of all of the litigation and the FDA rule is that no matter what, you certainly are going to be able to do more with consent and trying to work on the most extensive restrictions on a voluntary basis, if it is possible to do, whether through the kind of consent orders that the FTC has worked on in some areas, or whether it is through a larger legislation resolution, as was attempted after 12 years.

Thank you very much.

DR. SATCHER: Thank you.

MS. SUTTER: Could you give us the citation to the Central Hudson case, by any chance?

MR. PERRELLI: I don't have it sitting in front of

me, but I may be able to find it for you in a moment. 447 US 557.

MS. SUTTER: Thank you.

DR. SATCHER: There is also a reference in the Surgeon General's report. Yes?

PARTICIPANT: Given the position of many countries at the Framework Convention negotiations that protocols should deal with trans-boundary issues before they deal with national application, the issues that come up under advertising are those that involve advertising across national borders, such as satellite television and the Internet, and also the U.S. position that what it does at home, it can also -- feels most comfortable doing in a treaty.

Given the broad language of the Federal Cigarette Labeling and Advertising Act, prohibition on advertising on media subject to the FTC act, do you consider cigarette advertising on the Internet to be covered by that act?

MR. PERRELLI: I'm going to decline to answer that.

DR. SATCHER: But nice try. Any other questions? Nancy?

DR. KAUFMAN: Yes?

DR. SATCHER: Do you have any comments?

DR. KAUFMAN: No. I'm just glad to hear the

history of the court ruling that I have heard over time. I think we here are pretty familiar with Central Hudson and what it might allow us to do if we got a little bit more aggressive.

DR. CHALOUPKA: One of the things that we always talked about in some of the papers I've gotten is taxing advertising. Is that something that the Department is considering?

MR. PERRELLI: It is not in our bailiwick. I will say at least, the law on conditioning tax deductions on certain -- I think the law analyzes direct imposition of a restriction differently from imposition of a restriction by granting or denying a tax deduction.

This is actually a very complicated area of law. I think if you read a couple of different Supreme Court cases, you won't be sure of anything, frankly, but this kind of issue for example we are litigating right now in the context of the latest campaign finance legislation, which requires among other things kinds of disclosures, in the context of getting a tax exemption.

But as a general matter, you have more -- when you are removing a benefit that the government is granting, you have more leeway.

DR. CHALOUPKA: How about with respect to pricing laws? Is that something you have considered as a way of

getting around some of the value-added kind of --

MR. PERRELLI: It would likely not raise First Amendment issues.

DR. CHALOUPKA: How about placement issues? There are a places that have started --

MR. PERRELLI: Right. I think that comes in what I'll say is this next set of state and local ordinances. The cases are going to be litigated as to whether that is permissible. I think we have taken the position in the past that -- I forget what numbers we analyzed, but that those kinds of restrictions would be permissible. There may be limits, but you certainly could do things like that. There were things like that in the McCain bill.

MS. ROSSO: The First Circuit's decision in Massachusetts, their restrictions actually had some generous language on in-store displays, because Massachusetts had restrictions there as well. They at least were giving the state some amount of discretion in limiting those displays.

MR. PERRELLI: I think you are going to see states going back a little bit to the -- there are a number of states and localities that have imposed billboard restrictions when the master settlement agreement came around, that dealt with some of those issues, and now they are looking at some of these other issues, particularly in Massachusetts. That statute was a significant victory for

those who support the advertising regulation.

As Rosemary says, the language is very strong, particularly on the idea that there are other avenues, and that this kind of regulation be permissible.

DR. KOPLAN: This kind of falls between your presentations. One thing I have been interested in in what has been discussed here is, what percentage of sales of tobacco products are sold in pharmacies, which have always prided themselves as being health related institutions? There is somewhat of an irony there, but does someone have that information?

MS. ROSSO: Actually, you might be able to look at broad categories, but I don't think that there are national data that would go down to pharmacies specifically.

DR. SATCHER: It would be interesting.

DR. KOPLAN: There ought to be a movement against -- if pharmacists would like to be part of the broad health -- hospitals I don't think are selling cigarettes anymore.

PARTICIPANT: From the FDA, this is a non-random sample of the way they did their regulations. At least, what they have is which types of stores were more likely to sell to kids, versus which ones weren't. I can't remember what pharmacies came out in that. That is up on their website under their FOIA.

PARTICIPANT: That brings up a good question. Are

there restrictions for example in some states where there has been legislation on mixing the sale of alcohol at gas stations, for example, are there restrictions on the First Amendment sales where a certain product can be sold where another product is sold, for example, where medicine is dispensed, cigarettes shouldn't be sold.

MR. PERRELLI: I certainly wouldn't raise First Amendment issues as a general matter talking about the sale of a product. I think that would be the way -- I think frankly, from a lawyer's perspective, there have been restrictions for a long time in many states about, you can sell legal services, but you can't join together with an accountant to sell both kinds of services. The regulatory principles I think will move into -- it is economic regulation, not regulation of speech per se.

DR. CHALOUPKA: On the pharmacy issue, I think with the FDA data, pharmacies actually don't do any better than other stores. I was a little surprised by it. Then just in terms of the retail environment in general, we have been doing a lot of work collecting data on stores and what kinds of advertising and promotions are in stores, and pharmacies are by far the least likely to have any sort of advertising and promotion. They are much more likely to have health warnings and things like that than other types of stores.

DR. KOPLAN: Has there ever been a connection between freedom of religion and freedom of advertising or speech? If a religious group was actively anti-tobacco as part of their beliefs, and if we could promote them enough so that they were on every corner --

MR. PERRELLI: I must admit, I haven't thought about it quite in that way.

