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THE NEED FOR FDA REGULATION OF TOBACCO

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

EXAMINING S. 625, TO PROTECT THE PUBLIC HEALTH BY PROVIDING THE FOOD AND DRUG ADMINISTRATION WITH CERTAIN AUTHORITY TO REGULATE TOBACCO PRODUCTS

FEBRUARY 27, 2007

Printed for the use of the Committee on Health, Education, Labor, and Pensions

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THE NEED FOR FDA REGULATION OF TOBACCO PRODUCTS

TUESDAY, FEBRUARY 27, 2007

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in Room SD–430, Dirksen Senate Office Building, Hon. Edward Kennedy, chairman of the committee, presiding.

Present: Senators Kennedy, Reed, Sanders, Brown, Enzi, Burr, Isakson, Murkowski, Hatch, Allard, and Coburn.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. Good morning and I apologize to our panelists and to our members here. We have a ritual here in the Senate now, which is called the Early Bird Rules. So if you are on another committee and you have at least a little seniority, which I'm fortunate to have, you have to go down and check in at the start of the hearing, to preserve your questioning later on. All of my colleagues are familiar with it. You find out some of us come in here out of breath several minutes late at the opening of these hearings. So we appreciate your understanding and patience as I hope my colleagues do as well.

I thank all of our witnesses for being here and I'll have an additional word on that. This hearing focuses on the need for FDA regulation of tobacco products, the most lethal of all consumer products. Used as intended by the companies that manufacture and market them, cigarettes will kill one out of every three smokers. Yet the Federal agency most responsible for protecting the public health is currently powerless to deal with the enormous risks of tobacco use.

Public health experts overwhelmingly believe the passage of S. 625, bipartisan legislation that will at long last give the FDA authority to regulate tobacco products, is the most important action that Congress can take to protect children from this deadly addiction. If Congress fails to act and smoking continues at its current rate, more than 6 million of today's children will ultimately die from tobacco-induced disease.

Smoking is the No. 1 preventable cause of death in America. Nationally, cigarettes kill well over 400,000 people each year. That's more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDs, murders, and suicides combined and Congress cannot continue to ignore a public health crisis of this magnitude.

Giving FDA authority over tobacco products will not make the tragic toll of tobacco use disappear overnight. More than 40 million people are hooked on this highly addictive product and many of them have been unable to quit, despite repeated attempts. However, FDA action can play a major role in breaking the gruesome cycle that seduces millions of teenagers into a lifetime of addiction and premature death.

What can FDA regulation accomplish? It can reduce youth smoking by preventing tobacco advertising that targets children. It can help prevent the sale of tobacco products to minors. It can stop the tobacco industry from continuing to mislead the public about the dangers of smoking. It can help smokers overcome their addiction. It can make tobacco products less toxic and less addictive for those who continue to use them. And, it can prohibit unsubstantiated health claims about supposedly "reduced risk" products.

Regulating the conduct of tobacco companies is as necessary today as it has been in the years past. The facts presented in the Federal Government's landmark lawsuit against the tobacco industry conclusively demonstrate that the misconduct is substantial and ongoing. The decision of the Court states:

> "The evidence in this case clearly establishes that Defendants have not ceased in engaging in unlawful activity. . . . Defendants continue to engage in conduct that is materially indistinguishable from their previous actions, activities that continue to this day."

Only strong FDA regulation can force the necessary change in their corporate behavior.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The tobacco industry currently spends over $15 billion each year to promote its products. Much of that money is spent on ways designed to tempt children to start smoking before they are mature enough to appreciate the enormity of the health risk. The industry knows that nearly 90 percent of smokers begin as children and are addicted by the time they reach adulthood.

If we are serious about reducing youth smoking, the FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. This legislation will give FDA the authority to stop tobacco advertising that glamorizes smoking to kids. The FDA's authority must extend to the sale of tobacco products as well to ensure that children under 18 are not able to buy cigarettes.

The tobacco industry has a long dishonorable history of providing misleading information about the health consequences of smoking. The FDA must have clear and unambiguous authority to prevent such misrepresentations in the future. The largest dis-information campaign in the history of the corporate world must end.

The nicotine in cigarettes is highly addictive. Medical experts say that it is as addictive as heroin or cocaine. Yet for decades, while tobacco companies were publicly denying the addictiveness of their products, they were actually chemically manipulating the nicotine in them to make it even more addictive. A newly released analysis by the Harvard School of Public Health demonstrates that cigarette manufacturers are still manipulating nicotine levels. Between 1998

and 2005, they significantly increased the nicotine yield for major brand cigarettes.

FDA must have the power to take the necessary steps to help addicted smokers overcome their addiction and to make the product less toxic for smokers who are unable or unwilling to stop.

This legislation will require manufacturers to submit "reduced risk" products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA's satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety.

Enacting this bill this year is the right thing to do for America's children. They are depending on us. By passing this legislation, we can help them live longer, healthier lives.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

This hearing focuses on the need for FDA regulation of tobacco products, the most lethal of all consumer products. Used as intended by the companies that manufacture and market them, cigarettes will kill one out of every three daily smokers. Yet, the Federal agency most responsible for protecting the public health is currently powerless to deal with the enormous risks of tobacco use. Public health experts overwhelmingly believe the passage of S. 625—bipartisan legislation that will at long last give the FDA authority to regulate tobacco products—is the most important action Congress can take to protect children from this deadly addiction. If Congress fails to act and smoking continues at its current rate, more than 6 million of today's children will ultimately die from tobacco-induced disease.

Smoking is the number one preventable cause of death in America. Nationally, cigarettes kill well over 400,000 people each year. They die from cancers, from lung diseases, from heart diseases and strokes—all caused by smoking. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, and suicide combined. Congress cannot continue to ignore a public health problem of this magnitude.

Giving FDA authority over tobacco products will not make the tragic toll of tobacco use disappear overnight. More than 40 million people are hooked on this highly addictive product and many of them have been unable to quit despite repeated attempts. However, FDA action can play a major role in breaking the gruesome cycle that seduces millions of teenagers into a lifetime of addiction and premature death.

What can FDA regulation accomplish?

- It can reduce youth smoking by preventing tobacco advertising which targets children.
- It can help prevent the sale of tobacco products to minors.
- It can stop the tobacco industry from continuing to mislead the public about the dangers of smoking.
- It can help smokers overcome their addiction.
- It can make tobacco products less toxic and less addictive for those who continue to use them.

• And it can prohibit unsubstantiated health claims about supposedly "reduced risk" products.

Regulating the conduct of the tobacco companies is as necessary today as it has been in years past. The facts presented in the Federal Government's landmark lawsuit against the tobacco industry conclusively demonstrate that the misconduct is substantial and ongoing. The decision of the Court states:

> "The evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity. . . . Defendants continue to engage in conduct that is materially indistinguishable from their previous actions, activity that continues to this day."

Only strong FDA regulation can force the necessary change in their corporate behavior.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The Food and Drug Administration needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco.

The tobacco industry currently spends over $15 billion each year to promote its products. Much of that money is spent in ways designed to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risk. Four thousand children have their first cigarette every day, and one thousand of them become daily smokers. The industry knows that nearly 90 percent of smokers begin as children and are addicted by the time they reach adulthood.

Documents obtained from tobacco companies prove, in the companies' own words, the magnitude of the industry's efforts to trap children into dependency on their deadly product. Studies by the Institute of Medicine and the Centers for Disease Control show the substantial role of industry advertising in decisions by young people to use tobacco products.

If we are serious about reducing youth smoking, FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. This legislation will give FDA the authority to stop tobacco advertising that glamorizes smoking to kids. It grants FDA full authority to regulate tobacco advertising "consistent with and to the full extent permitted by the first amendment."

FDA authority must also extend to the sale of tobacco products. Nearly every State makes it illegal to sell cigarettes to children under 18, but surveys show that those laws are rarely enforced and frequently violated. FDA must have the power to limit the sale of cigarettes to face-to-face transactions in which the age of the purchaser can be verified by identification. This means an end to self-service displays and vending machine sales. There must also be serious enforcement efforts with real penalties for those caught selling tobacco products to children. This is the only way to ensure that children under 18 are not able to buy cigarettes.

The FDA conducted the longest rulemaking proceeding in its history, studying which regulations would most effectively reduce the number of children who smoke. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the Agency promulgated rules on the manner in which cigarettes are advertised and sold. Due to litiga-

tion, most of those regulations were never implemented. If we are serious about curbing youth smoking as much as possible, as soon as possible; it makes no sense to require FDA to reinvent the wheel by conducting a new multi-year rulemaking process on the same issues. This legislation will give the youth access and advertising restrictions already developed by FDA the force of law, as if they had been issued under the new statute. Once they are in place, FDA will have the authority to modify these rules as changing circumstances warrant.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, and in all print advertisements. These warnings will be more explicit in their description of the medical problems which can result from tobacco use. The FDA is given the authority to change the text of these warning labels periodically, to keep their impact strong.

The nicotine in cigarettes is highly addictive. Medical experts say that it is as addictive as heroin or cocaine. Yet for decades, tobacco companies vehemently denied the addictiveness of their products. No one can forget the parade of tobacco executives who testified under oath before Congress that smoking cigarettes is not addictive. Overwhelming evidence in industry documents obtained through the discovery process proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated the nicotine in their products to make it even more addictive.

A newly released analysis by the Harvard School of Public Health demonstrates that cigarette manufacturers are still manipulating nicotine levels. Between 1998 and 2005, they significantly increased the nicotine yield from major brand name cigarettes. The average increase in nicotine yield over the period was 11 percent.

The tobacco industry has a long, dishonorable history of providing misleading information about the health consequences of smoking. These companies have repeatedly sought to characterize their products as far less hazardous than they are. They made minor innovations in product design seem far more significant for the health of the user than they actually were. It is essential that FDA have clear and unambiguous authority to prevent such misrepresentations in the future. The largest disinformation campaign in the history of the corporate world must end.

Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public. Over 40 million Americans are currently addicted to cigarettes. No responsible public health official believes that cigarettes should be banned. A ban would leave 40 million people without a way to satisfy their drug dependency. FDA should be able to take the necessary steps to help addicted smokers overcome their addiction, and to make the product less toxic for smokers who are unable or unwilling to stop. To do so, FDA must have the authority to reduce or remove hazardous ingredients from cigarettes, to the extent that it becomes scientifically feasible. The inherent risk in smoking should not be unnecessarily compounded.

Recent statements by several tobacco companies make clear that they plan to develop what they characterize as "reduced risk" ciga-

rettes. Some are already on the market making unsubstantiated claims. This legislation will require manufacturers to submit such "reduced risk" products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA's satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety.

This legislation will vest FDA not only with the responsibility for regulating tobacco products, but with full authority to do the job effectively. It is long overdue.

Enacting this bill this year is the right thing to do for America's children. They are depending on us. By passing this legislation, we can help them live longer, healthier lives.

The CHAIRMAN. Senator Enzi.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you, Mr. Chairman. Good morning. I'd like to thank my colleague, Senator Kennedy, for calling this hearing. I believe it is always a good idea to discuss controversial issues like this one in order to better educate ourselves and the American people about the problem and the possible solutions.

We can all agree on what our common interest is, which is stopping people of all ages from starting to smoke and convincing current smokers to quit that deadly habit. While the tobacco industry may seemingly share our views on teen smoking, I am one who doubts they have bought into the idea of getting adult smokers to stop smoking.

The bill that is now before the Senate proves this point. Today we should ask ourselves, what will it mean to have cigarette and tobacco products truly regulated by the Food and Drug Administration? The FDA is the gold standard among public health regulators the world over. For the past century, the FDA has protected the public from filthy conditions in meat packing plants to thalidomide, which caused thousands of birth defects in Western Europe. The FDA's constant vigilance is not just a historical artifact. Last week, there was a recall of peanut butter due to salmonella contamination and baby food that had been tainted with botulism. This is how we've come to depend on the FDA every day to protect us and our children from poisons that could harm or even kill us.

Senator Kennedy and I have worked on FDA issues for the last 2 years. We held 10 hearings on the FDA during the 109th Congress. Again and again, we focused on the FDA's role in protecting and promoting the public health.

In all of our work together, it was evident that the FDA is overworked and under funded. We as a Nation currently ask the FDA to be responsible for so many things: ensuring that new drugs and medical devices are safe and effective, safeguarding the Nation's food supply, regulating the manufacture and distribution of food additives and drugs that will be given to animals and increasingly, the security of our blood supply.

In each of these key activities, the role of the FDA is to protect our health. In providing that protection, the FDA examines key scientific facts and ways to balance the benefit to our society and risks to our health. It baffles me why we are here today to talk

about the FDA doing a risk/benefit analysis of tobacco and cigarettes. Everyone agrees that smoking kills. There is no such thing as a safe cigarette. Any public statement by the FDA under their current authority would necessitate the finding that there is no benefit to the use of cigarettes—only harm.

The bill now before Congress would establish the FDA as a regulator for tobacco products. However, the bill explicitly states that the FDA will not be permitted to prohibit the sale of any tobacco product to adults 18 years or older. That's not true regulation. The bill would gut the authority that Congress has bestowed and staunchly defended for the FDA—the authority to remove health threats from the marketplace. Having the FDA review and approve cigarettes sends mixed and confusing messages to the public, creating the sense that cigarettes are safe or made safer. I can see it now. Tobacco companies being let off the hook in court because they can now say, "But judge, our product was reviewed and approved by the FDA." The FDA can not be put in the position of approving a product that years of science and personal experience for far too many Americans have shown to be dangerous. Simply put, it kills people.

So what can we do? I recognize we can't change behavior overnight but the data on smoking are trending in the right direction. Fewer people smoke and teenage smoking is down dramatically. We can always do more with educational outreach efforts.

Where are the funds going to come from? I recognize that the money from the Master Settlement Agreement, MSA, with 46 States came with no strings attached. We all know the genesis of the agreement was States suing for the cost of healthcare for smokers and former smokers. The spirit of that agreement was that the funds would be used for healthcare for smokers and former smokers, however that is not how the money is being spent. As the GAO will highlight later today, on average, States are spending less than 5 percent of the MSA funds on tobacco control and prevention, and the spending on healthcare items such as SCHIP may not be focused on assisting smokers with severe health conditions due to their use of cigarettes. While States are spending their funds on a variety of projects, they are not spending key funds on the care of smokers and former smokers or preventing tobacco use in the first place.

In fiscal year 2007, only three States—Maine, Delaware and Colorado, are meeting the CDC minimum recommendation of 8 percent of spending on tobacco prevention. The combined total the States are spending on tobacco prevention amounts to just 2.8 percent of the $21.7 billion in tobacco generated revenue the States will collect this year from the tobacco settlement and tobacco taxes. I think the States can do better.

The FDA approves cures not poisons. Forcing the FDA to regulate tobacco but not letting them ban it would undermine the long history of the agency protecting and promoting the public health. I ask my colleagues to think hard about what they are proposing. My record is clear when it comes to tobacco. I am no friend to big tobacco and I have never taken a dime of tobacco money. I don't intend to start now. I absolutely reject the notion that the way to show that you are for kids and against tobacco is by sending the

Nation's premiere public health watchdog out to fight for safety with one hand tied behind its back and allowing this premiere agency to provide its FDA seal of approval on a deadly product that has no health benefit.

Now, I have a number of statements from outside groups regarding this legislation. I ask unanimous consent that they be entered into the hearing record. I would mention that I think Philip Morris, by mistake, sent me their letter. I would still ask that it be made a part of the record but I would suggest that big tobacco figures that if the FDA controls tobacco, the cigarettes will have to be put behind the counter where nobody can see other brands, particularly not 18-year-olds, that will give the established brands a big push.

So I look forward to the testimony today and hope that we can do better.

[**Editor's Note: The materials presented by Senator Enzi may be found in Additional Materials.**]

The CHAIRMAN. Well, there you go. I look forward to our panel, their testimony.

Senator BURR. Mr. Chairman, could I ask consent of the Chair and of my colleagues to allow me to make an opening statement?

The CHAIRMAN. Sure. I'd like to accommodate you because this issue obviously has a particular, very special effect on your State. My colleague, Senator Brown, who is going to another hearing, wanted to say a brief word, too. We're trying to accommodate schedules as best we can but still try to keep this process moving. But I'll be glad to let both of you speak.

Senator Brown.

OPENING STATEMENT OF SENATOR BROWN

Senator BROWN. Thank you, Senator Burr and thank you Mr. Chairman. Senator Enzi, thank you for recounting the proud history of the Food and Drug Administration and the terrific work it has done for decades. I appreciate that. And Senator Kennedy, thank you for your work on tobacco issues.

Generally, the story of tobacco addiction is all too familiar for far too many of our young people. In my State of Ohio, 20 percent or 134,000 it is estimated, high school students smoke. Over 18,000 kids under the age of 18 become new daily smokers each year. The CDC estimates that in just this one State, 293,000 kids under the age of 18 will die prematurely as a result of smoking. These children are not aware of these staggering statistics when they tried their first cigarette but we are aware of these staggering statistics. That's why it's our responsibility to make sure our children are safe and don't fall victim to that unhealthy addiction.

I applaud the Chairman for holding this hearing and introducing bipartisan legislation that would grant the FDA authority to regulate tobacco products. Congress has a responsibility to the Nation to ensure that children are safe and are not the victims of suggestive marketing by tobacco companies and has an equal responsibility to ensure that citizens are protected from dangerous chemicals and are aware of all their risks associated with smoking. The Chairman's bill will give the FDA the authority to regulate tobacco as it does any other drug. I totally support this legislation. I again thank the Chairman for holding these hearings.

I, for about a decade, was the Ranking Democrat on the Health Subcommittee in the House and saw so much of this testimony and heard so much about this issue. It's time finally that the Senate and the House act. Thank you.

The CHAIRMAN. Thank you very much, Senator Brown. I appreciate your comments and your presence here.

Senator Burr.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman. Mr. Chairman, you should be applauded for bringing this up and you and I have a rich history of working on this issue when I was in the House. We share concerns.

Clearly, coming from North Carolina, I am somewhat passionate about this issue and as I told Matt Myers, we've been doing this a long time. The only difference is, we've both aged.

The approach that we are still taking today is exactly what we took 13 years ago when we first started this but so much has changed. The master settlement brought a lot of changes to the long list of advertising, the target of children, the use of cartoon characters, the sponsorship of sporting events—places where kids might be influenced. It's all gone.

But the framework of regulation that we've chosen to do is still the same thing. It doesn't take into account that. I'm not here to go through a long laundry list of items that I might take a different road than maybe what the Chairman would take.

I would only say this—that some who have read this bill suggest that it shields the tobacco companies in the future from liability. Some have read the bill and said, "This is a pathway to the elimination of tobacco products." And quite frankly, I'm not sure that any of us know what will happen if this legislation becomes law.

I think there are some assumptions that we can make that are fairly accurate and I just want to point everybody toward the FDA today. The FDA and its jurisdictions—the authority that the FDA currently has of 25 cents of every dollar of U.S. economy—this is not just about whether, in fact, the blood is safe, whether drugs and biologics and medical devices are, in fact, approved, labeled correctly and monitored for advertising effectively. It's a question of whether the safety of the system has been maintained and Sherrod worked with me on FDA modernization, now 12 years ago. The No. 1 objective was to make sure that that gold standard was preserved.

But there is so much that is currently in the FDA jurisdiction and that we count on as Americans. It's not just about children. This is about every American and a system that we are reliant on for our health.

The reality is that we all have to ask ourselves, is this the appropriate place to put all the regulatory responsibility of the most regulated industry in America? I'm going to ask for the other chart to go up.

To hear some describe the lack of regulation, the lack of oversight on this industry ignores the current regulatory framework that is in this country. Now granted, some of the Federal agencies have certain tobacco regulations internal to their areas of the Gov-

ernment. But when you look at the Department of Agriculture, when you look at the Federal Trade Commission, when you look at HHS, what you find is, you find the most regulated industry in America today before we ever talk about passing a bill.

So, Mr. Chairman, it's only my hope and my pledge to you and to our panelists, who are passionate and knowledgeable on many of the issues, that it is my hope that we will throw away that template that we created 13 years ago, that we will focus on the areas where I think we need to make progress. I think it is reasonable to say, what does it take to assure Matt Myers that children are not the target of advertising, of marketing, of promotion? But what allows us to continue some degree of marketing to consenting adults.

I used to be a tobacco smoker. I'm not today. You can quit. My children never started. They may be an anomaly. I don't think they are. It is reasonable for us as legislators, to expect that we can create a framework that provides more information for adults to make better choices? I think that is where our responsibility lies. When we can bring to the table new information, better information about the health consequences, then adults can choose, in fact, whether they want to participate in the use of this product.

Mr. Chairman, it is my hope that over the next days, weeks, months—whatever your timeline is—that we can sit down in an informal capacity and talk about a different framework, one hopefully that we would find tremendous agreement on where we end up, but possibly the flexibility of how we accomplish that might be left up to something other than the formal hearing process. I think we can achieve that and I look forward to working with the Chairman. I thank you.

The CHAIRMAN. Well, thank you very much, as always, a very provocative and well stated view, Senator. I think this has been helpful in trying to establish a framework. We've got a very experienced panel that have strong views from their vantage points. We all hope that they might be able to catch the spirit of this hearing. We've heard pretty diverse views about how we ought to approach it and the witnesses will be able to add to their own comments what they might, in terms of responding to some of these issues.

We have very distinguished witnesses. Let me introduce three panelists at a time and then I will introduce the others after the first group has spoken. I think that is probably the most effective way to proceed.

So we'll start with Matthew Myers, President and CEO of the Campaign for Tobacco-Free Kids, a privately funded organization established to reduce tobacco use and its devastating consequences in the United States and around the world. For over 25 years, Mr. Myers has participated in virtually every major national tobacco-related legislative effort, worked with State tobacco prevention advocates and officials around the country. In 1999, Mr. Myers was asked to serve on the first advisory committee established to advise the Director General of the World Health Organization on tobacco issues. In October 2004, Harvard School of Public Health bestowed its highest honor, the prestigious Julie Richmond Award on Mr. Myers for his work as an advocate in preventing tobacco industry marketing to children.

Elmer Huerta is the President-Elect of the National Board of Directors of the American Cancer Society, and a member of the American Cancer Society Action Network. Dr. Huerta is currently Director of the Cancer Preventorium at the Washington Cancer Institute at the Washington Hospital Center in Washington, DC., founded in 1994. He is President and Founder of Prevención, a nonprofit company dedicated to the production and dissemination of educational materials for the Latino community. He was a founding member of the Board of Directors of the American Legacy Foundation. He is a prominent figure on Spanish language radio and television.

Dr. Richard Land—Princeton and Oxford educated—has served as President of the Southern Baptist Convention Ethics and Religious Liberty Commission since 1988. He represented the Evangelicals before Congress and U.S. Presidents, and is a three-time commissioner of the U.S. Commission in National Religious Freedom. In 2005, Time named Dr. Land one of the 25 most influential Evangelicals. A renowned scholar, Dr. Land has worked as a pastor, a theologian and a public policymaker. He is a leading member of Faith United Against Tobacco.

I'm very grateful to have these three individuals here today.

Let's begin with Mr. Myers.

STATEMENT OF MATTHEW L. MYERS, PRESIDENT AND CEO OF THE CAMPAIGN FOR TOBACCO-FREE KIDS, WASHINGTON, DC

Mr. MYERS. Chairman Kennedy, Senator Enzi, Senator Burr and members of the committee, thank you very much for the opportunity to testify today.

S. 625, in the view of virtually every major public health organization, has the potential to save literally hundreds of thousands if not millions of lives. Rarely is Congress faced with an opportunity to do exactly that.

Today, tobacco—America's most dangerous consumer product, despite what Senator Burr said, is also the one consumer product that no Federal agency oversees for health and safety purposes, despite its other regulatory framework. This carefully crafted, thoughtfully balanced legislation would correct that glaring problem and bring to tobacco the kind of government oversight that is already provided to other consumer products.

As you know, S. 625 was only introduced on February 15, but the need for legislation giving FDA regulatory authority over tobacco has been debated for years. Indeed, a bill virtually identical to S. 625 was debated and overwhelming approved by the full Senate twice in 2004.

S. 625 has been examined by virtually every major public health organization in this country. It has broad bipartisan support, including liberals and conservatives and Senators from every geographic region of the country. It has been endorsed by every major national public health organization, many organizations representing healthcare providers as well as representative of a wide range of faith groups.

As the letter attached to my testimony reflects, support for this legislation is a virtual Who's Who of this Nation's health community and includes 48 national organizations. Rarely do you see this kind of consensus.

The need for FDA regulation is also supported by a wide range of Americans. We have just conducted a nationwide poll and found that 69 percent of voters favor FDA regulation of tobacco products. What is interesting about that poll is, that number does not vary by geographic region and it is also extraordinarily strong in the tobacco growing country.

As you said, Senator Kennedy, more than five decades after the Surgeon General's historic 1964 report, more than 400,000 Americans die prematurely every year from tobacco. That's roughly 1,200 people every single day. The critical word is prematurely. While some hope that the Master Settlement Agreement would end tobacco marketing to kids, as Federal Judge Gladys Kessler found just last August, the tobacco manufacturers continue to market in ways that appeal to young people and continue, to this day, to recruit children as new tobacco users. While helpful, the MSA addressed less than 20 percent of the marketing and promotional expenditures of the tobacco company and it did not even completely eliminate those practices.

Indeed, between 1998 and 2003, the last year for which we have data, promotional expenditures by cigarette companies rose from $6.73 billion a year to a staggering $15.15 billion a year. That means today and every day, the tobacco companies will spend more than $41 million marketing their products. We need to do more.

This legislation will provide FDA with the authority it needs to appropriately oversee the marketing, manufacture and sale of tobacco products. In a nutshell, this bill ensures that oversight of tobacco is based on sound science and conducted by an agency and personnel with scientific expertise and the ability to make adjustments based on new scientific evidence.

For the reason that FDA has previously been given authority of other products, the FDA is the only agency that possesses these qualities. It requires the tobacco industry to make the type of disclosures to FDA that other manufacturers are already required to make. It establishes commonsense standards for product regulations that are practical, achievable and directed toward protecting the public. It recognizes, as Senator Enzi did, that how a product is marketed can also have a major impact on the number of people who needlessly die from tobacco, both in terms of encouraging use and discouraging quitting.

Last and very importantly, it provides the FDA with the resources to do the assigned job capably and without detracting from FDA's other important missions. It should be noted that this legislation provides an independent source of funds for FDA to adequately do the job but even that independent source of funds would amount to no more than about 2½ cents per pack.

Let me just highlight one or two things quickly so that I don't use much time. Marketing—the bill would put in place a number of specific advertising restrictions that FDA has previously determined after a 2-year investigation, have the greatest impact on tobacco use on children, practices that continue until today.

And most importantly, it would authorize FDA to take further action as new marketing practices are discovered, to address those but in ways that are extraordinarily sensitive to the first amendment.

In terms of the new products and the products today on the market, today tobacco products contain more than 60 known cancer-causing substances and the incidence of disease among smokers, shockingly, has actually increased—not decreased, over the years. No Federal agency, no State agency currently has the authority to require tobacco companies to make technologically feasible changes to tobacco products to reduce the number and quantity of harmful substances in those products.

For the first time in history, this bill gives a Federal agency the authority to require those kinds of changes in both new and existing products.

Let me address an important issue. This bill does not use the same standards to evaluate products as is used for drugs. It recognizes that the standard FDA normally applies to many products under its jurisdiction, whether the product is safe and effective, does not make sense for tobacco products. There are approximately 50 million Americans already using these highly addictive products and there is no such thing, I think we can all agree, of a safe cigarette.

The CHAIRMAN. I'm going to ask you to begin to wind up, please.

Mr. MYERS. I just have about 1 minute left. Thus, the standard in this bill—but the fact that the current standard doesn't apply doesn't mean there isn't anything we can do. The standard in this bill is one based on what actions are appropriate to protect the public health, which in this case, means those actions that will reduce the number of people likely to die from tobacco. Changes to tobacco products today can reduce those harms.

Last, critically, this would prevent tobacco companies from making the kind of unsubstantiated health claims as they have for light and low-tar tobacco products and for a whole new generation of products, which have undermined efforts by the States and others, to encourage people to quit. This bill would eliminate the terms light and low-tar, producing an immediate benefit and equally important is it would set meaningful, reasonable scientific standards that would require a tobacco company to prove to FDA that any product for which they wanted to make a claim actually would result in a reduction in risks to both individual consumers and the population as a whole.

In conclusion, Senator Kennedy and members of the committee, this bill is a thoughtful, balanced approach to a problem that has plagued this Nation for over 50 years. It isn't perfect but it will result in literally hundreds of thousands of lives being saved.

Thank you.

[The prepared statement of Mr. Myers follows:]

PREPARED STATEMENT OF MATTHEW L. MYERS

Chairman Kennedy, Senator Enzi, and members of the HELP Committee, thank you for this opportunity to testify in support of S. 625, a bill to provide the U.S. Food and Drug Administration (FDA) with the authority to effectively regulate tobacco products and their marketing and to reduce the harms associated with tobacco use. My name is Matthew Myers, and I am President of the Campaign for Tobacco-Free Kids, the Nation's largest nonprofit, advocacy organization solely devoted to reducing the harm caused by tobacco use and exposure to secondhand smoke.

S. 625 has the potential to save many lives. Today, America's most dangerous consumer product—tobacco—is also the one consumer product that no Federal agency oversees for health and safety purposes. This carefully crafted, thoughtfully bal-

anced legislation would correct that glaring problem and bring the type of government oversight to the manufacture, marketing and sale of tobacco products that is already provided to other consumer products.

As you know, S. 625 was introduced on February 15, 2007, but the need for legislation giving FDA authority over tobacco has been discussed for years, and legislation similar to S. 625 has been before the Senate for close to a decade. A bill virtually identical to S. 625 was debated and overwhelmingly approved by the full Senate in 2004.

It is essential for Congress to act if the public is to be protected. In 1996, after a 2-year investigation, the U.S. Food and Drug Administration asserted jurisdiction over tobacco under current law. Then, in March 2000, the U.S. Supreme Court ruled that the FDA did not have the statutory authority to regulate tobacco products, and that only Congress could grant FDA this authority. In a highly unusual commentary, the Court urged Congress to act given the seriousness of the public health problem.

Thus, it is no surprise that S. 625 has broad bipartisan support including liberals and conservatives and Senators from every geographic region of the country. It has been endorsed by every major national public health organization, many organizations representing health care providers, and representatives of a wide range of faith groups. Virtually identical legislation was also previously endorsed by every major tobacco-farming group.

The Campaign for Tobacco-Free Kids has measured voter support for FDA regulation of tobacco products and, not surprisingly, it has broad support across the country, with 69 percent of voters in a national poll favoring. State surveys from around the country have consistently found similarly high levels of support, crossing party and ideological lines. It even has majority support among smokers. Voter support is particularly strong for the specific provisions of FDA regulation. When asked if tobacco companies should be required to take measures to make cigarettes less harmful; if tobacco companies should be prevented from making claims that some products are less harmful than others unless FDA determines those claims are true; or if FDA should restrict tobacco marketing aimed at children, voter support for each of these elements exceeds 75 percent.

It is truly time for Congress to act.

WHY THIS BILL IS NEEDED

S. 625 is essential for the protection of the public health. More than five decades after the Surgeon General's historic 1964 report, more than 400,000 Americans die prematurely every year from tobacco, roughly 1,200 people every day. The critical word is "prematurely." Fifty percent of the people who die from tobacco die in middle age, and almost every one of those deaths is a person who started smoking and became addicted before they were old enough to be sold tobacco products legally.

Death from tobacco is almost always the last chapter of a book that begins in childhood. Every day, approximately 4,000 kids will try a cigarette for the first time. Another 1,000 will become new, regular daily smokers, and one-third of these kids will eventually die prematurely as a result.

While some hoped that the 1998 Master Settlement Agreement (MSA) would end tobacco marketing to children, Federal District Court Judge Gladys Kessler found last July that the tobacco manufacturers continue to market in ways that appeal to young people and continue to recruit children as new tobacco users. The MSA, while helpful, addressed less than 20 percent of the marketing and promotional expenditures by the tobacco companies, and it did not completely eliminate even those practices. The tobacco companies have easily overcome these restrictions by dramatically increasing marketing expenditures and constantly finding new and sophisticated ways to market their products, many of which impact kids. Between 1998, the year of the MSA, and 2003, the latest year for which data are available, the major cigarette companies more than doubled their marketing and promotional expenditures from $6.73 billion to a staggering $15.15 billion—more than $40 million each and every day—much of it aimed at kids. As Judge Kessler concluded in her opinion:

> "In fact, the overwhelming evidence set forth in this Section—both Defendants' internal documents, testimony from extraordinarily qualified and experienced experts called by the United States, and the many pictorial and demonstrative exhibits used by the Government—prove that, historically, as well as currently, Defendants do market to young people, including those under 21, as well as those under 18. Defendants' marketing activities are intended to bring new, young, and hopefully long-lived smokers into the market in order to replace those who die (largely from tobacco-caused illnesses) or quit."

It's no wonder that our surveys continue to show kids are almost twice as likely as adults to remember tobacco advertising.

Judge Kessler also concluded that tobacco company marketing to kids is likely to continue in the future:

> "Similarly, Defendants continue to engage in many practices which target youth, and deny that they do so. Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents. Defendants are well aware that over 80 percent of adult smokers began smoking before the age of 18, and therefore know that securing the youth market is critical to their survival. There is therefore no reason, especially given their long history of denial and deceit, to trust their assurances that they will not continue committing RICO violations denying their marketing to youth."

In addition to allowing virtually unfettered promotion of tobacco products, the absence of any meaningful regulation continues to allow the tobacco industry to manipulate their products in ways that can make them more addictive and/or more harmful. The introduction of so-called reduced risk products, with no oversight, can also deceive consumers and undermine their efforts to reduce their risk by luring them into switching to products that they falsely believe are less hazardous rather than quitting. It can also attract new smokers with the promise of less harm.

The lesson is clear: more must be done. The status quo is not working and current efforts are inadequate. The need for FDA oversight of the tobacco industry is as great today as ever:

- The tobacco industry continues deceptive marketing that undermines prevention efforts and appeals to children.
- Tobacco products remain toxic and addictive and tobacco companies are free to manipulate products to make them more appealing and addictive.
- There continue to be unsubstantiated health claims made for new and low tar products.
- There are still critical gaps in the industry's acknowledgement of the health effects of their products.

WHAT THIS BILL WILL DO

This legislation will provide the FDA with the authority it needs to appropriately oversee the marketing, manufacture and sale of tobacco products. This authority will benefit public health by reducing illegal sales of tobacco to kids, by limiting marketing that targets kids to begin smoking and misleads smokers to discourage them from quitting, by ensuring that new products that purport to reduce harm actually do so, and by requiring tobacco companies to make changes in the products that make them less harmful to smokers unable to quit.

Key principles of the legislation include:

- Ensures that oversight of tobacco is based on sound science and conducted by an agency and personnel with scientific expertise and the ability to make adjustments based on new scientific evidence;
- Requires the tobacco industry to make the type of disclosures to FDA that other manufacturers are already required to make and that are essential to enable the agency to make well-informed decisions and take effective action;
- Establishes common-sense standards for product regulation and agency action that are practical, achievable and directed toward a single common goal—to protect the public health and reduce the number of Americans who die prematurely as the result of their use of tobacco products;
- Recognizes that how a product is marketed can also have a major impact on the number of people who needlessly die from tobacco use and establishes marketing standards that are both consistent with the first amendment and the FDA's public health mission; and
- Provides the FDA with the resources to do the assigned job capably and without detracting from FDA's other important missions.

I want to highlight just a few key provisions of the bill and also address some of the concerns that have been raised about the legislation.

Marketing.—Since the Master Settlement Agreement, the tobacco industry has more than doubled its marketing expenditures with knowledge of the impact of its marketing on children; continued marketing "light" and "low tar" cigarettes despite the evidence that they do not reduce the risk of disease and the public is misled by how they are labeled and sold; and introduced new tobacco brands backed by new unsubstantiated and unproven health claims that mislead the public. It has become

even clearer that State lawsuits, prior voluntary codes, and current laws have not prevented the tobacco industry from marketing to children or misleading the public.

This bill would put in place a number of specific advertising restrictions that FDA previously determined, after a 2-year investigation, impact tobacco use by children; would require the elimination of the use of the terms "light," "low tar" and similar terms unless the industry could scientifically demonstrate that products labeled "light" and "low tar" actually reduce the risk of disease; and would otherwise prevent the use of other health claims unless a manufacturer presents scientific evidence to support those claims. These are not radical concepts. Manufacturers of other products regulated by FDA are not allowed to make claims without adequate scientific substantiation because of the adverse impact on the health of potential consumers. This bill would finally force the tobacco industry to play by these reasonable rules.

Equally as important, this bill recognizes that the tobacco industry has often circumvented rules designed to curtail both marketing to children and misleading of the public and provides FDA the needed authority to adopt new rules to address new conditions as they arise.

Any advertising regulations must be consistent with the first amendment. The bill states that the authority to develop regulations that impose restrictions on the advertising and promotion of tobacco products must be consistent with, but can be exercised to the full extent permitted by, the first amendment. Given the history of the tobacco industry's aggressive and misleading marketing, strong authority to restrict marketing is justified.

The kinds of Federal restrictions on tobacco marketing contained in S. 625 are consistent with the U.S. Supreme Court's analysis in *Lorrilard Tobacco Company* v. *Reilly*. They would survive constitutional challenge because they are carefully tailored, scientifically proven measures to protect the recognized legitimate interests of the government in protecting (1) children from marketing that contributes to tobacco addiction and (2) adults from misleading marketing that encourages tobacco use and discourages quitting. Federal action is clearly needed because over 50 years of voluntary and State governmental efforts to change the tobacco industry's behavior have not solved the problem.

Establishing Appropriate Standards for the Content of Tobacco Products.—Today, tobacco products contain more than 60 known cancer-causing substances, and the incidence of disease among smokers has actually increased, not decreased, over the years, according to the National Cancer Institute.[1] Even as the tobacco industry touted that it had reduced tar and nicotine levels in its products, the level of potent carcinogens, like nitrosamines, increased without any public agency having any authority to evaluate the impact of that change.

No Federal agency currently has the authority to require tobacco companies to disclose, in a meaningful way, what is in each product;[2] to require manufacturers to provide evidence of the impact of product changes; or to require manufacturers to make technologically feasible changes to products to reduce the number or quantity of harmful substances in tobacco products and the smoke of tobacco products. S. 625 would address this gap in a practical and reasonable way. It recognizes that the standard FDA normally applies to many products under its jurisdiction—whether the product is "safe and effective"—does not make sense for tobacco products because there is no such thing as a "safe cigarette." A "safe and effective" standard would thus dictate a total ban on tobacco products, and with close to 50 million Americans addicted to tobacco use, virtually all public health experts recognize this as infeasible and unproductive. S. 625 recognizes that the goal is therefore to reduce the number of people who needlessly die prematurely from tobacco use. Thus, the standard in the bill is one based on what actions are "appropriate to protect the public health," taking into account the impact of any proposal on the health of the "population as a whole, including users and nonusers" of tobacco products. The bill puts in place measures to prevent kids from starting to smoke and to ensure that smokers are not dissuaded from quitting by misleading claims, and it establishes a process to reduce the harm from tobacco products to those who are unable to quit.

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[1] Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October, 2001. *http://cancercontrol.cancer.gov/tcrb/monographs/13/*.

[2] The ingredient disclosure requirements of the 1984 Comprehensive Smoking Education Act have proven wholly inadequate for this purpose. They do not provide the government with information to identify what chemicals and other ingredients are in each brand of cigarettes, the quantity of the different chemicals, in each cigarette or the type of information that is needed to understand or evaluate or warn the public about what is in each brand of cigarette.

The standard in S. 625 recognizes the unique issues raised by the regulation of tobacco products. This standard looks at the overall impact on the number of people who will die needlessly from tobacco and allows the FDA to broadly consider all factors that will affect whether a proposed product change will increase or decrease the death and disease caused by tobacco. It instructs the FDA to look at how a mandated product change will impact individual tobacco users but also look at its impact on the number of tobacco users by examining its effect on discouraging smokers from quitting or encouraging nonsmokers to start. The goal is protecting the pubic and saving lives, and the standard set forth in S. 625 is right on the mark.

Preventing Unsubstantiated Health Claims While Encouraging Real Scientific Innovation to Reduce the Harm Caused by Tobacco Products.—For decades, tobacco manufacturers have been marketing "light" and "low tar" products with claims that these cigarettes are less risky, leading millions of consumers to switch to these products thinking they are actually reducing their risk of disease or that they were taking a first step toward quitting. The National Cancer Institute, the U.S. Surgeon General and other credible scientific bodies have subsequently concluded that "light and "low tar" products did not reduce the risk of disease and did deter millions of smokers from quitting. Subsequent to the release of the scientific evidence demonstrating that "light" and "low tar" products have not reduced the risk of disease, tobacco companies have continued to mislead consumers and have come out with new products whose advertising includes even more specific claims of reduced risk.

The absence of any regulatory body to review health claims has led to a public health tragedy that has thwarted the well-intended personal efforts of tobacco users who have attempted to reduce their risk of disease. This bill would address that problem in a manner consistent with sound scientific standards. It requires FDA to prevent unsubstantiated and unproven claims, while permitting a manufacturer who produces a genuinely less hazardous product, and develops sound scientific evidence of its impact, to responsibly make claims about any such innovative product.

This provision by itself has the potential to save many lives. Before a manufacturer can make a health claim for a product, the legislation simply requires that manufacturer to demonstrate to FDA that the product significantly reduces the risk of disease when compared to other tobacco products, and when used in the manner a consumer will actually use the product. It also requires the manufacturer to show that any public health benefit for individual users will not be offset by the harm caused by marketing of the product resulting in increased tobacco use or decreased cessation.

This section will benefit manufacturers who develop a genuinely safer product and will adversely impact only those manufacturers who have been making unproven claims or marketing their products in ways that encourage nontobacco users to start or discourage potential users who would otherwise quit.

Concerns of Tobacco Product Retailers.—Convenience store owners have expressed concerns about provisions in the bill, including those that require retailers to check the ID of young persons seeking to purchase tobacco products. The youth access provisions of the original FDA regulations in place from 1996 to 2000 were effective in reducing illegal sales to youth. Congress appropriated funding for this program, and FDA enforced the youth access restrictions, not by employing Federal agents, but by contracting with State and local officials, such as health departments and police departments. By 2000, the FDA had contracts with every State to conduct the compliance checks and had an extensive outreach program that provided resources and information to retailers. This was a program that was producing solid results in reducing illegal youth access to tobacco in a manner sensitive to State and local interests.

Although this bill does hold store owners responsible for illegal tobacco sales to children, it establishes detailed procedures to protect retailers who diligently require young people to show government-issued IDs, including procedural protections that were not in place between 1996 and 2000. In addition, no fines are incurred until repeated violations occur, and retailers are warned after the first violation that additional compliance checks will be conducted. The only retailers who will be punished will be those who repeatedly sell tobacco to kids illegally.

Impact on FDA's Ability to Regulate Food, Drugs, Devices and Other Products Currently Under Its Jurisdiction.—We recognize that there are concerns about FDA's resources and whether it is successfully carrying out its current responsibilities. The expectation is that FDA would create a new office and hire additional staff to carry out the activities required by this legislation. The new responsibilities would be funded through a user fee on the tobacco industry, so it would have no impact on the funding provided to FDA to carry out its other important activities. The user fees are allocated among the manufacturers of tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S.-

tobacco product market. Many of the groups that support this legislation care deeply about the many important tasks of the FDA including drug and device approval and the work the agency does to protect our food supply. But we also believe that a key to improving the Nation's health is reducing the harm caused by tobacco products.

Impact on Tobacco Companies.—Some tobacco companies have argued that this bill will give an advantage to one tobacco manufacturer over others, claiming that certain tobacco companies can more easily comply with stringent FDA regulations and that industry leaders will benefit by the bill's restriction of tobacco marketing. Neither argument has any merit.

When the FDA sets safety standards for foods and drugs, its focus is on safety and efficacy, not the size of the manufacturer or the impact on market share. For those other products, the only manufacturers who are hurt are those who can't meet FDA's public health standards. This bill does the same for tobacco products and creates a level playing field for all manufacturers. The bill's marketing restrictions are also fair and balanced. Today, close to 90 percent of all new long-term smokers are children. It is a strength of this legislation, not a weakness, that it provides a comprehensive attempt to restrict marketing that appeals to children. The tobacco industry claims its marketing is about brand competition among smokers; the industry's own documents and Judge Kessler's decision last August reflects powerful evidence that the industry's advertising is a major contributor to tobacco use by youth. What is of paramount importance to public health is the size of the overall market for tobacco products, NOT the market share of any particular company. We believe that this legislation will significantly reduce the number of people who use tobacco and who become sick and die as a result.

State and Local Authority.—The legislation achieves a reasonable balance between Federal and State or local authority over tobacco. It allows the States to continue to regulate the sale, distribution, and possession of tobacco products and would expand State authority to regulate tobacco product marketing. To ensure consistent product standards nationally, however, the legislation reserves to the Federal Government the right to regulate the product itself, which is consistent with the way the FDA regulates other products under its jurisdiction.

We believe that States and localities ought to be able to control the time, place and manner of tobacco advertising in their communities, and this legislation will allow them to do that for the first time in almost 40 years. The bill cuts back, but does not fully eliminate, the exemption for the tobacco industry passed in 1969 as part of the Federal Cigarette Labeling and Advertising Act. That act prevented the States from regulating cigarette advertising, even purely local forms of cigarette advertising. The bill returns to State and local governments the ability to impose limitations on the time, place and manner of marketing and advertising practices, but not on the content of ads. The States already have this authority for smokeless tobacco products and other products regulated by FDA, and it has not created problems for the marketplace.

The sponsors of this legislation were careful to specifically make clear that the legislation does not curtail any of the areas States have traditionally used to reduce tobacco use. Under the legislation, State and local governments would continue to be free to adopt measures regulating exposure to secondhand smoke; restricting youth access to tobacco products; and enacting fire safety standards for tobacco products. In short, the bill in no way restricts States from pursuing policies such as smoke-free laws, tobacco taxes, fire-safe measures, age requirements, identification checks, retailer licensing and fines, and other restrictions on the sale and distribution of tobacco products that have been instrumental in reducing tobacco use. States would also be able to impose additional reporting requirements on tobacco manufacturers (as Massachusetts, Texas and Minnesota have done) if there was any information FDA was not getting or not sharing that a State thought would be useful.

The bill does give the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products. States could not establish requirements in these areas. This approach is consistent with Federal law regarding FDA regulation of drugs, devices, and food because it provides for a consistent national standard.

Permitting Cross Category Comparative Health Claims.—The bill permits the FDA to authorize tobacco manufacturers of one type of tobacco product to make health claims comparing the risks of its tobacco to other forms of tobacco products, but only if the manufacturer has presented sufficient scientific evidence that the advertised product is indeed safer and will reduce the user's risk of disease—in this regard, the bill is explicit. There has been a debate about whether the use of smokeless tobacco by committed, addicted smokers who can't or won't quit can be a useful harm

reduction strategy. This bill sets the scientific standard for FDA making such a determination, but doesn't prejudge the scientific result. If a smokeless tobacco manufacturer provides the FDA with adequate scientific evidence that a specific product or group of products is less hazardous than a cigarette product and will reduce the risk of disease among certain tobacco users, FDA is authorized to permit the smokeless manufacturer to make an approved claim. However, in making such a determination, FDA is required to consider the population-wide impact of permitting such claims, including the impact of any claims on the number of smokers who would otherwise quit using tobacco altogether and the number of people who begin using tobacco products.

Limitations on FDA's Authority Over Tobacco Growers and Leaf Tobacco.—The bill contains a number of specific prohibitions against the exercise of FDA authority on tobacco farms. The bill establishes FDA authority over tobacco manufacturers and their products and prohibits FDA from regulating leaf tobacco. Even FDA's standard-setting authority is limited to standards for manufactured tobacco products. Many tobacco growers believe American producers, much more easily than their foreign competitors, will be able to swiftly produce the quality tobacco leaf manufacturers require, and that consequently the legislation may provide American growers with a comparative advantage over foreign competition.

CONCLUSION

Mr. Chairman, in summary, the Campaign strongly suports this bill, and we firmly believe that it will help protect our kids from tobacco companies and their deadly products and deceptive advertising. It will help more adult tobacco users to quit, and it will greatly benefit the public health of the Nation.

The CHAIRMAN. Thank you. You're an old friend and I'm delighted to have you testifying today.

Dr. Huerta.

STATEMENT OF DR. ELMER HUERTA, M.D. M.P.H., PRESIDENT, AMERICAN CANCER SOCIETY, WASHINGTON, DC

Dr. HUERTA. Good morning, Mr. Chairman. Good morning distinguished members of this committee and thank you very much for allowing me to testify this morning.

I am Dr. Elmer Huerta. I am the incoming President of the American Cancer Society and Director of the Cancer Preventorium at the Washington Hospital Center here in Washington, DC.

As a physician and researcher who specializes in cancer prevention and the screening among the medically underserved, I see firsthand the toll tobacco takes on our country and the benefits of prevention in combating cancer.

On behalf of the more than 28 million volunteers and supporters of the American Cancer Society and its sister organization, the American Cancer Society Cancer Action Network, I thank you, Mr. Chairman, again and your committee for inviting me this morning.

The need for FDA regulation of tobacco is great and its benefits are clear. The tobacco industry made voluntary promises as part of the Master Settlement Agreement that it would stop marketing to children. Those promises have been broken. Our children have been left unprotected and the tobacco industry is taking advantage of that loophole in sinister fashion.

Indeed, the most popular cigarettes among children are the most heavily advertised brands—Marlboro, Camel and Newport.

How does it happen? Here are five ways. First, the MSA did not place any restrictions on advertising in print media such as magazines. In fact, cigarette advertising in youth-oriented magazines actually increased in the 2 years after the MSA.