DR. KOPLAN: You mentioned a Utah case. Did that have religious overtones?

MR. PERRELLI: It was sort of a sin. Sin was the foundation of that. I think that case would be analyzed completely differently today. Whether it would survive or not is another question. It was given much more cursory treatment.

Really, the Central Hudson and the commercial speech, all of the law that we talked about today as a given grows up in the 1970s.

MS. ROSSO: I'm aware of two cases, but none of them are really on point. There have been cases where in legal tobacco products the issue has come up on freedom of religion grounds.

There is currently a case, and I don't know if it is still in the administrative context, but there are two students in high school in one of the states, where they walked out of the school's anti-tobacco program because it

is against their religion to watch television, and it was a videotaped program.

MR. PERRELLI: I'll look forward to getting that case.

DR. SATCHER: Why don't we just have these last couple of comments or questions?

MS. RODDY: I was just wondering if the lawsuit filed in September is totally dependent on funding from Congress, and what your prediction might be with the change of administration on its liability?

MR. PERRELLI: I will certainly not make a prediction about change of administration. I think I will leave that to whoever else wants to take it. We have said without -- you can't do this lawsuit on the cheap. Without funding, we will probably have to dismiss the lawsuit.

We are currently seeking direct funding so that we have a sufficient amount of money to litigate this case as it should be litigated, give the American people their day in court. I know that the resources arrayed against us are enormous. As a number of people in various agencies have already been involved with our tobacco litigation team, they have been looking for documents in preparation, we estimate the number of documents, for example, the companies will seek in discovery are in the tens of billions -- or number of pages, excuse me.

DR. SATCHER: Last comment.

PARTICIPANT: In terms of the implications of this First Amendment discussion for the U.S. position in the Framework Convention on advertising issues, if other countries want a broader Framework Convention provisions than we feel comfortable with under our First Amendment law, will the United States' position be one of advocating that the Framework Convention that the world signs onto be -- that the bar be lowered, as it were, to our level of our peculiar jurisprudence, or will we seek some other way to protect our interests to either reserve our rights under that clause, or have language in there that specifically allows countries with constitutions like ours to sign on, while still protecting our rights?

MR. PERRELLI: Tom may be able to speak from his discussions, but I think as a general level, where the current Framework language is being discussed is, go as far as you can go to the extent permitted under domestic law. It wouldn't necessarily permit anybody from doing what they do under domestic law, but we are not signing something that goes beyond what we can do.

DR. NOVOTNY: I think the other thing is, our position is not weak. We have a lot of success based on what we have been able to do so far, so that is our baseline.

When it comes to other countries, there were other countries that had to deal with some similar free speech issues. I would say the smaller countries spoke out strongly in favor of a complete and total ban.

However, I think that the examination of this with respect to their constitutions and other regulations probably is not complete yet, so I'm not even sure that the vast majority of the countries are going to be able to do that anyway.

So when it comes down to stepping back from something that others might be able to do more strongly, the Framework Convention we hope doesn't have something in it that will keep us from signing at least the Framework document. If there is a protocol that calls for a complete and total ad ban, and maybe only five countries sign it, or 10 or 15, we might not be able to.

So I think I think is the way things might sort themselves out.

DR. KAUFMAN: David, can I ask a question?

DR. SATCHER: Sure, go ahead.

DR. KAUFMAN: I'm just curious from a Justice Department perspective. Are we convinced that a total ban on advertising and promotion of tobacco products would not meet the Central Hudson test?

MR. PERRELLI: That too I would decline to answer.

I think we're not prepared to opine on it at this point.

DR. SATCHER: Thank you very much. Now, before we conclude, we have allowed time for public comment. I know we didn't have anyone to sign up. I have tried to conduct this meeting in such a way that it was open for comments from the audience, because I thought it would work better. But we do have on our agenda time for public comments, if there are any.

Very good. The strategy worked pretty well. But I do want to take just a minute and express our appreciation to all of you who have attended this meeting for the very important and thoughtful discussion that we have had. I'm sure, Tom, that it will be helpful to the committee working with the Framework Convention if you would like to comment at all on that from your perspective.

DR. NOVOTNY: Nothing, other than the fact that this kind of public forum and these comments are critical to everyone understanding not just our positions, but for us to understand the more detailed information that can come from such a forum, but also to engage everyone around this table and on the outside of the table. This Framework Convention, if it is to be successful, will require that kind of public knowledge and commitment, to be able to bring it through the whole process that we face in the next two or three years.

DR. SATCHER: Thank you. Jeff, do you have any

final comments?

DR. KOPLAN: No.

DR. SATCHER: Let me say as I said at the beginning, this is the first meeting of this interagency committee since 1994, so I am sure you will not be surprised to hear me say that we are going to meet more frequently.

In fact, we are hoping to schedule a date in the spring, in which we can hear about the master settlement. CDC is actually doing a study of what states are doing as a result of the master tobacco settlement. So we would like to schedule a date in the spring when we can really take a critical look at what is happening in the country as a result of that. So keep that in mind. We probably will be contacting you for some good dates.

I should also say that our Department will prepare a summary of this meeting and get it disseminated to you all of you who have attended. We will also be placing this on the CDC website, and provide it to members of the interagency working group, which is coordinating this U.S. negotiating policy with FCTC.

So those are our plans. Again, thank you very much for being here, and thank you for your very enthusiastic participation, especially to those members who prepared the presentations for this meeting.

The meeting is adjourned.

(Whereupon, the meeting was adjourned at 12:35 p.m.)