Second, the MSA did not limit or restrict in-store tobacco advertising, knowing that 75 percent of teens visit a convenience store at least once a week. The cigarette companies increased their advertising and promotion in and around these stores.

Third, while the MSA banned large billboards, it permitted outdoor signs up to 14 square feet in size, even if it is placed right next to schools or playgrounds.

Fourth, the MSA lacks a quick and effective mechanism for identifying violations and compelling industry compliance.

Finally and most importantly, the MSA did not establish an enforceable system and comprehensive set of rules to restrict or eliminate all the major tobacco advertising and marketing tools that have the greatest influence on our children.

Because the tobacco companies remain unregulated and unchecked, they have circumvented the limited other tightened restrictions placed on them by the 1998 MSA and continue to target children.

Two recent examples include Brown and Williamson's Kool Mixx campaign and RJ Reynolds candy-flavored cigarettes. The Kool Mixx campaign focused its marketing images around music and hip-hop, which is particularly appealing to African American and Latino youth. The campaign included 14 music concerts, a DJ competition and special themed packs of cigarettes. In 2004, RJ Reynolds introduced flavored cigarettes such as Twista Lime and Winter Mochamint, using colorful graphics and scratch and sniff marketing tactics in both cases.

The State Attorney Generals asserted that tobacco companies had violated the MSA by targeting youth through their advertising and promotions.

This legislation introduced by you, Mr. Chairman and Senator Cornyn, would provide FDA with the authority and resources to effectively regulate tobacco products. The FDA would be authorized to restrict tobacco advertising and promotions, especially those targeted at children as evidenced in the examples stated previously. In addition, it would require the tobacco companies to disclose the ingredients of tobacco products and smoke constituents, prohibit unsubstantiated health claims about so-called reduced risk products and require larger and more informative health warnings on tobacco products, among other measures.

Last year, in a Department of Justice case against the tobacco companies, U.S. District Court Judge Gladys Kessler concluded, knowing that advertising and promotion has stimulated the demand for cigarettes, defendants use their knowledge of young people gained through tracking youth behavior and preferences in order to create marketing campaigns, including advertising, promotion and couponing that would appeal to youth in order to stimulate youth smoking initiation and to ensure that young smokers would select their brands.

Just this year, RJ Reynolds introduced a new version of its common brand of cigarettes specifically designed to appeal to women and girls. These new packs are laced in hot pink and teal. Ads include the slogans such as Light and Luscious. Shockingly, the industry is targeting women and girls at a time when lung cancer is the No. 1 killer of women.

Mr. Chairman, we think that these regulations in the bill introduced today are extremely important for the public health for the people and I would just say, with all due respect, Senator Burr, that the status quo only favors the tobacco industry. Thank you very much.

[The prepared statement of Dr. Huerta follows:]

PREPARED STATEMENT OF ELMER HUERTA, M.D., M.P.H.

I am Dr. Elmer Huerta, incoming President of the American Cancer Society and Director of the Cancer Preventorium at the Washington Hospital Center. As a physician and researcher who specializes in cancer prevention and screening among the medically underserved, I see firsthand the toll tobacco takes on our country and the benefits of prevention in combating cancer. On behalf of the more than 28 million volunteers and supporters of the American Cancer Society and its sister advocacy organization the American Cancer Society Cancer Action Network, I thank you, Mr. Chairman, and your committee colleagues for inviting me to testify today regarding the need for providing the Food and Drug Administration with meaningful authority over tobacco products as is found in S. 625 introduced by you, Senator Kennedy, and Senator John Cornyn.

As you know, the American Cancer Society is the nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy and service. In 2001, the Society created its sister organization, the American Cancer Society Cancer Action Network, referred to as ACS CAN, to more aggressively fight cancer through advocacy. Conquering cancer is as much a matter of public policy as scientific discovery, so building on the more than 90 years of excellence of the Society, ACS CAN serves as the lobbying arm and force necessary to push for legislative changes at the local, State and national levels.

The Society and ACS CAN have established aggressive goals to reduce cancer incidence and mortality—goals that we are pursuing with the cooperation and collaboration of the public, private, and nonprofit sectors. We know from data and scientific evidence that one of the key steps to achieving an accelerated reduction in cancer incidence and mortality is tobacco control—especially when it comes to children—through meaningful regulation of tobacco products and effective cessation programs that will help those currently addicted to quit.

The need for FDA regulation of tobacco is great. We're talking about an industry that sells and markets deadly products and does so without any accountability. In fact, tobacco products are the only consumable product not regulated by the FDA. This leaves consumers uninformed about tobacco products' ingredients and health dangers.

The benefits of FDA regulation are clear. FDA regulation will help us to combat the vicious marketing practices of a deceptive industry that has preyed upon our children, minorities, and existing smokers who are desperately trying to kick their habit. FDA regulation will protect these groups, and in the process it will help reduce what can only be considered disturbing disparities in cancer rates and death rates. Stated simply, FDA regulation will save lives.

We are at a huge disadvantage when it comes to combating the deceptive marketing practices and false health claims made by the tobacco industry. Mr. Chairman, over the years, the public health community and the public at large have worked hard at all levels of society to combat this Nation's deadly addiction. However, our efforts simply have not been strong enough. Voluntary guideline promises by industry have not worked and cannot be enforced. We all agree, Federal regulation of tobacco is absolutely necessary and now is the time for Congress to act.

Under your leadership, we have come close several times to passing this crucial piece of legislation. In 1998, we took a small step closer to regulation of the tobacco companies with the Master Settlement Agreement. The Agreement set a promise from the tobacco industry to the States that marketing to children would cease. But it was just a promise. The restrictions on cigarette marketing to children outlined in the MSA do not sufficiently restrict the companies' marketing practices. Instead, the MSA has changed the companies' public relations strategies so that the deceptive practices aimed at creating a new generation of smokers continues. In an attempt to burnish their public image as "good partners" seriously working to implement the spirit of the MSA, they have even initiated ineffective and sometimes harmful youth anti-tobacco campaigns.

Despite the MSA provision that the tobacco companies cannot "take any action, directly or indirectly, to target youth in the advertising, promotion or marketing of tobacco products," tobacco companies' marketing and promotion continue to have a direct impact on children. There are five ways in which the MSA is not strong enough. First, the MSA did not place any restrictions on advertising in print media, such as magazines. In fact, cigarette advertising in youth-oriented magazines actually increased in the 2 years after the MSA. It took R.J. Reynolds to be found guilty of directly marketing to children in 2002 before they decreased their magazine advertising that reached children. Second, the MSA did not limit or restrict in-store tobacco advertising. Knowing that 75 percent of teens visit a convenience store at least once a week, the cigarette companies increased their advertising and promotions in and around retail stores, such as convenience stores. Third, while the MSA banned large billboards, it permitted outdoor or outdoor-facing signs up to 14 square feet on the properties of businesses that sell tobacco products, even if those properties are right next to schools or playgrounds. Fourth, the MSA lacks a quick and effective mechanism for identifying violations and compelling industry compliance. And finally and most importantly, the MSA did not put into place an enforceable system and comprehensive set of rules to restrict or eliminate all the major tobacco advertising and marketing tools that have the greatest influence on our children.

Because the tobacco companies remain unregulated and unchecked, they have been able to circumvent the limited advertising restrictions placed on them by the 1998 Master Settlement Agreement, continuing to target children and have even increased their marketing expenditures by 125 percent since the MSA. Worse still, the tobacco industry is spending more than ever before to market its deadly products. In 2003, the most recent year data are available, the cigarette companies spent $15.1 billion, or more than $41 million a day, on marketing their products. Again and again, the tobacco companies have proven to us they will manipulate the system to encourage the uptake of smoking and keep current smokers from quitting by introducing new products and using creative marketing tactics, particularly aimed at children and other vulnerable populations. FDA regulation of tobacco is vital to control this rogue industry and to protect our most vulnerable members of society.

This is an industry that cannot be trusted. Last year, in the Depart of Justice case against the tobacco companies, U.S. District Court Judge Gladys Kessler concluded:

> "Knowing that advertising and promotion stimulated the demand for cigarettes, Defendants used their knowledge of young people, gained through tracking youth behavior and preferences, in order to create marketing campaigns (including advertising, promotion, and couponing) that would appeal to youth, in order to stimulate youth smoking initiation and to ensure that young smokers would select their brands."

The tobacco industry has demonstrated time and again that, if left to its own devices, it will falsely market its deadly products to our children, portraying this deadly addiction as glamorous and cool. In its March 2000 ruling, the U.S. Supreme Court found that tobacco use is "one of the most troubling public health problems facing our Nation." The industry continues to lure in new customers through its seductive advertising campaigns and price discounting, which has been proven to greatly affect the uptake of smoking by children.

Researchers and the tobacco companies alike know how great a role marketing plays in children's uptake of tobacco use. Numerous studies have shown that children are three times more sensitive to tobacco advertising than adults. The most popular cigarettes among children are the most heavily advertised brands—Marlboro, Camel and Newport. Research tells us that children are more likely to be influenced to smoke by cigarette marketing than by peer pressure and one third of tobacco use experimentation by children is attributable to tobacco advertising and promotions. The tobacco companies know this and use this information to target children.

The most recent effort by the tobacco industry to entice children into smoking has been the introduction of candy flavored cigarettes into the market in 2004. R.J. Reynolds introduced flavors such as Twista Lime and Winter MochaMint, using colorful graphics and "scratch and sniff" marketing tactics. In 2005, the States' Attorneys General asserted that R.J. Reynolds had violated the 1998 Master Settlement Agreement by targeting youth through its advertising and promotion of flavored cigarettes. As stated by Attorney General Eliot Spitzer,

> "Selling candy, fruit and sweetened alcohol flavored cigarettes is downright irresponsible, given the appeal of these products to youth. This result reflects

a recognition that the Attorneys General, together with the public health community, will not tolerate Reynolds' shameful ploys to introduce our children to smoking and to lure them into a lifetime of addiction to its deadly products."

This once again reminds us of the deceptive tactics the industry will continue to make to attract children to smoking and the desperate need for FDA regulation. It's a shameful reality, but it's just that—reality.

The industry also specifically targets minority youth. Brown and Williamson introduced its own version of flavored cigarettes as part of its Kool Mixx campaign. The Kool Mixx campaign focused its marketing images around music and hip-hop, which is particularly appealing to African American and Latino youth. The Kool Mixx campaign included 14 music concerts around the country and a DJ competition, as well as special-themed packs of cigarettes with cartoons displayed on them. In addition, Brown and Williamson placed advertisements in publications popular with Latino youth, including *Latina* and *Cosmoplitan en Espanol*. The slogans used in these ads included "It's about old world class and new world style" and "It's about pursing your ambitions and staying connected to your roots," aimed at appealing to the aspirations of ethnic minorities. The States' Attorneys General found the industry in violation of the 1998 Master Settlement Agreement, by using the Kool Mixx campaign to target youth, proving once again that the tobacco industry is incapable of regulating itself.

Brown and Williamson is not alone. Other tobacco companies have also specifically targeted minority populations. In 1999 and 2000, Philip Morris started a magazine ad campaign for Virginia Slims using the slogan "Find Your Voice." The ads targeted women and girls, featuring Latinos and other ethnic women, suggesting that independence and allure could be found by smoking. As recent as 2 weeks ago, R.J. Reynolds introduced a new version of its Camel brand cigarettes, specifically designed to appeal to women and girls. The pack of cigarettes is laced in hot pink and teal and the ads include slogans such as "light and luscious." Amazingly, the industry is increasing its attractiveness to women and girls at a time when lung cancer is the No. 1 cancer killer of women.

FDA regulation presents our country with an historic opportunity to protect all Americans from tobacco addiction, especially our children. This legislation is a critical step toward reducing health care disparities, as tobacco-related cancers remain disproportionately high among lower-income and minority communities. Because these groups have been repeatedly targeted by the tobacco industry, they unfairly carry a greater weight of the health and economic burden tobacco has on our Nation. I know from my experience as a doctor that prevention is effective at improving the health and well-being of people, but that minority groups and low-income populations do not have the same access to health programs, such as cessation services, as others do. This once again gives the tobacco industry the unfair advantage. Tobacco use is the most preventable cause of death and disease in this country and granting the FDA authority over tobacco products is the key prevention measure that is missing in this Nation in order to reduce tobacco's deadly toll.

Some minority and ethnic groups and the medically underserved suffer from a disproportionate burden of cancer and disease. Similarly, large differences in tobacco use exist in the United States. For example, currently, smoking prevalence is 37.5 percent among American Indian/Alaska Native men, 26.7 percent among African-American men, and 24 percent among white men. This leads to marked differences in tobacco-related cancer deaths among different groups within the population. This year, it is expected that the rate of lung and bronchus cancer deaths for white males will be 73.8 per 100,000 while for African Americans it will be 98.4 per 100,000. Lung cancer death rates for women have increased by at least 150 percent in the last two decades alone and have yet to go down.

We have made real progress on the cancer front. For the second straight year, we have seen a decrease in cancer deaths large enough to outpace the aging and growth of the U.S. population. These declines can be attributed in part to smoking cessation and other preventive efforts, such as earlier and better cancer screenings. Mortality rates from lung cancer in men decreased by about 1.9 percent per year from 1991 and 2003. We have also seen a decrease in the incidence of lung cancer in men, from a high of 102 cases per 100,000 in 1984 to 78.5 cases in 2003.

Despite the significant gains we have seen in decreasing overall cancer incidence and mortality rates, approximately 1.4 million Americans still will be diagnosed with cancer this year and more than 550,000 will lose their battle with the disease, costing more than $206 billion in direct and indirect health care costs. While we are encouraged by the overall decreased mortality from cancer, we have to recognize that death rates from lung cancer in women have not yet declined.

The health consequences from tobacco go beyond cancer and have an enormous health and economic impact on our Nation. Tobacco use is responsible for nearly one

in five deaths in the United States—a needless and tragically preventable loss of more than 400,000 American lives each year. Tobacco kills more Americans than AIDS, drugs, alcohol, car accidents, homicides, suicides, and fires combined. More than 30 percent of all cancer deaths, 80 percent of chronic obstructive pulmonary disease deaths, 21 percent of coronary heart disease deaths and 18 percent of stroke deaths are attributable to smoking and tobacco use. And sadly, we are starting to see the progress we've made in reducing youth smoking initiation slip away. Overall, tobacco costs our Nation over $96 billion in direct health care costs annually, and an additional $97 billion in lost productivity.

While we have made progress on some fronts of the fight against tobacco addiction, the enormous number of preventable deaths from tobacco tells us how important FDA regulation of these products is now. Deaths from tobacco can be prevented if our Nation seriously and comprehensively addresses tobacco and makes a long-term investment in a sustained campaign to prevent tobacco-related disease and death, which includes Federal legislation to regulate an industry that has evaded regulation for decades.

This legislation introduced by you, Mr. Chairman, and Senator Cornyn would provide the FDA with the authority and resources to effectively regulate the manufacturing, marketing, labeling, distribution and sale of tobacco products. The FDA would then be authorized to restrict tobacco advertising and promotions, especially those targeted at children, including banning candy-flavored cigarettes. It would also require the tobacco companies to disclose the ingredients of tobacco products and smoke constituents. The FDA would have the authority to prohibit unsubstantiated health claims about so-called "reduced risk" products, and require larger and more informative health warnings on tobacco products, among other measures.

The American Cancer Society and ACS CAN hope the introduction of your and Senator Cornyn's bill will encourage Congress to act now to grant the FDA authority to stop the tobacco industry's harmful and deceptive practices, before more children become addicted and more people die prematurely because of tobacco-caused disease. The Society and ACS CAN urge policymakers to take action to ensure that disparities in tobacco use and the associated adverse health outcomes are addressed. We have prioritized the reduction and elimination of the unequal burden of cancer as a top nationwide priority. As part of meeting this challenge, the Society is working at all levels of the organization to advance policies and programs that work to reduce health disparities among minority and ethnic populations and the underserved.

Mr. Chairman, on behalf of the Society and ACS CAN's nationwide volunteers and staff, again thank you for your ongoing leadership on tobacco issues and for providing us this opportunity to discuss with you and your colleagues the importance of Federal regulation of tobacco products. The need for FDA authority over tobacco products has never been greater. The Nation's deadliest consumer product must not continue to be unregulated. Mr. Chairman and members of the committee, we look forward to working with you and your colleagues to address this issue. We stand ready to join with you to protect our children from tobacco use and to help those currently addicted to quit.

The CHAIRMAN. Dr. Land, we want to welcome you and thank you very much for joining with us today and we know you've got an important message.

STATEMENT OF RICHARD LAND, D.PHIL., PRESIDENT, THE ETHICS AND RELIGIOUS LIBERTY COMMISSION OF THE SOUTHERN BAPTIST CONVENTION, NASHVILLE, TN

Mr. LAND. Thank you, Senator. Good morning, Mr. Chairman, Senator Enzi and members of the committee. I'm Richard Land, President of the Southern Baptist Convention's Ethics and Religious Liberty Commission. The Southern Baptist Convention is the Nation's largest Protestant denomination with more than 16 million members worshiping in nearly 44,000 autonomous local congregations with a physical presence in 99 percent of the counties of the United States.

The Ethics and Religious Liberty Commission is the official Southern Baptist entity charged by the Southern Baptist Convention to speak to our Nation's moral, cultural and religious liberty

issues. I appreciate this opportunity to testify in favor of S. 625, The Family Smoking Prevention and Tobacco Control Act, life saving legislation to authorize the Food and Drug Administration to regulate tobacco products. We have made the enactment of this tobacco legislation one of our top legislative priorities for the 110th Congress. This is an idea whose time has come.

Southern Baptists have strongly opposed the tobacco industry for a long time. We have a book containing all the resolutions passed by the Southern Baptist Convention in our offices in Nashville and Washington. I perused them before this testimony, Senator, and I found that—and these are just the resolutions that call for control, regulation, and restriction on the tobacco industry. There are about a dozen more that call upon Southern Baptist to refrain from the use of tobacco but the ones that actually call for action—2005, 1988, 1984, 1973, 1969, 1964—strongly commending the Surgeon General's report, the first opportunity the Convention had to do so—1937, 1933, and 1932. Interestingly, the 1984 resolution called upon Southern Baptists who grew tobacco to switch to another crop if at all feasible, to minimize the availability of this product.

I'm also here as a representative of a broad-based coalition of faith leaders known as Faith United Against Tobacco. Since it was founded in 2002, Faith United Against Tobacco has grown to include over 20 national faith denominations and organizations. In addition to the Ethics and Religious Liberty Commission of the Southern Baptist Convention, this coalition includes the General Board of Church and Society of the United Methodist Church, the National Council of Churches in Christ, the Presbyterian Church USA, the Commission on Social Action and Reform Judaism, the Seventh Day Adventists, the American Region of the World Seat Council and the Islamic Society of North America.

Just yesterday, 24 national faith leaders from our coalition sent a letter to every member of the U.S. Senate and House of Representatives, urging support for the FDA legislation. As you can see, the signers of this letter represent very diverse groups, including Christian, Jewish, Muslim and Seek Faith Traditions, whose members include many tens of millions of Americans from every part of the country.

We all know the terrible statistics about the toll of tobacco on our families. Over 400,000 Americans die every year from tobacco caused illnesses. Hundreds of thousands of others suffer every year from tobacco caused illnesses, such as lung cancer and heart disease.

I have too many relatives, personally, particularly paternal uncles who have had their lives tragically shortened by their addiction to nicotine. Millions of Americans have had their lives snuffed out before their time, often in their prime, at the peak of their careers, with a spouse and children at home, with many other responsibilities and joys before them.

The Southern Baptist Ethics and Religious Liberty Commission and the other faith groups in the coalition join America's public health community in viewing FDA regulation of tobacco as a critically needed tool to reduce tobacco use.

This legislation would allow the FDA to prevent tobacco companies from adding ever more deadly and addictive ingredients, re-

quire larger and more informative health warnings, prohibit candy-flavored cigarettes, prevent tobacco sales to under-aged children and limit advertising and promotion of tobacco products that lure children into a deadly habit. Like many of you, we find it incredible that the FDA can ensure the safety of everyday items like cold medicines, cookies and even dog food but has no authority over tobacco, a product that causes more preventable deaths than any other.

Faith leaders are not asking for a ban on tobacco products or even that they be treated differently than other items. We are simply asking that tobacco products be subject to the same common-sense rules that apply to other products. We want to level the playing field. Why should manufacturers of cessation products that help people quit smoking be subject to FDA regulation but not the products that kill over 400,000 Americans every year? No one wants too much government regulation. What we are asking for is not overly burdensome. It would simply assure the protection of consumers, particularly our children. There is a broad consensus in the faith community, both conservative and liberal, that this product must be regulated and that is why we support this bill.

We also support it for moral reasons. While each person bears responsibility whether he or she chooses to engage in tobacco use, responsibility also falls upon those in authority who have the power to end tobacco deception and significantly reduce the illness and the death that it can produce. My faith tradition teaches me that it is morally wrong to know the good that should be done and not do it. I also believe it is morally wrong to leave the most impressionable among us, our children, unprotected from the tobacco enticements that confront them. So I believe that those who are called to positions of leadership and power have a moral imperative to safeguard the men, women and children of our country from falling into the pitfalls of tobacco use.

The members of the Faith United Against Tobacco Coalition believe the U.S. Congress must do a better job of protecting our children from tobacco addiction and the suffering of tobacco-caused illness and death. As political leaders, you have a moral obligation to act, to protect our children and families. You have the means to curb the cycle of allurement and addiction of disease and death caused by tobacco. We believe you owe to the families of America to do so.

So we urge you to act quickly to enact this legislation, to provide the Food and Drug Administration authority to regulate tobacco products. I also have the copies of these resolutions that I'd like to have——

The CHAIRMAN. They will be included as part of the record.

Mr. LAND. Thank you.

[The prepared statement and resolutions submitted by Mr. Land follow:]

PREPARED STATEMENT OF RICHARD LAND, D.PHIL.

Good morning, Mr. Chairman, Senator Enzi, and members of the committee. I am Dr. Richard Land, President of the Southern Baptist Convention's Ethics & Religious Liberty Commission. As you are aware, the Southern Baptist Convention is the Nation's largest non-Catholic denomination, with more than 16 million members worshipping in nearly 44,000 autonomous local congregations, with a presence in 99

percent of the counties of the United States. The Ethics & Religious Liberty Commission is the official Southern Baptist entity charged by the Southern Baptist Convention to speak to our Nation's moral, cultural, and religious liberty issues.

I appreciate this opportunity to testify in favor of S. 625, the Family Smoking Prevention and Tobacco Control Act, life-saving legislation to authorize the Food and Drug Administration (FDA) to regulate tobacco products. We have made enactment of the tobacco legislation, introduced by Senators Kennedy and Cornyn and Representatives Waxman and Davis, one of our top legislative priorities for the 110th Congress. This is an idea whose time has come, and, on behalf of most Southern Baptists, I strongly urge you to take action now and enact this important legislation.

I am also here as a representative of a broad-based coalition of faith leaders known as Faith United Against Tobacco. Since it was founded in 2002, Faith United Against Tobacco has grown to include over 20 national faith denominations and organizations. In addition to the Ethics & Religious Liberty Commission of the Southern Baptist Convention, this coalition includes the General Board of Church and Society of the United Methodist Church, the National Council of Churches in Christ, the Presbyterian Church (USA), the Commission on Social Action of Reform Judaism, the Seventh-day Adventists, the American Region of the World Sikh Council, and the Islamic Society of North America. Other broad-based groups, such as Church Women United and the Health Ministries Association, which represents thousands of faith community nurses across the country, have also joined Faith United Against Tobacco.

In addition to our national effort to convince Congress to enact the FDA regulation of tobacco legislation now before you, Faith United Against Tobacco has worked successfully across the country to enact tobacco control measures such as increased tobacco taxes, full funding of tobacco prevention programs, and smoke-free workplace legislation. In Indiana in 2005, for example, there was a very serious effort to dramatically cut funding for that State's landmark tobacco control program. A group of faith leaders, led by United Methodists, Southern Baptists, and faith community nurses, formed the Hoosier Faith and Health Coalition and took the lead in preventing these cuts from happening, which has saved many Hoosiers, particularly children, from tobacco addiction. Similar collaborations exist in other States, including Alabama, Kentucky, New Jersey, North Carolina, Ohio, and Texas. You can learn more about the history and accomplishments of Faith United Against Tobacco at *www.faithunitedagainsttobacco.org*.

Our focus at the Federal level has always been on enacting legislation to give the FDA authority over tobacco products. Just yesterday, 24 national faith leaders from our coalition sent the attached letter to every Member of the U.S. Senate and House of Representatives, urging support for the FDA legislation. As you can see, the signers of this letter represent very diverse groups, including Christian, Jewish, Muslim, and Sikh faith denominations, whose members include many tens of millions of Americans from every part of the country. I think it is also important to note that the 24 leaders who signed this letter are often on opposite sides of other very important social and political issues. But we are united in our desire to reduce smoking, especially among children, and in our commitment to the enactment of legislation authorizing the FDA to regulate tobacco products.

We all know the terrible statistics about the toll of tobacco on our families—over 400,000 Americans die every year from tobacco-caused illnesses; hundreds of thousands of others suffer every year from tobacco-caused illnesses such as lung cancer and heart disease; and every day over 1,000 of our children become addicted to this deadly product. For us in the faith community, these statistics are especially tragic because every day we must bury mothers, fathers, sisters, and brothers who die early from preventable deaths caused by tobacco addiction that, more often than not, began at a young age. We, then, are left with the task of trying to comfort their grieving survivors. I speak this morning from personal experience. I have sought not only to bring comfort to families and individuals, but to find comfort for my own loss.

I have too many relatives, particularly paternal uncles, who have had their lives tragically shortened by their addiction to nicotine. One uncle, who died in his late forties from lung disease, horribly exacerbated by smoking, still smoked even when reduced to carrying a portable oxygen supply with him wherever he went in his final months. He was literally a fire hazard to those around him. I am grateful that both my father and my mother, once heavy smokers, were able with much difficulty to break their tobacco habit in their late fifties. And thus, they are still with us at 84 and 82, respectively. If they had not quit smoking, they would both be long dead by now, a fact they readily acknowledge. They would have missed their five grandchildren's graduation from college, if not high school, and three of their grand-

children's weddings. Other children have not been as fortunate as I have been. They lost their parents prematurely to that ferocious killer, tobacco.

Millions of Americans have had their lives snuffed out before their time, often in their prime—at the peak of their careers, with a spouse and children at home, and with many other responsibilities and joys before them. The families of America must not continue to be lured toward futures of incomplete chapters. Men and women deserve to know the toxic chemicals rolled into every cigarette. Young sons and daughters deserve to enjoy their youth without being confronted with tobacco marketing tailored to their age.

Like the many Members of Congress from both parties and across the political spectrum who are cosponsoring this legislation, the Southern Baptist Ethics & Religious Liberty Commission and the other faith groups in the coalition join America's public health community in viewing FDA regulation of tobacco as a critically needed tool to reduce tobacco use. This legislation would allow the FDA to prevent tobacco companies from adding even more deadly and addictive ingredients; require larger and more informative health warnings; prohibit candy-flavored cigarettes; prevent tobacco sales to underage children; and limit advertising and promotion of tobacco products that lure children into a deadly habit. Like many of you, we find it incredible that the FDA can ensure the safety of everyday items like cold medicines, cookies, and even dog food, but has no authority over tobacco, a product that causes more preventable deaths than any other.

Faith leaders are not asking for a ban on tobacco products or even that they be treated differently than other items. We are simply asking that tobacco products be subject to the same commonsense rules that apply to other products. We want to level the playing field. Why should manufacturers of cessation products that help people quit smoking be subject to FDA regulation but not the products that kill over 400,000 Americans every year? No one wants too much government regulation. What we are asking for is not overly burdensome; it would simply assure the protection of consumers, particularly our children. There is broad consensus in the faith community, both conservative and liberal, that this product must be regulated, and that is why we support this bill.

We also support this bill for moral reasons. My faith tradition informs me that our bodies are gifts from God and, therefore, should be treasured and treated with dignity. This means we should refrain from engaging in activities or abusing substances that pose grave threats to our health. Tobacco is one such substance. While each person bears responsibility for whether he or she chooses to engage in tobacco use, responsibility also falls upon those in authority, who have the power to end tobacco deception and significantly reduce the illness and death that it can produce. My faith tradition teaches me that it is morally wrong to know the good that should be done and not do it. I also believe that it is morally wrong to leave the most impressionable among us, our children, unprotected from the tobacco enticements that confront them. And so, I believe that those who are called to positions of leadership and power have a moral imperative to safeguard the men, women, and children of our country from falling into the pitfalls of tobacco abuse.

I find it unconscionable that Congress, knowing the deadly effects of tobacco use, continues to leave tobacco companies virtually unchecked, left to use their own discretion to determine what carcinogenic chemicals to include in their products. I find it unconscionable that Congress, knowing that the overwhelming majority of adult smokers began their habit as minors, would do nothing more than call unfortunate the tobacco companies' marketing targeted at children.

Almost 10 years ago, in 1998, Congress debated comprehensive tobacco control legislation but failed to enact anything. In 2004, the Senate overwhelming passed legislation virtually identical to S. 625, but it was killed in a conference committee. Throughout this time tobacco companies have continued to spend billions of dollars every year marketing their deadly products to children and, as a result, far too many high school students smoke and far too many people will die prematurely from tobacco-caused diseases.

The Ethics & Religious Liberty Commission of the Southern Baptist Convention and all other members of Faith United Against Tobacco believe that the U.S. Congress must do a better job of protecting our children from tobacco addiction and the suffering of tobacco-caused illness and death. As political leaders, you have a moral obligation to act to protect our children and families. You have the means to curb the cycle of allurement and addiction, of disease and death, caused by tobacco. You owe it to the families of America to do so. We, therefore, urge you to act quickly to enact S. 625, bipartisan legislation to provide the Food and Drug Administration authority to regulate tobacco products.

Mr. Chairman, Senator Enzi, and other members of the committee, I thank you for permitting me to testify this morning. I will be happy to entertain any questions.

RESOLUTION OF REDUCING TEEN SMOKING (JUNE 2005)

WHEREAS, Human beings are created in the image of God (Genesis 1:26-27); and

WHEREAS, Being created in the image of God endows humans with great dignity and inestimable worth; and

WHEREAS, More than four hundred thousand Americans die every year from tobacco-caused diseases; and

WHEREAS, Every day in our Nation, five thousand children under the age of eighteen, including adolescents of childbearing age, smoke their first cigarette; and

WHEREAS, Every day in our Nation, two thousand children become regular daily smokers, one-third of whom will die prematurely as a result of tobacco-caused diseases; and

WHEREAS, Approximately one out of five pregnant teenagers passes the risks of smoking on to her baby directly or through exposure to secondhand smoke; and

WHEREAS, Preventing and reducing smoking and other tobacco use among teenagers and other children requires a strong commitment from a broad, diverse range of organizations and individuals concerned about our Nation's youth and public health; and

WHEREAS, According to the American Cancer Society and other national health organizations, one of the most effective ways to reduce smoking and other tobacco use, particularly among adolescents, is to raise the price of cigarettes, smokeless tobacco, and other tobacco products through tax increases; now, therefore, be it

RESOLVED, That the messengers to the Southern Baptist Convention meeting in Nashville, Tennessee, June 21–22, 2005, commit to add our efforts to those of such national organizations as the American Cancer Society, American Heart Association, Campaign for Tobacco-Free Kids, and the American Lung Association to work to reduce tobacco use, especially among teens; and be it further

RESOLVED, That we encourage our churches to redouble their efforts to educate our youth about the dangers of tobacco use; and be it further

RESOLVED, That we applaud those jurisdictions that have helped reduce teen smoking with substantial tax increases on tobacco products; and be it finally

RESOLVED, That we commit ourselves to seek ways, through personal efforts and coalitions, to become more involved in our communities and States to prevent and reduce smoking and other tobacco use, especially among teens.

RESOLUTION ON EXPORTATION OF ALCOHOL AND TOBACCO (JUNE 1988)

WHEREAS, The United States Government is actively pursuing export markets for alcohol and tobacco industries; and

WHEREAS, The alcohol and tobacco industries are making profits at the expense of the health of those who consume their products; and

WHEREAS, The United States Government is involved in the war against addictive drugs; and

WHEREAS, Alcohol and tobacco are addictive.

Be it RESOLVED, That we encourage the United States Government to cease to assist these industries via trade talks; and

Be it finally RESOLVED, That Southern Baptists in their annual meeting, June 14–16, 1988, in San Antonio, Texas, declare their opposition to these hypocritical practices by the United States Government on behalf of the alcohol and tobacco industries.

RESOLUTION ON CIGARETTE SMOKING (JUNE 1984)

WHEREAS, We as Christians know that our bodies are temples of the Holy Spirit, and that we should therefore refrain from defiling our bodies; and

WHEREAS, The United States Government has for many years required that tobacco companies state in their advertising and on cigarette packages that smoking is hazardous to health; and

WHEREAS, Cigarette smoking is habit forming and often becomes a physical addiction comparable to other drug addictions; and

WHEREAS, The Surgeon General of the United States, C. Everett Koop, M.D., has described cigarette smoking as "the most important health risk in the country"; and

WHEREAS, Cigarette smoking is causally related to lung cancer and coronary heart disease, as well as other diseases, and is the leading cause of chronic bronchitis and emphysema; and

WHEREAS, The Surgeon General's report blames chronic lung disease for more limitation of activity than any other type of disease, with more than 500,000 hospital admissions a year attributed to this disease; and

WHEREAS, More than 62,000 Americans have died of chronic obstructive lung disease in 1983 with as many as ninety percent of these deaths blamed on cigarette smoking, and costs the Nation forty billion dollars a year in health expense and productivity; and

WHEREAS, The Surgeon General's report stated that children of smoking parents have a higher prevalence of respiratory symptoms and more frequent bouts of bronchitis and pneumonia in early life; and

WHEREAS, Mothers who smoke during their pregnancy have a higher incidence of congenitally deformed and low-birth weight babies.

Therefore, be it RESOLVED, That the messengers of the Southern Baptist Convention meeting in Kansas City, Missouri, June 12–14, 1984, encourage churches to give people the facts regarding the physical harm involved in cigarette smoking, beginning with children of an early age; and

Be it further RESOLVED, That we encourage schools to make information regarding the harm of cigarette smoking part of the curriculum for students of all ages; and

Be it further RESOLVED, That we encourage parents by personal example to teach abstinence from cigarette smoking; and

Be it further RESOLVED, That our churches, associations, State conventions, and the Southern Baptist Convention take leadership in encouraging our people, pastors, and SBC leaders to refrain from using tobacco in any form, including cigarettes; and

Be it further RESOLVED, That we encourage Southern Baptists presently engaged in the growing of tobacco, which has no use except for cigarettes and related products, to cease such agriculture and, where feasible, to switch to another cash crop in order to make such products less accessible; and

Be it finally RESOLVED, That we encourage the Congress and Senate to terminate all agricultural funding and subsidies to those who plant, grow, or sell any tobacco products.

RESOLUTION ON ALCOHOL AND OTHER DRUGS (JUNE 1973)

WHEREAS, The drug problem a complex and intricately interrelated phenomenon in our society, now including a widespread misuse of valuable prescription products, a broad spectrum of unscientific self-medication, a deeply implanted custom of cigarette smoking, deeply entrenched customs of drinking alcohol beverages, and an alarmingly developing culture involving marijuana and other illegal drugs, and

WHEREAS, This pervasive drug orientation of our culture is resulting in widespread social disruption and destruction of life by cancer, emphysema, coronary heart disease, accidents, alcoholism and other drug addiction, and is a factor in other serious social problems such as crime, family disruption, industrial waste, and automobile accidents, and

WHEREAS, Basic factors now recognized as perpetuating the drug approach to life are commerical promotion of alcohol, tobacco, and over-the-counter drugs; glamorization of the use of alcohol and tobacco; social pressures for smoking, drinking, and other drug usage; and widespread ignorance of accurate information pertinent to personal usage of these drugs, and

WHEREAS, Contemporary efforts of government, church, civic groups, and other independent agencies are failing to cope effectively with the drug orientation of our culture.

Therefore, be it RESOLVED, that we encourage the Congress—also such agencies as Food and Drug Administration; Department of Health, Education, and Welfare; Department of Environmental Control; Federal Communications Commission; Office of Consumer Affairs; Federal Trade Commission; Office of the Attorney General; and the Office of the President—to take action to control advertising of alcohol, tobacco, and other addictive drugs which perpetuate the drug orientation of the culture, and

Be it further RESOLVED, that we call for the broadcast possible offensive to be mounted to restrain commercial promotion of all such products, and

Be it further RESOLVED, that we pledge our cooperation with others to neutralize social pressures and minimize glamorization of drug usage, and

Be it further RESOLVED, that preventive education in the homes, the churches, and the schools be strongly encouraged, and

Be it further RESOLVED, that the Christian Life Commission be encouraged to work diligently with appropriate agencies of the Southern Baptist Convention to

publicize this position and to encourage cooperation with others seeking these same objectives.

RESOLUTION ON CIGARETTE AND LIQUOR ADVERTISEMENT (JUNE 1969)

WHEREAS, There is pending legislation in the National Congress dealing with the regulation and possible deletion of cigarette and liquor advertisement from the mass media,

Therefore, be it RESOLVED, That we give encouragement and support to all Congressmen who are backing this legislation.

RESOLUTION ON A REQUEST OF PRESIDENT LYNDON B. JOHNSON (JUNE 1964)

WHEREAS, The Surgeon General's Committee appointed by President Kennedy rendered our Nation a much-needed service in pointing out the hazards of cigarette smoking, which report can have far-reaching benefits to human health and well-being,

WHEREAS, The serious problem of beverage alcohol also deserves the same careful medical and scientific investigation,

We go on record as a Convention as requesting President Johnson to appoint a similar commission to investigate and to make known to our American people the hazards to personal health and to society presented by the use of alcohol as a beverage.

AMENDMENT TO REPORT BY THE SOCIAL SERVICE COMMITTEE (ADOPTED) (MAY 1937)

"It is the sense of this Convention that the prevalence of smoking among Christian people, especially among preachers, church leaders and denominational workers, is not only detrimental to the health of those who participate, but is hurtful to the cause of Christ in that it weakens the message and lowers the influence of those who are charged with the preservation and spread of the Gospel."

RESOLUTION ON TOBACCO (MAY 1933)

J. M. Shelburne offered the following amendment and it was adopted:

RESOLVED, That we respectfully suggest to the ministers of our churches and to the teachers in the schools of our land, and to the fathers and mothers of our boys and girls, that they consider the probable ultimate effect of the growing and excessive use of tobacco by our boys and girls, with a view to arriving at some kind of cooperative measures by which at least some of our young people may hope to escape the experience of an habitual slavery to tobacco.

SOCIAL SERVICE COMMITTEE RECOMMENDATION CONCERNING RACE RELATIONS (ADOPTED) (MAY 1932)

10. That we respectfully suggest to the ministers of our churches and to the teachers in the schools of our land that they consider the probable ultimate effect of the growing and excessive use of tobacco by our boys and girls with a view to arriving at some kind of cooperative measure by which some of our young people, at least, may hope to escape the experience of an habitual slavery to tobacco.

The CHAIRMAN. Thank you very much.

Senator HATCH. Mr. Chairman, could I just take 1 minute because I have to——

The CHAIRMAN. OK.

Senator Hatch.

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. I'm very interested in what all of you have to say and I will read all of the record. I'm really appreciative of the Chairman and what he is trying to do here.

On the other hand, I'm worried sick about burdening FDA with more responsibilities with maybe not enough finances to take care of it. So I just want to express my concern because I have a tremendous interest in everything you're talking about regarding this matter. I have a tremendous interest in FDA. I'm just really worried about it and I want to work with other members of this committee to try and resolve these problems and get them resolved in a way that is equitable for all but will help to advance the cause of healthcare in our society. I just appreciate your letting me say that, Mr. Chairman, because I'm concerned about it and I appreciate the efforts that all of you have made and I feel guilty that I have to leave. But I just wanted to make that as clear as I could under the circumstances. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Hatch has had a long career ensuring that we're going to have an FDA that is going to meet its responsibilities in terms of oversight. This has been something that he has been very much involved in. So we appreciate his comments and involvement.

I'll introduce now the remainder of the panel. Dr. Jack Henningfield is Adjunct Professor of Behavioral Biology in the Department of Psychiatry at the Johns Hopkins University School of Medicine. He is also Vice President for Research and Health Policy at Pinney and Associates. He is the former head of the laboratory of the National Institute of Drug Abuse, where he evaluated the addictive potential of drugs, including cocaine, sedatives, nicotine in various forms. He was assigned to be editor of the 1988 Addiction Report of the Surgeon General, advised the FDA on its tobacco regulations in the 1990s, and advised the World Health Organization on issues related to tobacco control.

Greg Connolly, is an old friend from Massachusetts, now a Professor at Harvard School of Public Health who teaches and conducts research in tobacco control policies and projects. He has published over 70 scientific articles on smoking and health issues. He is the former Director of the Massachusetts Department of Public Health's Tobacco Control Program, one of the largest campaigns to curb tobacco use in the world. Over the 10 years that he directed the program, cigarette consumption fell 50 percent in Massachusetts, three times the national average. That is an impressive record. I don't think there is a State in the country that used the money from the Master Tobacco settlement more effectively, during this period to combat tobacco use, and Gregory Connolly was the head of that program. Under our recent governors, the money was cut out for that program, which is very unfortunate.

Dr. Alan Blum is Professor and Endowed Chair in Family Medicine, University of Alabama. He directed the Center for the Study of Tobacco and Society. From 1977 to 2002, he led the Doctor's Ought to Care. He has written over 100 articles on tobacco problems. In recognition of his efforts to prevent smoking, Dr. Blum has received the first Surgeon General's Medallion from Dr. Koop, and the first public health award by the American Academy of Family Physicians. We very much appreciate your presence.

And Ms. Lisa Shames is currently GAO Acting Director for Food and Agricultural Issues. Her portfolio covers issues of food safety,

agro-terrorism, agricultural conservation and farm program payments.

Let's start with Dr. Henningfield.

STATEMENT OF JACK E. HENNINGFIELD, PH.D., VICE PRESIDENT, RESEARCH AND HEALTH POLICY, PINNEY AND ASSOCIATES, BETHESDA, MD, AND PROFESSOR OF BEHAVIORAL BIOLOGY AT JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, BALTIMORE, MD

Mr. HENNINGFIELD. Mr. Chairman, members of the committee, thank you for the opportunity to testify and to serve. I have studied drug addiction and health for three decades at Johns Hopkins Medical School, the National Institute on Drug Abuse and through my consulting at Pinney Associates to GlaxoSmithKline on smoking cessation medications.

Many people think of tobacco products as relatively simple concoctions of tobacco and flavorings that people smoke for simply pleasure and with full awareness of the dangers and that smoking is a completely free choice. Nothing could be further from the truth.

Tobacco products are sophisticated drug delivery systems. They are engineered and manufactured to increase addiction risk and without any meaningful regulatory oversight to draw the line on practices that unnecessarily increase harmful and addictive effects.

FDA authority could lead to less addictive and less harmful products and regulation of marketing could reduce deception. Existing and future products need to be regulated. Existing products are used by more than 50 million Americans a year, killing more than 1,000 every single day. Setting standards for chemicals that can heighten addictiveness, such as ammonia and acetaldehyde and flavorings, such as menthol and chocolate could be steps toward less addictive and less attractive tobacco products.

Developing performance standards for toxicants such as pesticide residues, tobacco specific nitrosamines, carbon monoxide and formaldehyde could reduce toxic exposure in those who continue to use tobacco. Regulation is needed to prevent deceptive designs that are killing Americans.

Today, more than two-thirds of cigarette smokers smoke light cigarettes. My sister was one of them. As she told me, you can tell Marlboro Reds are worse. They felt stronger and left my throat raw compared to lights.

Well, let me tell you a few things she didn't know. She assumed there were government standards for light cigarettes. She assumed that the FTC test method for tar and nicotine reflected health effects or at least actual intake, as is the case for food labeling. She assumed that cooler, smoother smoke meant it was weaker and less harmful. She couldn't believe the Government would allow such a scam.

Cigarette ventilation is one deadly scam you can see for yourself. If you tear the paper from just about any cigarette filter and especially a light cigarette and if your cameras are looking for what I'm going to show you, they won't be able to see them. You have to look close. You tear the paper off, hold it up to the light, you can see tiny bands of holes. These holes allow air to come into the smoking machine and fool the machine into thinking the smoke is much

weaker than it is. They do the same thing for the smoker. What the smoker does is inhale more deeply and more smoke and more deeply into the lungs. The holes are right where they can be easily covered by fingers or lips.

Unbeknownst to most smokers, covering some of the holes can double or triple the amount of tar and nicotine. I did this demonstration a few years ago for my son's third grade class. They reacted with passion and clarity. They said, "that's cheating." They can't do that. The third graders got it.

Well, Senators, that is cheating and there is a means of preventing and stopping such deception for food products but not for tobacco, not until tobacco is regulated by the FDA.

But light cigarettes are just the tip of the iceberg. New generations of products appear to be following the commercially effective model of light cigarettes, which is to develop highly addictive products with designs and marketing efforts that assuage fears about tobacco so as to hook more people and keep them using tobacco. These products will need their own standards. They will need their own standards so that their potential effects are understood before they are marketed, before they are allowed on the market and to make sure that marketing does not inappropriately promote use, including does not inappropriately use FDA's regulation to promote use.

FDA is the right agency and the only agency with appropriate experience to develop and enforce product performance standards. I have heard the entire range of arguments about why FDA should not be granted regulatory authority, including that FDA was not designed to evaluate cigarettes or inherently dangerous products. The fact is, FDA was designed to assess a few ingredients and toxic exposures for a broad range of products. Furthermore, tobacco products are drug delivery systems at heart. Even the tobacco industry documents admit this. Moreover, tobacco products are designed and marketed to deceive and heighten addiction risk.

Finally, let me emphasize that FDA's authority will not make tobacco products safe, will not make them nonaddictive and should not been seen as a substitute for comprehensive tobacco control efforts to reduce all forms of tobacco use and disease. This is not an either/or situation. In fact, FDA regulation should be viewed as a partner to tobacco control, finally bringing FDA, the most powerful health regulatory agency in the world, to the table alongside tobacco control professionals to position and be positioned to serve these efforts because it will restrict the ability of the industry to modify products and use descriptors that undermine prevention and cessation.

I therefore urge expeditious passage and implementation of the bill. Thank you for the opportunity.

[The prepared statement of Mr. Henningfield follows:]

PREPARED STATEMENT OF JACK E. HENNINGFIELD, PH.D.

Thank you for the opportunity to testify on S. 625, the Family Smoking Prevention and Tobacco Control Act, that would provide "*the Food and Drug Administration with effective authority to regulate tobacco products.*" FDA regulation is not only the right thing to do, it is urgent. More than 4 million Americans have died prematurely since FDA asserted jurisdiction and issued its Final Rule to regulate cigarettes and smokeless tobacco in 1996. Although we have made modest progress in reducing to-

bacco use, I believe FDA regulation would have made the progress significantly greater. Furthermore, the tobacco industry is unleashing new products, new claims, and clandestinely modifying conventional products at a terrifying rate, with no plausibly-effective regulatory mechanism in sight, except for the approach embodied in the Senate bill. Even the FTC has thrown in the towel and apparently given up on its own widely criticized and deeply flawed method of cigarette testing.

BASIS FOR TESTIMONY

I am speaking on my own behalf and not as a representative of the organizations, of which I am a member, consult for, or voluntarily serve. I am an Adjunct Professor of Behavioral Biology (Adjunct), Department of Psychiatry, The Johns Hopkins University School of Medicine; and Vice President for Research and Health Policy, Pinney Associates. I was trained in behavioral science, pharmacology, and other disciplines relevant to understanding addictive substances. I have focused on tobacco-related issues for nearly three decades. From 1980 to 1996, I conducted and led tobacco and other drug research at the National Institute on Drug Abuse (NIDA). While at NIDA, I was liaison frequently to the FDA on tobacco products and tobacco addiction treatment. I contributed to numerous Surgeon General's reports as well as reports by other agencies. I presently serve on the World Health Organization (WHO) Tobacco Regulation Study Group (TobReg) which provides scientific guidance for implementation of several articles of the international tobacco treaty, the WHO Framework Convention on Tobacco Control (FCTC); a treaty (signed by not yet ratified by the United States) which includes many directives in harmony with the proposed FDA tobacco regulation.

By further way of disclosure and to provide you with some basis for my perspective, let me tell you that part of my role at Pinney Associates is to advise companies on how to minimize the risk of abuse, addiction, misuse and harmful effects of drugs with a known or suspected potential to cause addiction, including opioid analgesics, stimulants, sedatives, and many others. In many cases it is not only the chemical entity itself but the formulation and marketing of the drug that poses the challenge for risk minimization. This work includes advising GlaxoSmithKline Consumer Healthcare on its treatments to help people quit smoking. I also share two patents on a tobacco dependence treatment product under development which has given me additional perspectives on FDA regulation. On the tobacco side, I have reviewed thousands of pages of previously secret document and testified on behalf of the U.S. Department of Justice (DOJ) and other plaintiffs against the tobacco industry concerning the many ways by which this industry has been able to manipulate its products to heighten their addiction risk under the cover of darkness left by the regulatory vacuum. I have gained first hand experience in understanding the challenges and benefits of FDA regulation of the tobacco industry and its products through these activities.

TOBACCO PRODUCTS ARE SOPHISTICATED DRUG DELIVERY SYSTEMS—ENGINEERED AND MANUFACTURED TO INCREASE THEIR POTENTIAL TO CAUSE AND SUSTAIN ADDICTION

Tobacco products are diverse and all are harmful and share the common feature of being designed to cause and sustain addiction to nicotine. The World Health Organization said in its 2006 World No Tobacco Day report, an effort to which I contributed: *all tobacco products are deadly and addictive in any form or disguise*. Products vary widely in their form and degree of sophistication in engineering. The most elaborately designed and manufactured product, the cigarette, accounts for the vast majority of the more than 1,000 tobacco-attributable deaths that occur every day in the United States.

For most consumer products, extensive research and design expertise by manufacturers is often used to improve safety and reduce risk. However, this is not true for cigarettes: much of the research and engineering has been dedicated to increasing their risk of causing and sustaining addiction and high levels of use. In fact, many features are intended to make it easier to inhale the deadly poisons deep into the lungs where the damage is greatest. Why? Because this increases the addictive impact of nicotine by producing explosively fast absorption in the massive alveoli bed of the lung. This undoubtedly helps explain why lung cancer risk increased in the 1980s and 1990s even though machine measured tar levels declined. It also may help to explain the increasing proportion of the especially deadly deep airway small cell adenocarcinomas relative to squaemous cell lung cancer in the recent decade.

Cigarette design and manufacture is extensively researched and engineered to control features that contribute to deceiving smokers into thinking they are getting less harmful exposures, to make it easier to take up smoking, and to cause and sustain addiction. Much of this was summarized in the FDA's Final Tobacco Rule

(1996) and more recently in the 1,700-page findings by Judge Kessler in her ruling in the U.S. Department of Justice litigation against the tobacco industry. She wrote:

> "Every aspect of a cigarette is precisely tailored to ensure that a cigarette smoker can pick up virtually any cigarette on the market and obtain an addictive dose of nicotine." (Paragraph 1368).

Further, Judge Kessler concluded:

> "Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction." (Paragraph 1366).

The remarkable range of features includes control over the following aspects of cigarette design, delivery, and addictive impact. Ignition propensity and burn rate are controlled with burn accelerants and paper porosity to help control nicotine dosing and make cigarettes convenient to use. Smoke particle size is engineered to facilitate efficient inhalation of smoke deep into the lung. Smoke temperature and harshness are controlled to make it easier to take up smoking, to inhale deeply and provide smoother smoke that fools the smoker into assuming it's not as harmful. Smoke and ash color are controlled with chemicals in the tobacco and paper to make the process as neat and attractive-appearing as possible. Ingredients are further added to smooth, flavor and make the smoke more attractive to target populations, even if they yield additional carcinogens to the smoke (such as burned chocolate does). Still other chemicals are added that prolong shelf life and control humidity, which, in turn, helps control nicotine dosing and smoke sensations. The inclusion of some of these ingredients on FDA's Generally Recognized as Safe (GRAS) list is virtually meaningless when they are used in cigarettes. These ingredients have not been tested and approved for use in burned products. They are "GRAS" for use in food, not for inhalation in combination with burned tobacco material. Certain agricultural practices, storage, shipping and handling add still other questionably-safe chemicals, such as herbicides, pesticides, fertilizer residues, heavy metals, cyanide, arsenic, and insect parts. The fact that many American tobacco growers maintain high standards does not obviate the need for regulation of the substances in tobacco plant material, particularly since so much tobacco is imported.

A number of chemicals used in manufacturing process further alter the addictiveness of the product through manipulation of the chemical form of nicotine (e.g., ratio of free-base or unionized nicotine to ionized nicotine). These compounds increase the amount of free base nicotine, probably increasing the addictiveness of cigarettes because free-base nicotine is more readily released from the cigarette and absorbed in the mouth. For example, ammonia compounds can alter the free base fraction of the smoke while also making it easier to inhale. The practice of manipulating the free base fraction of nicotine is not unique to cigarettes: smokeless tobacco products marketed as "starter" products (an industry term) are mildly alkaline to yield a smaller proportion of free base nicotine than the more alkaline maintenance products such as Copenhagen. Why? Too much nicotine delivered too rapidly to the novice user can cause acute nausea and discourage further use. By contrast, highly tolerant smokeless users who have "graduated" (another industry term) to higher levels of daily use seek stronger and faster doses to satisfy their addictions.

Cigarette filter technology is also extremely sophisticated and reduces certain throat burning sensations but not necessarily the deadliest of the toxicants. Filters can help ensure that nicotine is readily delivered in a form that can be easily inhaled deep into the lung where addiction potential is maximized, and lung disease risk is increased by the inhalation of smoke particles that carry nicotine molecules into the lung. Filters also commonly include elaborate ventilation systems (described in greater detail below), which can increase the free-base fraction of nicotine and enable smokers to obtain addictive levels of nicotine regardless of its advertised yield.

It is time to rein in the addictiveness and harmfulness of tobacco products by giving FDA the authority to enact performance standards to regulate and restrict levels of ingredients (added or residual) that are toxic, and to reduce the ability of the industry to maximize the addictive potential of their products.

IT IS VITAL TO GIVE FDA THE AUTHORITY TO REGULATE TOBACCO PRODUCTS AND DEVELOP PRODUCT PERFORMANCE STANDARDS AS WILL BE ACCOMPLISHED THROUGH SENATE BILL S. 625

FDA could develop performance standards that, over time, could lead to less addictive and less harmful products. One key feature of the legislation is that mere compliance with a performance standard cannot be used as the basis for product claims. This will help ensure that communications about the dangers are not weak-

ened. After all, the products will still remain highly toxic and addictive by any ordinary standards and communications should not be used to imply anything contrary to these facts.

Performance standards can and should be developed for all smoke constituents including those that affect addictiveness and attractiveness as ammonia compounds, acetaldehyde, menthol, flavorings, as well as substances emitted in the normal course of use of the products, such as carbon monoxide gas and carcinogens. In addition, performance standards could cover substances that may not have been intended for the final product but are residual from tobacco growing, storage and processing, such as pesticide and herbicide residues, as well as contaminants including heavy metal residues, cyanide, insect parts and other materials. Performance standards can also be developed for product emissions commonly known as tar but which include deadly carcinogens such as tobacco specific nitrosamines, and formaldehyde.

Nicotine content and dosing need to be regulated. Nicotine is regulated in medicines and it must be regulated in tobacco products where content and delivery are often much higher than is allowable in medicines. For example a typical "pinch" of some of the most popular snuff products contains 10–20 mg nicotine compared to 4 mg in the highest dose of nicotine gum or lozenge.

Tobacco delivered nicotine, particularly from cigarettes, is particularly addictive because of the various ingredients and design features that function to increase the addictiveness of the products. For example, the level of free-base nicotine allowed in cigarette smoke needs to be examined and considered for performance standard development. Other ingredients that appear to synergistically increase the addictiveness of the product such as acetaldehyde need to be examined from this perspective in performance standard development.

Perhaps most controversial is whether performance standards should be developed with the intent of phasing nicotine out of cigarettes. I have published papers on the potential benefits (e.g., making tobacco products less addictive) and obstacles (e.g., precipitating increased use, mass withdrawal, and inadequate treatment infrastructure for tobacco dependence) for such an effort. However, I am in agreement with the World Health Organization, that at present it would be premature to attempt to drastically alter levels through regulation. The bill will give FDA the flexibility and authority to develop the additional science, as necessary, to set performance standards for nicotine content and delivery.

Regulatory flexibility to address emerging science and evolving products is part of FDA's strength that will be enabled by the Senate bill. If we think of tobacco products as analogous to deadly globally spread viruses, then we must also think of them as constantly evolving, requiring vigilant oversight and the sort of authority to regulate that FDA exerts over foods and drugs. This means that performance standard setting and evaluation will be a continuous process as long as tobacco products are marketed. This is also important because we need to assume that in any science-based regulatory process, new science will emerge that requires an agency like FDA to reconsider and, if needed, modify previously issued regulations. By contrast, as described below, the light cigarette fraud emerged and persisted over several decades and was not even irrefutably unmasked until the 2001 publication of National Cancer Institute Monograph 13. But yet the fraud continues unabated in the regulatory vacuum!

PRODUCT MISREPRESENTATION, HEALTH AND HARM REDUCTION RELATED CLAIMS NEED TO BE REGULATED

With the recognition by the Surgeon General in 1964, that cancer risk was related to overall tobacco exposure, cigarette smokers were encouraged to quit. Those who did not quit were encouraged to reduce their exposure. The focus was on "tar" because this conglomerate smoke condensate contained many substances that separately and together were clearly implicated in cancer and lung disease. This gave birth to the Federal Trade Commission's method for tar and nicotine assessment and communications. Nicotine was included in part because of its presumed role (probably over estimated at the time) in heart disease. The intentions of the FTC were good but it is not a science and health agency, and it adopted a method that was well understood and easily defeated by the tobacco industry. Armed with a flawed method and little expertise in understanding drug delivery systems, assessing drug delivery, or monitoring and evaluating health effects, the FTC was no match for the tobacco industry. The industry co-opted the FTC's ratings of tar and nicotine as marketing tools to reduce smokers concerns about smoking. By designing cigarettes that generated lower tar and nicotine ratings, labeling those below certain levels "light" and "reduced tar and nicotine" the industry had a powerful force to prevent or at least delay life-saving smoking cessation by many people.

After reviewing evidence and listening to various experts, Judge Kessler, in the *Findings* from the DOJ trial concluded as follows:

> "They [tobacco company defendants] also knew that the [FTC] Method was totally unreliable for measuring actual nicotine and tar any real life smoker would absorb" (Paragraph 2627).

Further,

> "By engaging in this deception, Defendants dramatically increased their sales of low tar/light cigarettes, assuaging fears of smokers about the health risks of smoking . . . " (Paragraph 2629).

THE LIGHT CIGARETTE FRAUD CONTINUES: REGULATION IS NEEDED TO PREVENT DECEPTIVE DESIGNS THAT ARE KILLING AMERICANS

Today, more than two thirds of cigarette smokers smoke light cigarettes. My sister was one of them. As she told me: "You can tell Reds (Marlboro Regular Cigarettes) are worse: they felt stronger and left my throat raw compared to Lights." Let me tell you a few things she didn't know and that angered her when she found out. She assumed that there were government standards for light cigarettes and that the FTC testing method intended to measure tar and nicotine yield reflected health effects or at least actual intake as is the case for food labeling. She assumed that cooler, smoother smoke meant that it was weaker and less harmful. She had no idea that a hidden ventilation system was diluting the poisons for smoking ventilation by allowing fresh air to be "inhaled" by smoking machines, whereas she and other smokers were probably taking in two to three times as much tar and nicotine than indicated by the ratings. She couldn't believe "the government" would allow such a scam.

Since the light and low-tar scam began with a vengeance in the late 1960s America has lost tens of millions of its citizens prematurely as they smoked light cigarettes to their graves, all the time not knowing that tobacco industry marketing of "light" and "low" cigarettes was completely misleading and that these products were not any less harmful than other cigarettes. In 2001, the National Cancer Institute in Monograph 13 finally concluded definitively: "Epidemiological and other scientific evidence . . . does not indicate a benefit to public health from changes in cigarette design and manufacturing over the past 50 years."

HOW DID IT HAPPEN? WHAT CAN WE LEARN? LOOKING INTO LIGHTS—THROUGH THEIR HOLES

Most aspects of cigarette design that contribute to harm and addiction require sophisticated equipment and procedures to detect, such as CDC's approach to measuring free-base nicotine. However, cigarette ventilation is one deadly scam you can see for yourself. If you tear the filter paper from a cigarette filter and hold it up to the light, you can see bands of tiny vent holes about ⅜ to ½ inch out from the filter end. This is right where they can be easily covered with lips or fingers. Unbeknownst to most cigarette smokers, blocking of the holes with lips or fingers can easily double or triple delivered tar and nicotine. On most cigarettes they are difficult to see because the designs are intended to hide them. When the cigarettes are smoked according to the FTC method, the holes leak anywhere from about 20–90 percent air into the testing apparatus, thereby contributing to the deceptively low advertised rating. I did this demonstration a few years ago for my son Vincent's third grade class and his classmates reacted with clarity and passion. Their comments included: "that's cheating!" and "they [the companies] can't do that."

By analogy, this is like punching holes in a fruit drink container, allowing some of the beverage to leak out, *then* testing the residual beverage for calorie and sugar content and listing those figures on the box even though consumers may consume several times more sugar than was listed on the package or in advertisements. That would be cheating, and there is a means of stopping and preventing it with food products, but not for tobacco products—not until tobacco is regulated by FDA, which routinely addresses such issues with food and drug products. In fact, for any food or beverage in America, including Kraft cheese, Miller Lite beer, Oreo cookies, and potato chips made by tobacco company affiliates, such fraudulent misrepresentation of products can result in the products being pulled from shelves and/or penalties. Manufacturers can't even claim dog food is low fat if it is not true. Companies that market addictive drugs for therapeutic use must formulate and market them to reduce risk of addiction and other adverse side-effects, or the drugs can be refused approval, pulled from the market, or be subject to new limitations on marketing, as has happened to several potentially addictive medications in recent years. Tobacco products are not therapeutic but many of the same principles apply.

"Light" and "low tar" cigarettes can be considered the first generation of putative but fraudulent "harm reduction" products designed to address smokers concerns about health but not really to reduce their health risks. Light cigarettes may just be the tip of the iceberg though.

New generations of products appear to be following the commercially effective model of light cigarettes, which is to ensure that new products are highly addictive to sustain use, with designs and marketing efforts to assuage fears about tobacco. There is the theoretical potential to reduce actual toxin exposure and an Institute of Medicine Report released in 2001 acknowledged this, giving the potential product category a new name: Potential Reduced Exposure Products or PREPS. It urged, however, regulation by FDA to provide a framework for evaluation of the products, determine what communications would be appropriate, and monitor their use and impact. Absent with such regulation, products termed PREPS by an unfettered industry could be the next generation of lights, further undermining prevention and cessation, and killing many of their users.

Fortunately, we have learned a lot in the past decade that will arm FDA in its regulation of PREPS, lights, and all other tobacco products. Much of this information emerged thanks to the 1990s investigation by FDA as part of its Tobacco Rule development. More information emerged through litigation against tobacco companies that made public millions of pages of previously secret internal tobacco industry documents, giving birth to a new research discipline called "tobacco document research," which involves increasingly sophisticated analysis to determine what the industry knew about health effects and addiction engineering, as well as many of its actual practices. We also have empirically derived knowledge from NIH and CDC research relevant to tobacco product design and effects. Perhaps most importantly, we have learned, through the tobacco industry documents, how much more the industry knows than it discloses, how much it knows about designs and ingredients to heighten addiction risk, and how much more we need to learn if we are to more effectively prevent continued product manipulation. I believe that an empowered FDA could demand and evaluate such information, and put it to use to serve public health.

For example, as you have learned, the State of Massachusetts cigarette testing program shows nicotine levels had gradually increased in many brands since the late 1990s. There has been considerable debate as to why this was done. My opinion is that this was done to make it easier for cigarette smokers to get their daily addictive fix of nicotine when faced with restrictions on smoking and higher costs that drive their daily cigarette intake down. To tobacco companies, keeping their customers addicted and satisfied is better than allowing cigarette smokers to reach that point that sustaining nicotine is such a hassle that they are more driven to quit. However, that is my opinion, and in the absence of regulatory oversight there is no way to find out the basics: the how, what, why and when. You see, regulation would give FDA the authority to demand an explanation and even to ban the manipulation if it deemed that it was contrary to the interests of public health. FDA could freeze levels; it could even require reduction of various toxicants and nicotine over time.

Senators, it is time that the American public be truthfully told what the tobacco industry knows about the ingredients, delivery, and effects of the products, and that the products they buy and use are honestly labeled regarding ingredients and maximum possible exposure levels. We would not tolerate such deception with food manufacturers or the makers of any other products consumed by Americans. It is time to stop protecting the tobacco companies and start making them play by the same rules as the manufacturers of other products consumed by Americans. The deception continues and is poised to worsen: tobacco products are mutating undeterred by regulatory oversight. Learning the truth and developing appropriate communications for consumers for existing products and the pipeline of new drugs or consumed products, is central to FDA's mission.

Absent regulation, the deadly deception I have described continues. Cigarettes and smokeless tobacco products are designed to addict, designed to go beyond the addiction risk of their relatively crudely manufactured ancestors. Cigarettes are designed to taste smooth and garner misleadingly-low tar and nicotine ratings because consumers react to such information as meaning substantially-less harmful. Tobacco products are researched, designed, manufactured and marketed to maximize the likelihood of trial, the graduation from trial to addiction, and to retain their addicted users despite efforts to quit. Products are fine tuned to attract various populations, including the young, with flavors, designs, and dosing characteristics. This is far beyond simply satisfying existing needs and desires of adults.

And the problem appears to be worsening: More Americans than ever before are concerned about smoking, and want to quit. But without regulation these individuals will turn to light cigarettes or new tobacco products that falsely claim (at least

implicitly) to be less harmful. These products have been shown to reduce the motivation to quit smoking because of the false reassurance that the smoker is "doing something" that represents a healthier step in the right direction. But delaying tobacco cessation is deadly: disease risk is more strongly related to years of smoking than to the number of cigarettes smoked per day.

Worse still, the pipeline of new products and claims is growing. Some of you may have seen advertisements in widely-circulated magazines such as Parade, trumpeting cigarettes such as Omni and Eclipse that are "lower in carcinogens" and "may present less risk of cancer, chronic bronchitis and possibly emphysema." Eclipse, delivers very high levels of the deadly odorless gas carbon monoxide. Marketed versions were also reported to deliver glass fibers from its aluminum and glass inner chamber that can penetrate the lung.

Philip Morris is now test marketing what many smokers might be truly waiting for, a Marlboro with reduced risk claims: Marlboro Ultra Smooth. Philip Morris has admitted that it is premature to make harm reduction claims for the product though they tout the product's potential to reduce exposure to harmful substances. In the void of regulation, however, Philip Morris is test marketing the product and creating the illusion of reduced harm through its clever name and descriptions of the potential of the product to reduce certain substances. Furthermore, it is using messaging such as "Filter Select" and "new carbon filter" which might be reasonably construed by a consumer to indicate advances in filtration of harmful elements.

One widely-advertised cigarette, Quest from Vector, even claimed to be "nicotine-free" supporting the claim by asserting it met the "standard" of Benowitz and Henningfield. Now, without detracting from my own work with Dr. Benowitz, we are not FDA, and we never intended a recommendation for reducing the addictiveness of cigarettes to stand in place of FDA evaluation and regulation. This would be laughable if it were not deadly and still being perpetuated.

I am not here to testify, that products such as Quest and Marlboro Ultra Smooth are, in fact, as deadly as conventional products. The problem is there is no way to know if they are potential steps in the right direction or as fraudulent and deadly as light cigarettes. And there will be no way to tell until we have an authorized and empowered FDA to find out.

There is also an increase in widely advertised smokeless tobacco products from "for when you can't smoke," implying you don't need to quit smoking because you can use their products when you can't smoke. The lure is increased by touting new products and implied benefits. One product is packaged to resemble a medicinal cessation product with its label reading "for when you can't smoke." These manufacturers are using Americans as guinea pigs without informed consent. They are introducing new products; modifying products with new designs and ingredients; and making claims, implicit and explicit, without regulatory oversight from the one agency, FDA, that is charged with the oversight of consumable products that have health effects, and require consumer communications that are honest and do not mislead. These efforts not only are deceptive, they help the industry thwart tobacco prevention and cessation efforts.

REGULATION IS OVERDUE AND URGENT

For several decades, the tobacco industry anticipated but fought FDA regulation, as illustrated by Philip Morris scientist William Dunn's warning to his superiors in 1969:

> "I would be more cautious in using the pharmic-medical model—do we really want to tout cigarette smoke as a drug? It is of course, but there are dangerous FDA implications to have such a conceptualization go beyond these walls."

Dr. Dunn was right in his apparent assumption that FDA authority could have reined in many deceptive practices of the tobacco companies.

FDA IS THE RIGHT AGENCY AND THE ONLY AGENCY WITH APPROPRIATE EXPERIENCE TO DEVELOP AND ENFORCE PRODUCT PERFORMANCE STANDARDS

I have heard the entire range of arguments about why FDA should not be granted regulatory authority, including that FDA was not designed to evaluate cigarettes. The fact is that FDA was designed to assess safety, ingredients, and resultant exposure to a broad range of drugs and foods. Tobacco products are drug delivery systems at heart. They are sophisticated and complicated with many ingredients, just as many drugs are. Even the tobacco industry admits this in their documents. Moreover, they are designed to deceive, and designed to heighten addiction risk.

Foods and drugs that are designed and/or marketed to deceive, whether by intent or not, can be judged as misbranded or recalled, and lead to various correctional actions ordered. This happens frequently and routinely many times each year for foods

and drugs. FDA has more experience and sophistication in the regulation of drugs and drug delivery systems than any agency in the world. This is the same expertise that needs to be applied to tobacco.

For any product, whether food, drug or dog food, FDA can ask and must be given answers to the basic questions that many consumers of those products undoubtedly believe are being addressed for tobacco products: WHO is the product for? WHAT is in it? WHY is it designed and manufactured as proposed or done? HOW is it manufactured? WHEN were changes made? FDA can require surveillance to detect unintended consequences of products already marketed or proposed for marketing approval if it has residual concerns.

Finally, what is communicated to consumers about product content will be vital, so that eventually tobacco products, like other consumable products, are labeled in meaningful ways that do not confuse or obscure the truth, do not inappropriately make or imply claims, and do not unintentionally undermine efforts to prevent tobacco use from beginning and tobacco users from quitting.

FDA's authority will not make tobacco products safe, and should not be seen as a substitute for comprehensive tobacco control efforts to reduce all forms of tobacco use and disease. In fact, FDA regulation should be viewed as a partner in these efforts and be positioned to serve these efforts because it will restrict the ability of the industry to modify products and descriptors to undermine prevention and cessation. For all of these reasons and more, FDA regulation of all tobacco products is vital in setting our Nation on a healthier path. Directing the FDA to develop its regulatory system with urgency, empowering it to rise to the challenge of tobacco regulation, and providing it with the support to get the job done can be accomplished through Senate bill S. 625. I therefore urge its most expeditious passage and implementation.

Senator SANDERS. Mr. Chairman.

The CHAIRMAN. Yes?

Senator SANDERS. I'm going to apologize. I have to leave as well. I just wanted to thank all of our guests here today and I would just say, Mr. Chairman, the idea that we throw drug pushers and heroin dealers into jail because of what they do to our kids and the idea that we do not regulate those people who are pushing cigarettes and addicting kids and killing kids, cause lung disease and emphysema and everything else, it's incomprehensible. So thank you very much for holding this important hearing.

The CHAIRMAN. Thank you.

Senator SANDERS. I look forward to working with you.

The CHAIRMAN. Dr. Connolly.

STATEMENT OF GREGORY N. CONNOLLY, D.M.D., M.P.H., PROFESSOR, HARVARD SCHOOL OF PUBLIC HEALTH, FORMER DIRECTOR OF THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH'S TOBACCO CONTROL PROGRAM, BOSTON, MA

Mr. CONNOLLY. I think it's over 20 years of coming before this committee and it's like watching the Red Sox. We always hope that next year, next year. Not only being a Red Sox fan, my son-in-law is from Columbus so we watch the Buckeyes every year very carefully.

When I was in Massachusetts, we achieved a 50 percent decline but we still got stuck at 18 percent of our adults. We still got stuck with youth rates and not enough change. So we tried to fill the void with the Federal Government. We regulated advertising on schools and playgrounds. We acquired ingredients. We have a new testing protocol that the feds don't apply in Massachusetts but we found we lacked the resources and we lacked the legal authority to do so.

Clearly we need the Federal Government to step in and fill this void. If we wanted to put a warning label on Marlboros, as a State we couldn't do it, the way they do it in Britain, the way they do

it in Brazil, a developing country. We couldn't do it. So States like Massachusetts, Ohio, Wyoming, North Carolina—basically that's third-world states with Brazil, Jordan and others having much more effective warning labels.

We looked at—and I have a slide, could we see it, please? We looked at nicotine through the Massachusetts testing system and we found that over the past 8 years, there has been a 11 percent increase of nicotine, both in the smoke and the raw and you can see here, there is significant increases.

Next slide, please, next chart, please. We looked at Marlboros in particular and we found that—we took into account random fluctuation that this was, in fact, a significant increase. I wish we didn't see this increase. I wish we saw post the MSA, nicotine levels going down.

Why did this occur? We have no clue as a State. We don't have the resources. The Harvard School of Public Health doesn't have the resources. Why did they do it? We don't know. Did this increase addiction among kids or adults trying to quit? We don't know. But all of those questions can be answered by the Food and Drug Administration if this bill is passed.

We just don't know. Is it a real increase? The industry has challenged us and said, "no it is a real increase." We took into account through very good statistics, which haven't been applied by the tobacco industry, we found an increase. Is it new? It's not new. This has been occurring through decades. The only new issue here is that this occurred after the MSA.

Also, the train has left the station on reduced risk products. There are over 38 that have been marketed, mostly after the MSA with claims that they reduce cancer risk, that they lower carcinogens.

Next chart, please.

We conducted research among 600 smokers and we asked the question, do these reduced-risk products lower your risk to disease versus light cigarettes and versus regular cigarettes. Even if you are seeing an implied claim, universally the smokers who looked at the advertisements for these reduced-risk products—Eclipse, Omni, Advance—perceive the implied claim as an explicit claim. They perceived it as a way to forestall quitting. They perceived it as a way to reduce their cancer risk. So it's a repetition of the failed history of light cigarettes.

What we found through the Harvard research at the Nurse's study that light cigarettes only increase the risk of disease versus others. So we need FDA regulation, not to regulate only explicit claims but implied claims until we show it is safer.

Are we saying we want to ban Marlboros? I don't think so. I think it's unrealistic. I think it's unreasonable but we maybe want to create Marlboros so that they are like lard. They are legal but we regulate the constituents, we regulate the toxicity, we regulate whatever—so it sits back on the shelf and no one uses it.

And FDA tomorrow can give us warning labels or a ban on lights. They can give us restrictions on ads near schools but it may take some time to come up with a product where we can make perhaps a claim that it is safer, but it's worth waiting for that. It's worth that legislation.

Next chart, please.

Post the MSA, we looked at advertising and we scored youth ads versus adult ads and we found on this chart here that at least for two companies, that the exposure to adults and youth are equivalent. That is a rating of 100—100 exposures and the same for adults and kids. They haven't changed their marketing to youth. They've just gotten smarter. This is an ad for the new custom Kool and I've asked how many people wear running shoes like this into the committee room today. But this is in magazines like Rolling Stone, with more youth readership, enough for the FDA provision.

Next, please.

The CHAIRMAN. Could you adjust the chart. The light is reflecting off of it. I don't understand quite what's going down and what's going up.

Mr. CONNOLLY. OK, what we did here is we looked at pre- and post- the MSA and we looked at exposures to advertising among youth and adults. So before the MSA—1997, 1998, we had about 160 exposures on average to adults and about the same for youth. That was 12 through 17. MSA came in and we saw a general reduction in advertising so that was good, primarily driven by Philip Morris and I'm not thanking them for that because they could still get rid of their marketing but for RJ Reynolds, Brown and Williams and RAI, the youth exposure equals the adult exposure. So there is no change. Kids are still being exposed to advertising at the same levels that adults are being exposed.

One of the tragedies is, we went from—in the advertising, we went from 19 percent of the ads for menthol ads, which are popular with black kids—we're now at 50 percent. Half of the advertising is for menthol. Like this. We found the industry is manipulating the menthol levels, post the MSA, to make those products more attractive with young African Americans. And what happened? OK, the youth rights went down with the adolescent white kids, is old men wear ties. That's great. But for black African Americans, the young adults, rates had gone up 30 percent from 2002 to 2005, based on the SAMSA research. Yeah, we've been successful with those guys. But this industry clearly is going after the high-risk population with manipulation of menthol, increased marketing and advertising for menthol and what is the result? It's a negative population impact.

Next please and I'm going to finish up here. This is the candy-flavored cigarette. No one knew this was here. RJ Reynolds had this in the tank prior to the MSA. But after the MSA, they introduced this new pellet, which impart a candy-like flavor to the smoke. No one knew it was there, not even smokers. The only people who knew it was there was Philip Morris. We went out and we found an internal document, brought it and—would we allow this to be put in a food product without telling anyone? We then ran a gas spec and we found foreign constituents in that pellet and no one had a clue what those constituents did, either in helping youth to start or its toxicity and the FDA can do that with this action.

Has the industry changed after the MSA? Yeah, but maybe not for the better. And I'll end by saying 40 years ago, a Senator from New York gave the opening address at the First World Conference on Smoking and Health and he prophetically warned that 28 mil-

lion Americans will be killed by smoking unless urgent action was taken. Fifty million Americans have been killed since that date, since that Senator made that statement. He told the attendees at that meeting to be equal to the task, for the stakes are nothing less than the lives and health of millions all over the world. I know it is a battle which will be won. Our battle—that Senator's vision—will be won when this Congress passes this historic legislation. The States can't do it alone, Senator. As one who has fought in the trenches, pushed the envelope of the States, we can't do it alone. We need your help. Thank you very much.

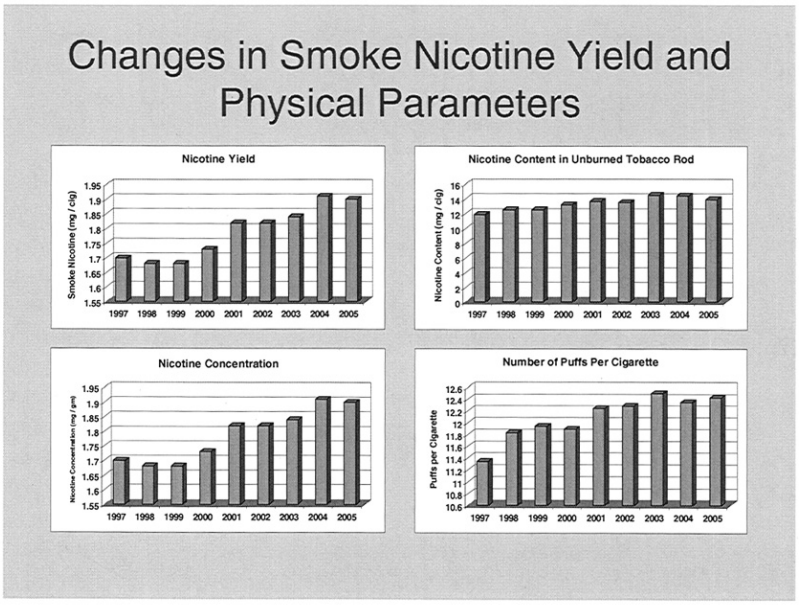
[The prepared statement of Mr. Connolly follows:]

PREPARED STATEMENT OF GREGORY N. CONNOLLY, D.M.D., M.P.H.

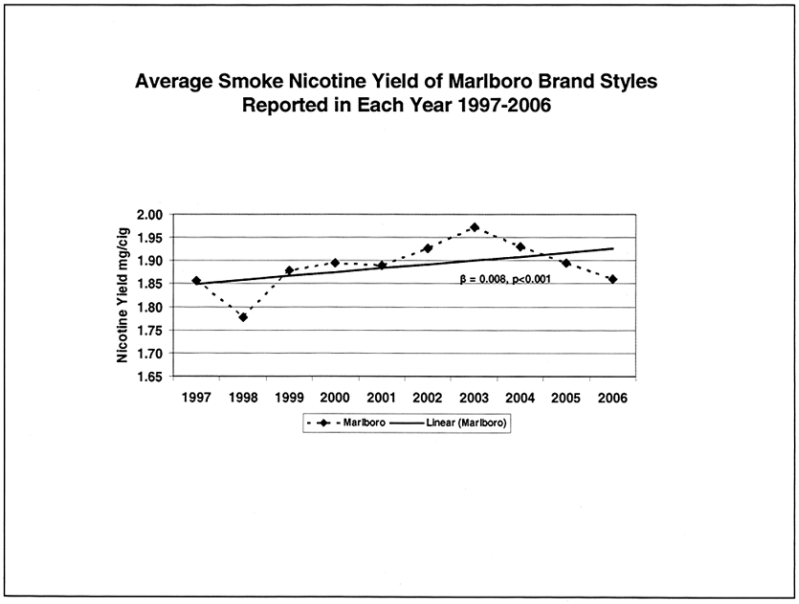
My name is Gregory N. Connolly. I am a professor at the Harvard School of Public Health (HSPH) and direct the Tobacco Control Research Program. Prior to coming to Harvard, I served as the director of the Massachusetts Department of Public Health's Tobacco Control Program and in that capacity, oversaw one of the largest public health programs to curb tobacco use in the United States achieving a 50 percent decline in cigarette consumption from 1993 to 2003. Massachusetts was the first State to require warning labels on smokeless tobacco, the second for warnings on cigars and the first to require public disclosure of tobacco product additives and nicotine yield. Massachusetts has led all States in attempting to fill the Federal void in regulating tobacco products and marketing. We clearly found that States lack the resources and legal authority to effectively do so. FDA regulation is urgently needed today. My opinion is based on the following:

1. *Despite the Tobacco Industry's Admission that Nicotine is Addictive, Following the MSA Manufacturers Have Increased Nicotine Content in Cigarettes and Cigarette Smoke.*

Our research has found a significant increase in nicotine to cigarette tobacco and smoke from 1997 to 2005 (12 percent). Industry manipulation of nicotine is nothing new, what is new is that it is still occurring post the MSA. A statistically significant trend confirmed an increase in smoke nicotine yield of 0.019 mg per cigarette (1.1 percent) per year over the period 1997–2005 for an 11.7 percent increase. The increasing trend was observed within all major market categories (mentholated vs. nonmentholated and full flavor vs. light, medium (mild), or ultralight).



Increasing smoke nicotine yield was associated with increasing nicotine concentration in the tobacco and number of puffs per cigarette, and decreasing percent filter ventilation of the cigarette. Such changes increased the elasticity of the cigarette making it potentially more addictive.



In her August 2006 decision, Judge Kessler devoted 140 pages to describing the tobacco industry's long history of nicotine manipulation. She concluded that tobacco manufacturers:

• ". . . have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction."

• ". . . have extensively studied smoking intake and inhalation, compensation, addiction physiology, smoker psychology, the pharmacological aspects of nicotine, the effects of nicotine on brain waves, and related subjects."

• ". . . intentionally developed and marketed cigarettes which, in actuality, delivered higher levels of nicotine than those measured by the FTC method."

These studies consisted not only of consumer smoking panels but also large-scale human clinical trials, electrophysiological studies of brain waves, chemical and physical brand analyses, and other sophisticated techniques. Factors such as use of blends, genetic modification of tobacco, and in particular, ammonia or other chemical agents are used to alter the chemical form of nicotine delivered to the smoker. Detailed evidence shows that manufacturers could and did manipulate free nicotine delivery through product changes and that even "small" increases in free nicotine delivery could significantly increase their ability to deliver an "optimum" dose of nicotine capable of creating and sustaining addiction in cigarette smokers.

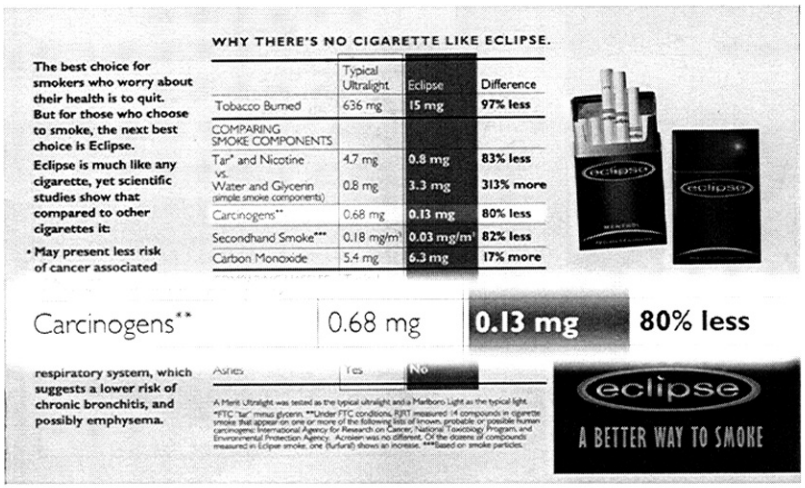
Our research is not new but only shows that this historical pattern of nicotine manipulation has not changed. We don't know why nicotine has increased. The tobacco industry regulatory oversight by the FDA is necessary to evaluate changes in product delivery and their effects on smoker initiation and use; and possibly to make the product less addictive.

2. *Since the MSA Tobacco Manufacturers Have Greatly Increased the Marketing of "Safer" Cigarettes to Health Conscious Smokers in the Absence of Independent Scientific Evidence They are Actually "Safer."*

This Nation has already suffered immensely from the failed history of light cigarettes when they were presented in the 1970s as a "safer" alternative to regular brands. The Harvard School of Public Health's Nurses Study found that smokes of "lights" had the same risk of cardiovascular diseases as smokers of regular brands. The National Cancer Institute concluded in 2001 that smoking "lights" did not reduce the risk of lung cancer. In the absence of FDA regulation, the failed history of "lights" will only be repeated with the promotion of cigarettes today as being safe.

Potentially Reduced (tobacco) Exposure Products (PREPS) are being marketed with explicit and implicit claims that they reduce health risks in the absence of scientific evidence to show they actually do. Over 35 PREPS have been marketed over the past few years (see Appendix A).

In 1998, RJR claimed that there is "No Cigarette Like Eclipse" based on a comparison of its smoke chemistry to a typical ultralight cigarette (Merit) and also claimed that Eclipse may reduce cancer risk. We analyzed the smoke chemistry of Eclipse versus two conventional ultralight cigarettes (NOW and Carlton) and found that Eclipse had up to five times the levels of cancer causing agents than the existing Now or Carlton brands. There are "Cigarettes like Eclipse" in the marketplace. A careful review of other research conducted by RJR on Eclipse found serious problems with the methodology that supported the lung cancer reduction claim.



WHY THERE'S NO CIGARETTE LIKE ECLIPSE.

The best choice for smokers who worry about their health is to quit. But for those who choose to smoke, the next best choice is Eclipse.

Eclipse is much like any cigarette, yet scientific studies show that compared to other cigarettes it:

- May present less risk of cancer associated respiratory system, which suggests a lower risk of chronic bronchitis, and possibly emphysema.

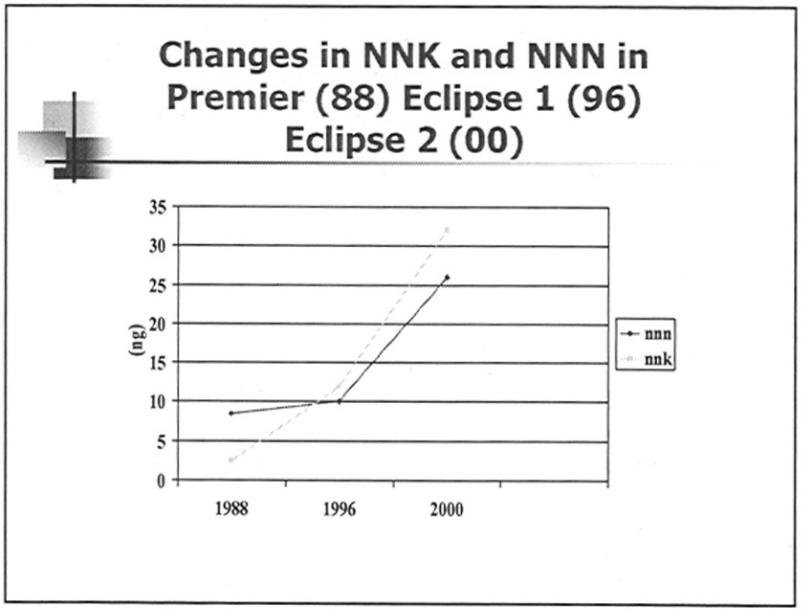
	Typical Ultralight	Eclipse	Difference
Tobacco Burned	636 mg	15 mg	97% less
COMPARING SMOKE COMPONENTS			
Tar* and Nicotine vs. Water and Glycerin (simple smoke components)	4.7 mg	0.8 mg	83% less
	0.8 mg	3.3 mg	313% more
Carcinogens**	0.68 mg	0.13 mg	80% less
Secondhand Smoke***	0.18 mg/m³	0.03 mg/m³	82% less
Carbon Monoxide	5.4 mg	6.3 mg	17% more
Carcinogens**	0.68 mg	0.13 mg	80% less
Ashes	Yes	No	

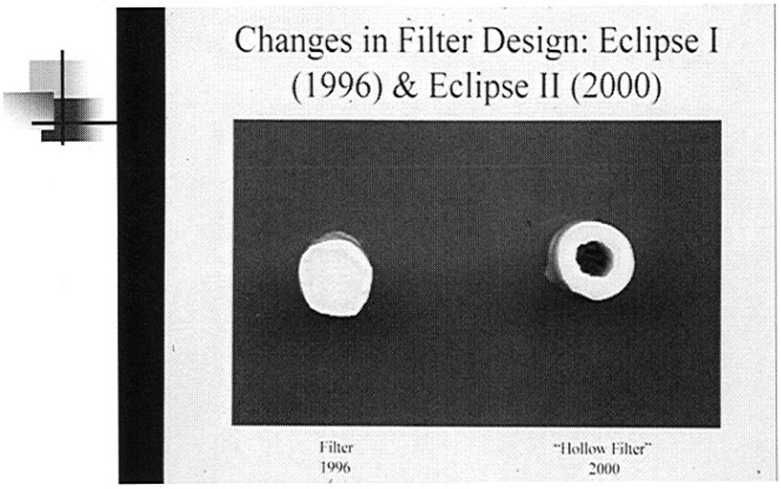
A Merit Ultralight was tested as the typical ultralight and a Marlboro Light as the typical light. *FTC "tar" minus glycerin. **Under FTC conditions, RJRT measured 14 compounds in cigarette smoke that appear on one or more of the following lists of known, probable or possible human carcinogens: International Agency for Research on Cancer, National Toxicology Program, and Environmental Protection Agency. Acrolein was no different. Of the dozens of compounds measured in Eclipse smoke, one (furfural) shows an increase. ***Based on smoke particles.

eclipse

A BETTER WAY TO SMOKE

When sales for Eclipse faltered in the late 1990s, RJR altered the filter design by drilling a hole in it but not alerting consumers to the change. The new design resulted in an increase of 300 percent in two cancer causing agents called NNN and NNK. Consumers were not informed of the design change on increase in toxins.

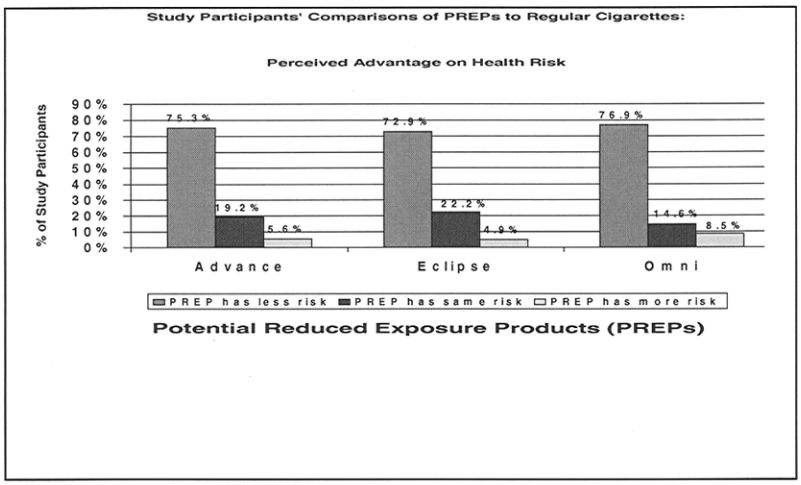




We tested two prototypes of the new carbon filtered PREP, Marlboro UltraSmooth (MUS), test marketed in the United States beginning in 2005, using both standard (FTC/ISO) and intensive (Health Canada) machine methods to measure gas/vapor and particulate phase smoke constituents. When tested under the standard regimen, gas phase constituents of MUS prototypes were reduced compared with a conventional low yield cigarette. However, far smaller reductions in gas phase constituents were observed under the intensive regimen, suggesting that the carbon technology employed in MUS is less effective when smoked under more intense conditions. Particulate phase constituents were not reduced by the carbon filter under either machine smoking regimen. Studies of human smoking show that MUS is likely to be smoked intensively, thus negating its potential for toxic constituent reductions.

PREPS have been marketed include nicotine hand gel, nicotine chewing gum, modified cigarettes (Omni, Advance and Marlboro UltraSmooth) and electrically heated nicotine inhalers (Accord) (see Appendix). All of these products have been sold with implied or explicit claims of reduced risk without review or approval of independent scientific agencies such as the FDA.

Other research we conducted showed that consumers perceive implied claims for reduced levels of toxins in smoke as explicit claims for reduced health risks when, in fact, there is no science to support the claims. We studied 600 adult smokers who reviewed advertisement for regular and PREP cigarettes. Smokers perceived PREP products as having lower health risks (mean=5.4 on a scale of 1–10) and carcinogens (6.6) than light cigarettes (5.8 and 6.9, respectively, $p < .001$), and lights as having lower health risks and carcinogen levels than regular cigarettes (8.2 and 8.8, respectively, $p < .001$). Although no advertisements explicitly said that the products were healthy or safe, advertisements for PREP products and light cigarettes were interpreted as conveying positive messages about health and safety. Most smokers believed that claims made in cigarette advertisements must be approved by a government agency. The results indicate that advertisements can and do leave consumers with perceptions of the health and safety of tobacco products that are contrary to the scientific evidence. This supports regulating the promotion, advertising, and labeling of PREP tobacco products and light cigarettes. Effective FDA regulation should focus on consumer perceptions resulting from advertisements not just the explicit content of advertising text. This is needed to prevent a repeat of the failed history and disease burden by the marketing of "lights." The unintended consequences of PREP marketing by youth initiation and deterrence of quitting can also be monitored by the FDA.



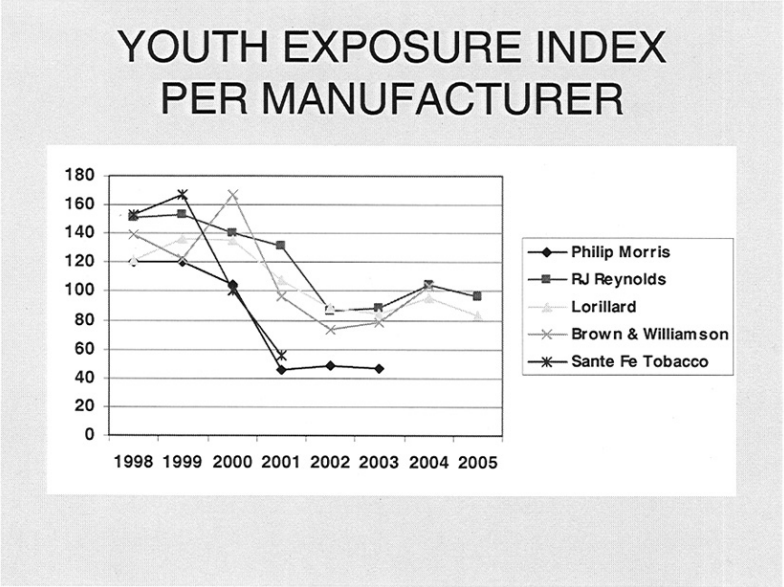
The bill will give the FDA authority to prevent such unsubstantiated claims from being made. FDA will require scientific support and closely examine the real world performance of PREPs such as Eclipse and MUS. Regulation of PREPS by independent health agencies such as the Food and Drug Administration is needed to protect the public health and validate both the industry science and its claims.

3. Advertising After the Master Settlement Agreement has Become More Targeted to Youth, Minorities and Other High-Risk Groups.

Following the Master Settlement Agreement (MSA), youth and other high-risk groups, including low-income women and African Americans, have been targeted with disproportionate levels of magazine advertising for tobacco products. Our analysis of tobacco magazine advertising post the MSA found, from 1998–2005 on average, every youth in the United States was exposed to 559 tobacco ads, every adult female 617 advertisements, every African American adult 892 ads, and every Hispanic adult 605 ads.

Exposure to a magazine advertisement is measured as the percentage of a population group that reads the magazines that runs the advertisement in the studied time period.

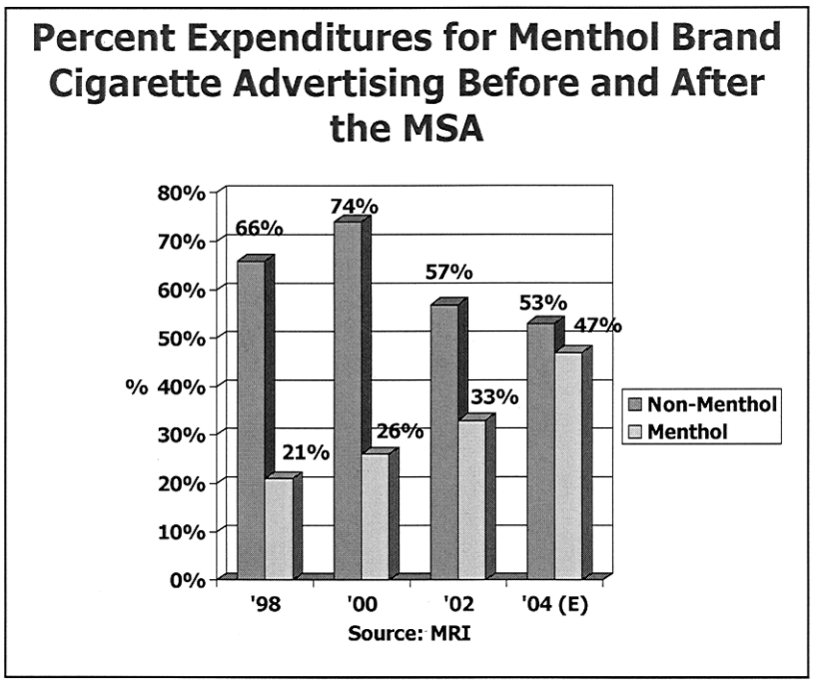
Compared to adults, youth had greater exposure to magazine advertising for cigarettes or major manufacturers including R.J. Reynolds, Brown & Williamson and Lorillard and were disproportionately exposed to magazine advertising for brands and varieties preferred more by youth including Newport and Camel, and mentholated and full flavor cigarettes. Philip Morris ended magazine advertising in 2003 but the other companies have more than made up for PM's absence. Despite the MSA, cigarettes were advertised in magazines with 15 percent or greater youth readership and in magazines with 2 million or more youth readers in every year from 1998 to 2005, criteria used in the 1994 FDA rule to define a youth magazine.



Regulation by the FDA can eliminate cigarette advertising to youth.

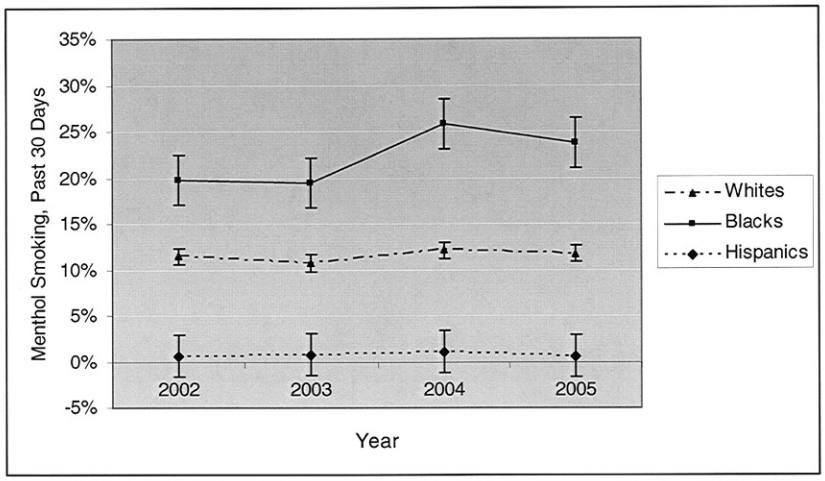
Among young, Black smokers, Newport has traditionally been the most popular menthol brand. Newport has the lowest menthol levels (0.24 percent weight of tobacco filler among King-size, full flavor) compared to its major competitor (Kool, 0.36 percent). Between 1993 and 2005, Newport's market share doubled, from 4 percent of market to 8 percent, while Kool and Salem's share of market has remained relatively steady.

Reynolds American Tobacco aggressively competed against Lorillard and recently re-designed Kool under the name Kool XL and heavily advertised it to compete against Newport's dominance among young Blacks. Kool Smooth Fusions is a candy-flavored menthol brand, promoted through dance clubs and hip hop music venues beginning in 2004. Philip Morris has followed Reynolds American promotion of Kool with Marlboro Smooth, a new menthol product, available in March 2007. Both brands employed the selling message "smoother" a possible connation of a reduction in menthol levels to target young Black smokers. Expenditures for magazine advertising of mentholated cigarettes has increased from 13 percent of total ad expenditures in 1998 to 49 percent by 2005.



Among Black young adults (age 18 to 25) menthol smoking rates increased significantly by 30 percent between 2002 and 2005 from 19.8 percent (95 percent CI: 17.7–21.9 percent) to 25.8 percent (95 percent CI: 23.5–28.1 percent), but did not increase significantly among same-aged Whites and Hispanics during that time. Nonmenthol cigarette use decreased by 39 percent among African-American young adults, although this change was not significant (from 7.9 percent in 2002 to 4.8 percent in 2005). In 2002, 19.8 percent (95 percent CI: 17.7–21.9 percent) of African Americans age 18–25 smoked menthol cigarettes (an additional 7.8 percent smoked nonmenthols). In 2004, 25.8 percent (95 percent CI: 23.5–28.1 percent) of African-American young adults smoked menthol (while an additional 4.0 percent smoked nonmenthols). In 2005, this proportion decreased slightly, but remained above pre-2004 levels.

Menthol Use in Past 30 Days Among Young Adults, by Race, 2002–2005



• The rates of menthol smoking among African Americans ages 18–25 years have increased by 10 percent per year since 2002 (OR = 1.10, 95 percent CI = 1.04–1.18).

• No statistically significant trends over time since 2002 are seen in the rates of menthol smoking among Whites and Hispanics ages 18–25 years or among Blacks or Hispanics ages 12–17 years.

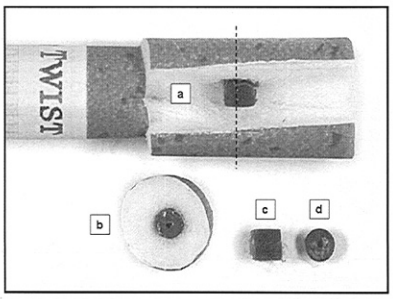
• The rates of menthol smoking among Whites ages 12–17 years have decreased since 2002 (OR = 0.95, 95 percent CI = 0.90–0.99).

Following the MSA, R.J. Reynolds acquired the second largest smokeless company Conwood for $4.8 billion and introduced its own smokeless brand called Camel Snuss. Philip Morris introduced its new smokeless tobacco brand in Indianapolis called Taboka and acquired a Swedish smokeless company the same year. Lorillard has entered into an agreement with Swedish Match North America to produce its smokeless brand in 2007. The cigarette companies, rather than offering smokeless products as an alternative to cigarettes, have only produced and sold smokeless products as a temporary way to receive nicotine through smokeless tobacco in places where smoking is banned thus perpetuating smoking.

FDA regulation is needed to prevent cigarette companies from marketing smokeless tobacco to perpetuate smoking. FDA authority is needed to require manufacturers to adopt new technologies to reduce toxins in all smokeless products not just the ones they make "safer" claims for.

In 2002, RJR introduced Camel "Exotic" Blends and Brown and Williamson "Kool Fusion" brands all with candy-like flavors in the product. The Exalt Camel brand used a plastic pellet in the filter to deliver flavors to smokers. No public health agency knew it was present, its toxicity or how it contributed to youth initiation. Candy-like flavorants mask the natural toxicity of smoke and could enhance initiation and addiction.

Examples of recent candy flavored cigarettes and flavor delivery systems



Camel Twist: Emission of This the Blue Flavor Pellet

- Laboratory test of compounds released by the blue pellet
  - Flavors on 599 list (linalool, citronellol, citral, cubeb oil, caryophyllene)
  - Flavors not on 599 list (elemene, copaene, muurolene,candinene, p-menth-1-en-8-ol)
  - Hydrocarbons (tetradecane, pentadecane, dodecane, hexadecane, heptadecane, octadecane)

The use of flavorants to appeal to young nonsmokers is consistent with other research on the reformulation of Camel cigarettes in the 1980s, a brand then popular with older men. The newly designed Camel was targeted to first-time young smokers by using additives that masked the harshness, making it smoother and easier to inhale. Market share for Camels rose among adolescent males three-fold post the reformulation from 3 to 10 percent.

CONCLUSION

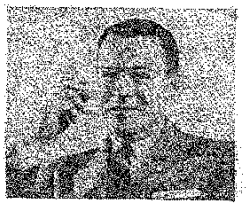
Post the MSA manufacturers have become more aggressive in targeting high risk groups including minorities and youth with aggressive advertising, re-designed products with more not less nicotine, introducing candy-like flavored product and aggressively marketing brands popular with young African Americans.

Forty years ago, a Senator from New York gave the opening address at the First World Conference on Smoking and Health and prophetically warned that 28 million

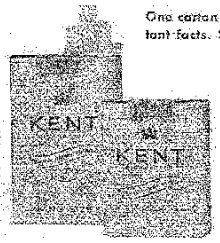
Americans would be killed prematurely by smoking unless urgent action was taken at that time. None was taken. The same Senator urged the attendees to: "be equal to the task. For the stakes are nothing less than the lives and health of millions all over the world. I know it is a battle which will be won." (Robert Kennedy, First World Conference on Smoking or Health) Our battle will be won and that vision fulfilled when the Congress passes this historic legislation.

Your voice of wisdom says SMOKE KENT

Your voice of pleasure says ENJOY KENT



One carton of KENTs will convince you of two important facts. Smoke KENTs for just a few days and . . .



King Size or Regular
. . . both same price

1. Gain the real assurance you can get only with KENT's Micronite Filter. Not just cotton, paper or cellulose, KENT's filtering material is so efficient it is recommended by scientists where filter effectiveness is vital. No wonder KENT's Micronite Filter has been proved effective in test after test . . . *the best filter you can buy.*

2. Give yourself an honest chance to adjust to KENT's mild flavor. See how KENT *stays fresh-tasting,* cigarette after cigarette.

There is a difference in KENTS
. . . buy a carton and see.

KENT

and only Kent has the
MICRONITE FILTER
the filter that takes out even microscopic particles

"KENT" AND "MICRONITE" ARE REGISTERED TRADEMARKS OF P. LORILLARD COMPANY

MARCH 26, 1958

MEDICINE

Britain & Barbiturates

Britain, once proud of the epithet "nation of shopkeepers," is in danger of becoming a nation of barbiturate addicts. At least, so thinks Sir Heneage Ogilvie, one of its most eminent surgeons. About one-tenth of all the 200 million prescriptions written annually by the doctors in the National Health Service are for barbiturates. Half the 545 suicides in 1951 were committed with barbiturates.

Writes Sir Heneage in the *Practitioner*: "It would not be a particularly difficult feat . . . to produce quite a convincing thesis that the present lackadaisical outlook of the country, so repeatedly lamented by the Chancellor of the Exchequer, is a symptom of chronic [barbiturate] intoxication."

Protein Prober

The intense young man who went to Harvard as an assistant professor in 1922 was no physician but a biochemist, ready to dedicate his life to probing the secrets of proteins. He would never get to treat a patient. But across the U.S. and around the world, hundreds of thousands are alive and well today, thanks to his biochemistry, and the vast majority of his beneficiaries have never so much as heard his name.

Edwin Joseph Cohn, son of a wealthy Manhattan tobacco importer, had just finished his doctoral thesis when World War I drew him into the Army Sanitary Corps. There he was sidetracked on an unrewarding assignment: trying to find a substitute for bread. As soon as possible, Scientist Cohn returned to his beloved proteins, learned what others knew about them in Copenhagen and Cambridge, then settled at Harvard to find out what nobody else knew.

No Time to Retire. By the time he was 40, Edwin Cohn had an imposing reputation in the narrow circle of protein specialists, and nowhere else. Then his doctors told him to retire: his high blood pressure might kill him any day. Dr. Cohn simply dosed himself with palliative drugs and kept on working. His first great success so far as medicine was concerned came in 1929 when he extracted from livers the substance that controls pernicious anemia. It meant that patients could take medicine, instead of having to eat a pound (or more) of liver every day.

When the clouds gathered for World War II, Cohn was again sidetracked, as he say it, from his protein work. The armed forces wanted to be assured of a supply of blood plasma, and the Navy thought Cohn should try to get it from beef blood because human donors would never suffice. Cohn found beef blood unpromising, and started a neighborhood donor service from which the Red Cross learned a lot. So the armed forces used human plasma.

But to Cohn, a perfectionist, this was grossly wasteful. Usually, only one or two components of plasma were needed for each case. So he set to work in his laboratory, separating blood fluid into its many fractions, and soon had a practical method for extracting serum albumin. This was less bulky than plasma, keeps better, and was far more economical. But it was not good enough for Cohn.

No Shotgun Blast. Driving himself as relentlessly as he drove the assistants who performed the practical experiments to prove his brilliant theoretical flashes, Cohn identified more and more of the components of blood, and developed improved methods for extracting many of them. There was fibrinogen, raw material from which fibrin film and fibrin foam are made, to close wounds and cover the brain in daring, delicate surgery. There

Walter S. Del Regno

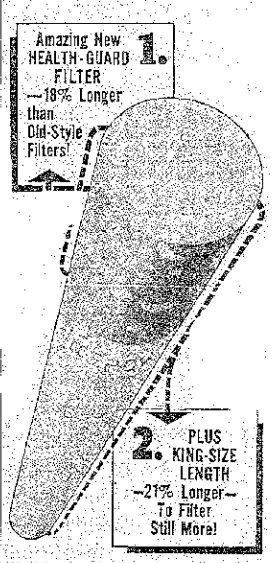
BIOCHEMIST COHN
To living Semiphilopics, unknown.

was thrombin, which combines with fibrinogen but is used separately in some cases. There was a special kind of globulin for Semophiliacs. There were globulins which made possible the immediate typing of any individual's blood.

Finally—and so far the most important—was gamma globulin, which prevents measles or soften its severity, and wards off infectious hepatitis. Most recently, gamma globulin has won fame in the fight against polio. A less-exacting researcher might have been satisfied, but not Cohn. He hated the waste (and doubted the wisdom) of using whole gamma globulin as a shotgun blast against any of these diseases, and wanted to break it down into still finer fractions for pinpoint use against each disease.

Last week portable fractionators of thirking-machine complexity were being built to Cohn's specifications for taking blood direct from a donor's arm and fractionating it on the spot. (Time, Oct. 23,

New KING-SIZE
VICEROY
GIVES YOU
DOUBLE-BARRELLED
HEALTH PROTECTION



Now, for the first time, you can get all the advantages of Filter Tip and King-Size combined in one great cigarette. Yes, new King-Size, Filter-Tip VICEROYS cost you only a penny or two per pack more than cigarettes without filters.

KING-SIZE FILTER-TIP
VICEROY

The CHAIRMAN. Thank you.
Dr. Blum.

STATEMENT OF ALAN BLUM, M.D., DIRECTOR, UNIVERSITY OF ALABAMA CENTER FOR THE STUDY OF TOBACCO AND SOCIETY, TUSCALOOSA, AL

Dr. BLUM. Chairman Kennedy, Senator Enzi and members of the committee, the public entrusts the Food and Drug Administration to evaluate the safety and efficacy——

The CHAIRMAN. Do you have your button on there? Just bring your microphone closer, thank you. I think we're going to be okay.

Dr. BLUM. The public entrusts the Food and Drug Administration to evaluate the safety and efficacy of medications. Having served on an FDA advisory panel, I have sympathy for the overextended staff at this beleaguered agency. But placing the Nation's most lethal consumer product, cigarettes, under the control of FDA would be unwise. And asking a food and drug bureau to promulgate product safety standards for cigarettes is an oxymoron that will perpetuate the myth long fostered by the tobacco industry that this inherently harmful product can be made safer.

The promotion of this bill by Philip Morris USA, maker of Marlboro and by far the biggest of big tobacco, with 50 percent of the market, should prompt skepticism about the measure and its purported public health benefits. Although the bill will strictly regulate new and potentially less hazardous noncombustible tobacco products, it would not apply these standards to the most harmful form of tobacco, namely Marlboro and other cigarettes, which caused the deaths of nearly half a million Americans a year and although the bill bans candy flavorings and no doubt will get rid of the term lights and will have new, bigger and improved warning labels, it does not require the FDA to eliminate menthol, the mint-flavored anesthetic agent added to the brands most heavily targeted to African American and Latino American consumers.

Nor is there a mandate for the FDA to eliminate toxic gases, including cyanide or the more than 40 known cancer causes in cigarette smoke, such as benzene, nitrosamines and radioactive polonium. The bill will most assuredly cause confusion about the difference between reduced exposure and reduced harm. If consumers are told that 1, 2, or even 22 cancer causes in tobacco smoke have been reduced, they are going to assume that a problem has been taken care of. They are going to believe that cigarettes are safer and they are going to continue to smoke.

This is, of course, déjà vu all over again. For more than 70 years, every report on the dangers of cigarette smoking was disputed by the tobacco industry, who claim more research was needed and who promised to identify and remove any component of smoke that was found to cause disease. This led to marketing gimmicks to allay public anxiety about smoking, such as filters that promised double-barreled health protection and claimed to be "just what the doctor ordered" or in at least one instance, was made of asbestos.

In spite of the fact that the cigarette filter does not confer any reduced health risk whatsoever, more than 95 percent of persons who smoke buy filtered brands in the false belief that they are safer. Yet this bill will not ban the filter, the biggest and longest running scam of big tobacco.

Similarly, when the Federal Trade Commission mandated that tar and nicotine levels be printed on cigarette advertisements, to-

bacco companies were only too happy to oblige. Carlton is lowest. It's official, confirmed by the U.S. Government, now is lowest. To this day, hardly a day goes by when a patient doesn't proudly tell me, but doc, I smoke Marlboro Lights because it's got only one milligram of tar. I try to tell these young ladies that they are being duped but they don't want to believe it.

Few consumers have caught on that such numbers mean nothing. History has shown that the tobacco industry has circumvented every attempt to impose Federal regulations on cigarette marketing. The goal of the Cigarette Advertising and Labeling Act of 1970 was to remove cigarette ads from the broadcast media but no sooner had the commercials ended than televised sporting events began, such as Nascar Winston Cup racing and the Virginia Suns Women's Tennis Circuit, providing even greater cigarette brand image exposure than ever.

We still see Marlboro logos on TV, auto racing worldwide. Research has documented that the kinds of marketing restrictions imposed by this bill are not effective in reducing youth exposure to cigarette advertising. The proposed FDA bill will simply change who is committing consumer fraud. Currently, it is still the tobacco companies marketing reduced tar and nicotine cigarettes in a way that deceives consumers into believing that these products are safer. If the FDA bill is enacted, then the Government will be doing the dirty work for the tobacco companies. Small wonder why Philip Morris embraces this bill, which will permit it to tell consumers that it is complying with strict product safety standards, making government-approved cigarettes.

In summary, there is no evidence that this bill will save any lives at all. It goes from A to Z without telling us how B to Y are going to work. To the contrary, the bill will perpetuate great harm to its grandfathering of high risk cigarette products, its hindering of the introduction of reduced risk, noncombustible tobacco products and its eliminating litigation for consumer fraud. However well intended, the bill is misguided. It could well be renamed, the Marlboro Protection Act. It should carry its own Surgeon General's warning that this legislation is deceptive and it will prove devastating to public health.

[The prepared statement of Dr. Blum follows:]

PREPARED STATEMENT OF ALAN BLUM, M.D.

Mr. Chairman and members of the committee, the public trusts the Food and Drug Administration (FDA) to safeguard the medicines and food products that contribute to good health and well-being. Having served as a member of an FDA advisory panel, I have great respect for this agency's work in assuring the safety of medications and medical devices used in the diagnosis and treatment of disease.

As we have known for decades, cigarettes are the Nation's leading cause of cancers, heart disease, and emphysema. Placing our most lethal consumer product under the control of the Food and Drug Administration makes no sense. Asking this agency to promulgate "product safety standards" for this death-dealing device is an oxymoron and will perpetuate the myth that cigarettes can be made safer. Safer than what, one might ask, fresh air?

The championing of this bill by Philip Morris USA, America's top cigarette manufacturer with 50 percent of the market, should prompt skepticism about the measure and its alleged public health benefits. Reading the fine print bears this out. Consider these three points:

First, the bill would stringently regulate new and potentially less hazardous tobacco products but would not apply these same standards to the most harmful form

of tobacco, namely Marlboro and other existing cigarettes which cause the deaths of nearly half a million Americans each year.

Second, although the bill will enable the FDA to prevent the introduction of new cigarette brands, it seems inappropriate for the protection of public health that the bill permits Marlboro and the other most popular existing cigarette brands to remain on the market, even though they are far and away the leading public health threat.

Third, although the bill specifically bans the use of strawberry, grape, chocolate, or similar flavoring additives in cigarettes, it does not require the FDA to eliminate (or even reduce the level of) toxic gases, including hydrogen cyanide or the more than 40 known cancer-causers in cigarette smoke such as benzene and radioactive polonium. The agency would be given the authority to take such action but there is no *mandate* to regulate these poisons.

The only sensible and ethical action for a health agency charged with regulating cigarettes could be to ban them, which is an unrealistic prohibition.

As Yogi Berra would say, this bill is déjà vu all over again. For more than 70 years, every newly published scientific report on the countless diseases caused by cigarette smoking was disputed by the tobacco industry, which claimed more research was needed and which promised to remove any constituents of smoke that might be found to cause disease. This led to a proliferation of marketing gimmicks to allay growing public anxiety about smoking, foremost among them filters that promised "Double-barrelled health protection," or claimed to be "Just what the doctor ordered," or in at least one instance was made of asbestos.

In spite of the fact that the cigarette filter does not confer any reduced health risk whatsoever, more than 95 percent of persons who smoke buy filtered brands in the false belief that they are safer. The second most sensible and ethical action for a health agency charged with regulating cigarettes would be to ban the filter, but this would hardly pass muster with Philip Morris.

When the Federal Trade Commission mandated that tar and nicotine levels be printed on cigarette packs and in advertisements, tobacco companies were only too happy to engage in a "tar derby." "Carlton is lowest," was a long-running ad campaign. "It's Official: U.S. Government proves NOW is lowest," was another. Few consumers caught on that such numbers are meaningless. It's akin to advertising Wonder Bread as having "only one ounce of poison in every loaf" or Campbell's touting its soups as "low-arsenic." Hardly a week goes by when a patient doesn't proudly tell me, "But Doc, I smoke Carlton 'cause it's got only 1 milligram of tar." I try to tell these women they're being duped, but it's very difficult.

History has shown that the tobacco industry has outwitted us at every attempt to impose Federal regulation on cigarette manufacture and marketing. The main goal of the Federal Cigarette Advertising and Labeling Act of 1970 was to remove cigarette ads from the broadcast media. Yet no sooner had cigarette commercials left the airwaves than televised sporting events such as NASCAR Winston Cup and The Virginia Slims Women's Tennis Circuit began airing for hours on end, providing even greater cigarette brand name exposure than ever before. Today we still see Marlboro logos on televised auto racing worldwide.

Tobacco companies have also out-maneuvered health advocates who believed they had found a way to utilize the industry's money to fund anti-smoking education. The Master Settlement Agreement of 1998 has resulted in a tiny fraction of settlement funding being directed toward smoking prevention and cessation programs. Only four States are currently allocating to tobacco prevention the minimum amount recommended by the Centers for Disease Control and Prevention; all told, only 2.6 percent of tobacco revenues are being spent on tobacco prevention and cessation.

Meanwhile, Philip Morris has not skipped a beat in cultivating financial relationships with dozens of career centers at universities across the country in an aggressive attempt to recruit college students as Marlboro sales interns and Marlboro territory sales managers. Thus these well-educated individuals who are least likely to smoke are being hired to promote cigarettes to the least educated and poorest sectors of our population. Bold ads in college newspapers brag about Philip Morris' innovative, redefined marketing strategies. When I asked one student why he was interviewing with Philip Morris, he told me "It's a great company. They don't just sell cigarettes. They help prevent smoking."

Instead of concentrating on regulation, we should be putting most of our efforts into reducing demand, especially major multimedia paid counter-advertising campaigns that young people will see daily and remember. In other words, we need to fight smoke with fire.

Research has documented that the kinds of marketing restrictions imposed by this bill are not effective in reducing youth exposure to cigarette advertising. There are simply too many venues for tobacco companies to market their products, and any-

thing short of a near-total ban on advertising and promotion of tobacco products (which could violate the first amendment) is unlikely to have a substantial effect on youth smoking.

There is no evidence that the system of product safety standards set up by the bill would result in a safer product. Essentially, the bill gives the FDA a mandate which it cannot carry out. The only way to know whether any reductions in specific constituents of tobacco smoke would result in a safer product would be to conduct long-term studies, using smokers as guinea pigs. Perhaps some would view that as acceptable because the product is dangerous anyway. However, the problem is that smokers are going to assume that these reduced exposure products are safer.

There are an estimated 40 compounds in tobacco smoke that cause cancer. What sense does it make to require the manufacturers to take out 2 or 3 of them or even 25? What if smokers then believe that this is a safer product and start smoking more? This approach will kill people, not save lives.

The bill would make it virtually impossible for modified *risk* products to enter the market, while at the same time permitting reduced *exposure* products to be falsely marketed as reduced *risk* products. At least that's how consumers are going to perceive them. How else would someone interpret a claim of reduced exposure?

The bill will diminish the public's appreciation of the inherent, irredeemable harmfulness of cigarettes. By promulgating health standards, the FDA will be fostering the perception that cigarettes are now safer to smoke. Few of my patients who still smoke realize that there are 4,000 poisons and 40 cancer-causers in cigarette smoke. If they are told that the nitrosamines have been reduced or removed, they are going to assume that a problem has been taken care of. Since we know that smoking prevalence is directly proportional to the degree of perceived harm from smoking, this will lead to an increase in smoking prevalence, compared to what would have occurred without this bill.

In her opinion, in the Department of Justice lawsuit against the tobacco companies, Judge Gladys Kessler ruled last year that decade after decade the defendants had engaged in fraud by marketing cigarettes that rated lower tar and nicotine yields via machine testing in a way that misled consumers to believe that these product offered a health benefit over higher machine-yield products. The basis of her decision was the body of literature demonstrating that machine-yields of nicotine and other tobacco smoke constituents have no direct relationship with actual human exposure, and thus with actual health risk, either on an individual or a population level.

The bill implies that reductions in nicotine yields would be a good thing. But the reality is that reduced nicotine yields could be harmful to public health because they would likely increase cigarette consumption due to the smoker compensating by inhaling more deeply leading to increased exposure to poisons (tar and toxic gases) and resulting in higher rates of lung cancer and emphysema.

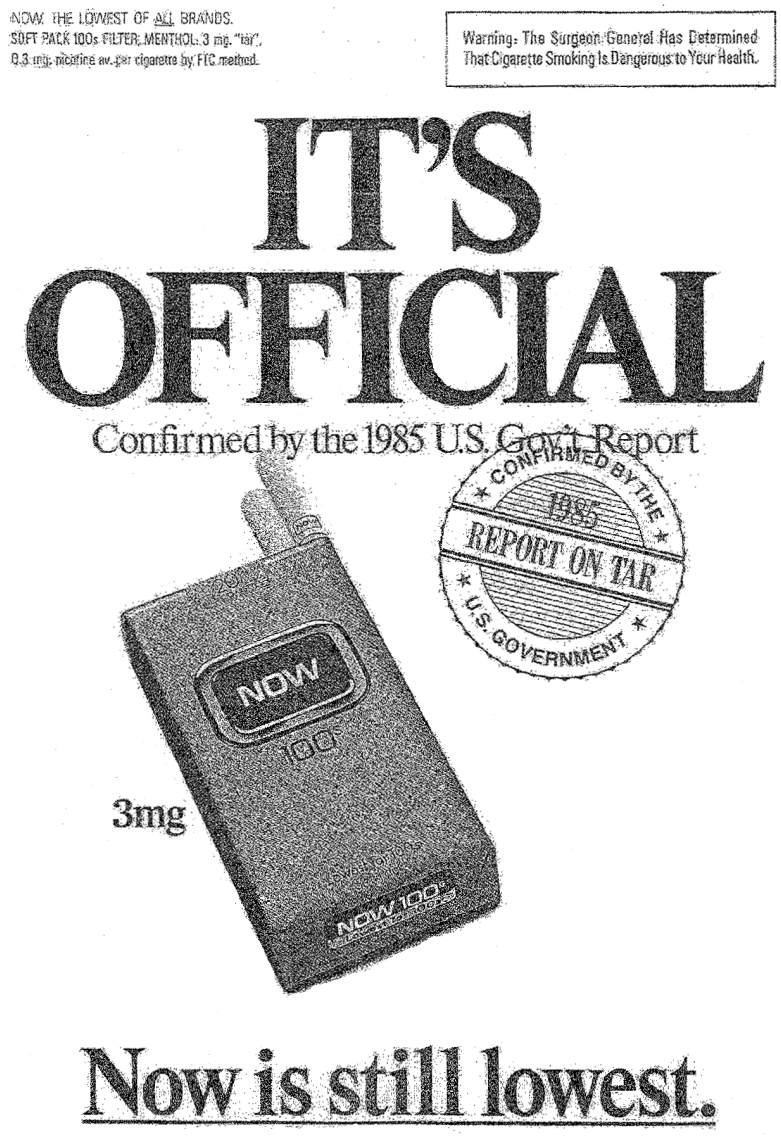
The proposed FDA bill will simply change who is committing consumer fraud. Currently, it's still the cigarette companies, marketing reduced tar and nicotine cigarettes in a way that deceives consumers into believing that these products are known to be safer. If the FDA bill is enacted, then the government will be doing the dirty work. Small wonder why Philip Morris embraces this legislation. It completely removes the risk of litigation for fraud, yet allows the tobacco companies to tell consumers that they are complying with stringent product safety standards, assuring a safer product produced under the nose of the FDA.

In summary, I regret that there is no evidence to suggest that this bill will save any lives at all. To the contrary, there is well-documented evidence to suggest that the legislation will not reduce the risks of cigarette smoking. The bill is likely to cause harm through its grandfathering of high-risk products; its hindering of the introduction of reduced risk products; its eliminating litigation for fraud; and its inhibiting tougher State and local legislative tobacco control efforts.

However well-intended, the Family Smoking Prevention and Tobacco Control Act is misguided. While setting up an impossible standard for new products, it gives the most harmful (and most consumed) existing product a free ride. This bill could well become known as the Marlboro Protection Act. At the very least, it should come with its own Surgeon General's warning: "This legislation is harmful to public health."

This submission is an extension of a commentary in the medical journal, *The Lancet*, co-authored with Michael Siegel, M.D., Professor of Social and Behavioral Sciences, Boston University School of Public Health. (Siegel M., Blum A. FDA regulation of tobacco: reprieve for the Marlboro man? *Lancet* 2006; 368: 266–68.) I also relied on additional critical analysis of the Family Smoking Prevention and Tobacco Control Act by Dr. Siegel (mbsiegel@bu.edu).

"Carlton.
It's lowest."
Carlton
CARLTON IS LOWEST
TAR 1 mg.
NICOTINE 0.1 mg.
Carlton
LOWEST SOFT PACK
"And the taste is right for me."
1 mg.
tar, 0.1 mg. nic.
U.S. Gov't. Test Method confirms of all king soft packs:
Carlton is lowest!
King Size Soft Pack: 1 mg. "tar", 0.1 mg. nicotine, av. per cigarette by FTC method.
SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
© The American Tobacco Co. 1989



The CHAIRMAN. Ms. Shames.

STATEMENT OF LISA SHAMES, ACTING DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT TEAM, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Ms. SHAMES. Thank you. Chairman Kennedy, Senator Enzi and members of the committee, I am pleased to be here today to present GAO's findings on the State's tobacco settlement payments under the Master Settlement Agreement.

There have already been a number of references to the MSA. As you know, in 1998, 46 States signed what is called the Master Settlement Agreement, with four of the largest tobacco companies. The States sued these companies to be reimbursed for healthcare costs caused by the public's use of tobacco.

The settlement was the largest civil settlement in U.S. history. It committed the tobacco companies to pay what was then an estimated $200 billion over the first 25 years. Payments are to continue in perpetuity. Congress required GAO to report annually on how the 46 States allocated their tobacco settlement payments.

This morning, I will present our findings from these reports.

First, we found collectively that States received over $52 billion in tobacco settlement payments over fiscal years 2000–2005. Of the $52 billion, about $36 billion were payments from the tobacco companies and about $16 billion were advance payments that 15 States received by issuing bonds, backed by their future payments from the tobacco companies. Annually, total payments ranged from a high of $14.1 billion in 2001 to a low of $5.8 billion in fiscal year 2005. These total payments varied because they are adjusted for fluctuations in cigarette sales, inflation and other variables.

Second, we found that States have allocated their payments to a wide variety of activities. Let me emphasize that the Master Settlement Agreement imposed no restrictions on how States could spend these payments. Some States told us that they viewed the tobacco settlement payments as an opportunity to fund those needs that they were not able to fund in the past, because of the high cost of healthcare.

Many States deliberated, such as through special commissions, on how to allocate their payments. This chart to my left shows how the States allocated their payments, from fiscal years 2000–2005. The purple slice shows States allocated the largest portion of their total payments, 30 percent or $16.8 billion, toward healthcare activities, such as Medicaid, health insurance, hospitals, medical technology and research. The white slice shows a closely related category, tobacco control. States allocate about $1.9 billion or 3.5 percent of their total payments. Tobacco control addresses prevention, education enforcement and cessation activities. The red slice shows States allocated the second largest portion of their payments, about 23 percent or $12.8 billion, to help balance their budgets or reduce their deficits.

In descending order, States used their tobacco settlement payments on general purposes and for structure projects, education and debt service on secure-type funds. The other tan slice category includes economic development for tobacco regions, social services reserve funds, tax reductions and payments to tobacco growers.

In summary, tobacco settlement payments have varied from State to State and from year to year. The Master Settlement Agreement imposed no restrictions on how States could spend these settlement payments. As such, the States have allocated their payments to a wide variety of activities. States allocated the largest portion of their payments toward healthcare and the second largest to budget shortfalls.

Mr. Chairman, this concludes my statement. I'd be pleased to respond to any questions that you or other members of the committee may have.

[The prepared statement of Ms. Shames follows:]

PREPARED STATEMENT OF LISA SHAMES

TOBACCO SETTLEMENT—STATES' ALLOCATIONS OF PAYMENTS FROM TOBACCO COMPANIES FOR FISCAL YEARS 2000 THROUGH 2005

WHY GAO DID THIS STUDY

In the 1990s, States sued major tobacco companies to obtain reimbursement for health impairments caused by the public's use of tobacco. In 1998, four of the Nation's largest tobacco companies signed a Master Settlement Agreement, agreeing to make annual payments to 46 States in perpetuity as reimbursement for past tobacco-related health care costs. Some States have arranged to receive advance proceeds based on the amounts that tobacco companies owe by issuing bonds backed by future payments.

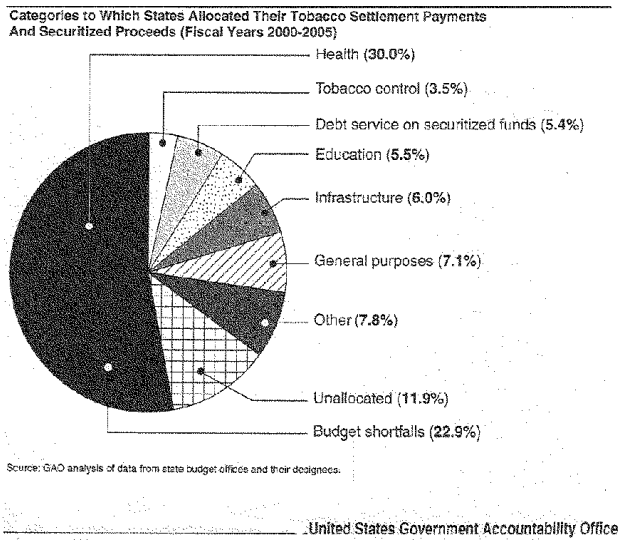
This testimony discusses (1) the amounts of tobacco settlement payments that the States received from fiscal years 2000 through 2005, the most recent year for which GAO has actual data, and (2) the States' allocations of these payments. We also include States' projected fiscal year 2006 allocations.

The Farm Security and Rural Investment Act of 2002 required GAO to report annually, through fiscal year 2006, on how States used the payments made by tobacco companies. GAO based this testimony on five annual surveys of these 46 States' Master Settlement Agreement payments and how they allocated these payments.

WHAT GAO FOUND

From fiscal year 2000 through 2005, the 46 States party to the Master Settlement Agreement received $52.6 billion in tobacco settlement payments. Of the $52.6 billion total, about $36.5 billion were payments from the tobacco companies and about $16 billion were advance payments which several States had arranged to receive by issuing bonds backed by their future payments from the tobacco companies.

The Master Settlement Agreement imposed no restrictions on how States could spend their payments, and as such, the States have chosen to allocate them to a wide variety of activities. Some States told us that they viewed the settlement payments as an opportunity to fund needs that they were not able to fund previously due to the high costs of health care. States allocated the largest portion of their payments to health care—$16.8 billion or 30 percent—which includes Medicaid, health insurance, hospitals, medical technology, and research. States allocated the second largest portion to cover budget shortfalls—about $12.8 billion or about 22.9 percent. This category includes allocations to balance State budgets or reduce deficits that resulted from lower than anticipated revenues, increased mandatory spending, or essential expenditures. Included among the next largest categories are allocations for infrastructure projects, education, debt service on securitized proceeds, and tobacco control.



Mr. Chairman and members of the committee, I am pleased to be here today to contribute to your deliberation on the need for the Food and Drug Administration to regulate tobacco products. Tobacco use is the leading cause of preventable death in the United States. Most adults who use tobacco started using it between the ages of 10 and 18. A Surgeon General's report to the Congress concluded that preventing youth from starting to use tobacco is key to reducing tobacco-related deaths and disease. The Centers for Disease Control and Prevention reported a few years ago that, on average, more than 440,000 deaths and $76 billion in medical expenditures are attributable to cigarette smoking annually. Reducing tobacco-related deaths and the incidence of disease, along with their associated costs, is a significant public health challenge.

Beginning in the mid-1990s, States sued the major tobacco companies for reimbursement of the cost of health impairments caused by the public's use of tobacco. The States alleged that the industry had violated antitrust and consumer protection laws, withheld information about the adverse health effects of tobacco, manipulated nicotine levels to keep smokers addicted, and conspired to keep less risky and less addictive tobacco products out of the market. Forty six States,[1] along with the District of Columbia and the five U.S. territories, negotiated and signed a settlement agreement, called the Master Settlement Agreement, with four of the largest tobacco companies—Philip Morris, USA; R.J. Reynolds Tobacco Company; Brown & Williamson Tobacco Corporation; and Lorillard Tobacco company. The settlement was the largest civil settlement in U.S. history. It committed the tobacco companies to pay the 46 States an estimated $200 billion[2] over the first 25 years of the agreement, with payments to continue in perpetuity. In addition, it restricted the tobacco companies' marketing and advertising practices, among other things.

Today, I will focus on how the 46 States party to the Master Settlement Agreement have allocated their settlement payments. Specifically, I will discuss (1) the amounts of Master Settlement Agreement payments that the States received from fiscal years 2000 through 2005, the most recent year for which we have actual data, and (2) the States' allocations of these payments. The Farm Security and Rural Investment Act of 2002 (the 2002 Farm bill) required GAO to report annually, from fiscal years 2002 through 2006, on how these 46 States used their Master Settlement Agreement payments.[3] My testimony is based primarily on these annual reports.

[1] The four States that are not party to the Master Settlement Agreement—Florida, Minnesota, Mississippi, and Texas—reached earlier, individual settlements with the tobacco companies.

[2] This original estimate does not take into account adjustments in tobacco companies' payments that have and will occur.

[3] GAO, *Tobacco Settlement: States' Allocations of Phase II Funds,* GAO–03–262R (Washington, DC.: Dec. 3, 2002); GAO, *Tobacco Settlement: States' Allocations of Fiscal Years 2002 and 2003*

Our reports were based on our yearly surveys of the 46 States. Each year we asked the States to report (1) the amount of payments they received for the current State fiscal year, (2) the amount of payments they expected to receive for the next State fiscal year, and (3) their allocations of these payments among 13 spending categories. We independently corroborated the States' data to the extent possible by analyzing budget-related and legislative documents, and interviewing State budget officials, staff from State attorneys generals' offices and governors' offices and others as needed to clarify information. We performed our work in accordance with generally accepted government auditing standards.

In summary, from fiscal year 2000 through fiscal year 2005, the States received $52.6 billion in Master Settlement Agreement payments from the tobacco companies in amounts that varied from state-to-state and from year to year. Of the $52.6 billion, about $36.5 billion were payments from the tobacco companies and about $16 billion were advance payments (securitized proceeds) that 15 States arranged to receive by issuing bonds backed by their future payments from the tobacco companies. The annual payments from the tobacco companies' are adjusted based on several factors that include fluctuations in the volume of cigarette sales, inflation, and other variables, such as the participating companies' shares of the tobacco market. Also, each State's share of the tobacco companies' annual payments is a fixed percentage based on smoking-related health care costs, which reflect population and smoking prevalence.

The Master Settlement Agreement imposed no restrictions on how States could spend these settlement payments and, as such, the States have allocated their payments to a wide variety of activities. Some States told us that they viewed the settlement payments as an opportunity to fund needs that they were not able to fund previously due to the high costs of health care. States allocated the largest portion of their payments—30 percent or $16.8 billion—toward health care activities such as Medicaid, health insurance, hospitals, medical technology, and research. States allocated the second largest portion of their payments—about 23 percent or $12.8 billion—to help balance State budgets or reduce deficits that resulted from lower than anticipated revenues, increased mandatory spending, or essential expenditures.

In descending order, the next largest categories where States used their tobacco settlement payments were general purposes, infrastructure projects, education, debt service on securitized funds, and tobacco control.

STATES' ANNUAL TOBACCO SETTLEMENT PAYMENTS HAVE VARIED

The 46 States reported receiving a total of nearly $52.6 billion in payments in varying annual amounts from fiscal year 2000 through fiscal year 2005. Of the nearly $52.6 billion, about $36.5 billion were payments from the tobacco companies and about $16 billion were securitized proceeds that 15 States arranged to receive, as shown in table 1.

Table 1.—Master Settlement Agreement Payments and Securitized Proceeds Received by the 46 States (Fiscal Years 2000–2005)

Fiscal year	Payments	Securitized proceeds	Total
2000–2001	$13,200,000,000	$928,900,000	$14,128,900,000
2002	6,238,393,496	3,838,376,465	10,076,769,961
2003	6,306,329,459	6,482,764,469	12,789,093,928
2004	5,340,128,223	4,374,698,723	9,714,826,946
2005	5,453,132,303	389,977,667	5,843,109,970
Total	$36,537,983,481	$16,014,717,324	$52,552,700,805

Sources: GAO–01–851, GAO–03–407, GAO–04–518, GAO–05–312, GAO–06–502, State budget offices or their designees, and GAO analysis.
Note: This table does not include payments to cities and counties in California and New York.

The tobacco companies' annual payments are adjusted based on several factors contained in the Master Settlement Agreement that include fluctuations in the volume of cigarette sales, inflation, and other variables, such as the participating companies' share of the tobacco market. Declining tobacco consumption alone would re-

Master Settlement Agreement Payments, GAO–03–407 (Washington, DC.: Feb. 28, 2003); GAO, *Tobacco Settlement: States' Allocations of Fiscal Year 2003 and Expected Fiscal Year 2004 Payments,* GAO–04–518 (Washington, DC.: Mar. 19, 2004); GAO, *Tobacco Settlement: States' Allocations of Fiscal Year 2004 and Expected Fiscal Year 2005 Payments,* GAO–05–312 (Washington, DC.: Mar. 21, 2005); and GAO, *Tobacco Settlement: States' Allocations of Fiscal Year 2005 and Expected Fiscal Year 2006 Payments,* GAO–06–502 (Washington, DC.: April 11, 2006).

sult in lower Master Settlement Agreement payments than originally expected. Tobacco consumption has declined since the Master Settlement Agreement was signed in 1998—by about 6.5 percent in 1999 alone—mostly due to one-time increases in cigarette prices by the tobacco companies after the agreement took effect. Analysts project that, in the future, tobacco consumption will decline by an average of nearly 2 percent per year.[4] As a result, tobacco consumption is estimated to decline by 33 percent between 1999 and 2020.

However, the Master Settlement Agreement also includes an inflation adjustment factor that some analysts have estimated increases payments more than any decreases caused by reduced consumption. The inflation adjustment equals the actual percentage increase in the Consumer Price Index for the preceding year or 3 percent, whichever is greater. The effect of these compounding increases is potentially significant, especially given that the payments are made in perpetuity. Assuming a 3-percent inflation adjustment and no decline in base payments, settlement amounts received by States would double every 24 years.

Also, several tobacco companies' interpretation of the provision that addresses participants' market share led them to lower their payments in 2006. Under this provision, an independent auditor determined that participating tobacco companies lost a portion of their market share to nonparticipating companies. An economic research firm determined that the Master Settlement Agreement was a significant factor in these market share losses. Based on these findings, several participating companies reduced their fiscal year 2006 payments by a total of about $800 million. Many States have filed suit to recover these funds.

Each State's share of the tobacco companies' total annual payments is a fixed percentage that was negotiated during the settlement. These percentages are based on two variables related to each State's smoking-related health care costs, which reflect each State's population and smoking prevalence. In general, the most populous States receive a larger share of the tobacco companies' total annual payments than the less populous States. For example, California and New York each receive about 13 percent, while Alaska and Wyoming each receive less than 1 percent. However, these percentages are not strictly proportional to population.

In addition to the annual payments States receive, the Master Settlement Agreement requires that a Strategic Contribution Fund payment begin in 2008 and continue through 2017. The base amount of each year's Strategic Contribution Fund payment is $861 million, which will be adjusted for volume and inflation and shared among the States. Strategic Contribution Fund payments are intended to reflect the level of the contribution each State made toward final resolution of their lawsuit against the tobacco companies. They will be allocated to the States based on a separate formula developed by a panel of former State attorneys general.

STATES ARE EXERCISING THEIR FLEXIBILITY TO USE TOBACCO SETTLEMENT PAYMENTS FOR A WIDE VARIETY OF ACTIVITIES

The Master Settlement Agreement imposed no restrictions on how States could spend their settlement payments and, as such, the States have allocated their payments[5] to a wide variety of activities, with health-related activities the largest among them. As part of their decisionmaking on how to spend their payments, some States established planning commissions and working groups to develop recommendations and strategic plans for allocating their States' payments. In six States, voter-approved initiatives restricted use of the funds and, in 30 States, the legislatures enacted laws restricting their use.

Overall, we identified 13 general categories to which States have allocated their Master Settlement Agreement payments, as shown in table 2. Appendix I provides more details on the categories to which States allocated their payments.

Table 2.—Amount and Percentage of States' Allocations of Master Settlement Agreement Payments and Securitized Proceeds by Category, Fiscal Years 2000–2005

[Dollars in millions and percent]

Category	Dollars	Percent
Health	$16,807	30.0
Budget shortfalls	12,806	22.9

[4] Cigarette consumption peaked in 1981 and has been declining since.

[5] When States allocate payments, they may include carry-over funds from prior years and interest earned; therefore, in any 1 year, States' payments and securitized proceeds may not equal payments allocated for spending.

Table 2.—Amount and Percentage of States' Allocations of Master Settlement Agreement Payments and Securitized Proceeds by Category, Fiscal Years 2000–2005—Continued

[Dollars in millions and percent]

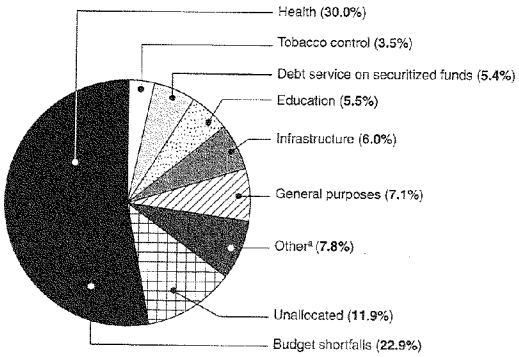
Category	Dollars	Percent
Unallocated	6,639	11.9
General purposes	3,955	7.1
Infrastructure	3,350	6.0
Education	3,078	5.5
Debt service on securitized funds	3,005	5.4
Tobacco control	1,943	3.5
Economic development for tobacco regions	1,490	2.7
Social services	961	1.7
Reserves/rainy day funds	810	1.4
Tax reductions	616	1.1
Payments to tobacco growers	521	0.9
Total	$55,981	100.1

Source: GAO analysis of data from State budget offices and their designees.

Note: Percentages do not total to 100 due to rounding. Also, States' allocations do not match the payment amounts on an annual basis because States have carried over funds from 1 year to the next and earned interest on their payments.

States allocated the largest portion of their payments—about $16.8 billion, or 30 percent of the total payments—to health-related activities. To a closely related category—tobacco control—States allocated $1.9 billion, or 3.5 percent of their total payments. States allocated the second largest portion of their payments—about $12.8 billion or 22.9 percent—to cover budget shortfalls. Some States told us that they viewed the settlement payments as an opportunity to fund needs that they were not able to fund previously due to the high cost of health care. Figure 1 illustrates the relative magnitude of the categories receiving allocations.

Figure 1: States' Allocations of Master Settlement Agreement Payments and Securitized Proceeds by Category, as a Percent of Total Allocations, Fiscal Years 2000-2005



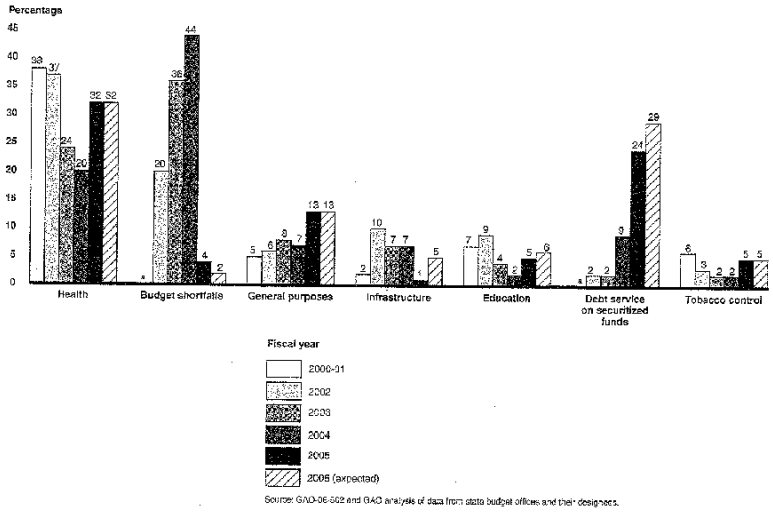
Source: GAO analysis of data from state budget offices and their designees.

Note: Percentages do not total to 100 due to rounding.

[a]The "other" category includes economic development for tobacco regions, social services, reserves/rainy day funds, tax reductions, and payments to tobacco growers.

The seven largest categories of allocations, in descending order, are health, budget shortfalls, general purposes, infrastructure, education, debt service on securitized funds, and tobacco control. States' allocations to these categories have varied considerably from year to year—with some categories showing wide fluctuations. For example, for budget shortfalls, the States allocated from 2 to 44 percent of the total payments. On the other hand, for health care, the States allocated from 20 to 38 percent of the total payments. Figure 2 shows these annual changes for these seven categories.

Figure 2: States' Allocations of Combined Master Settlement Agreement Payments and Securitized Proceeds to Seven Categories, Fiscal Years 2000 through 2005; and Expected Allocations for Fiscal Year 2006



Source: GAO-06-562 and GAO analysis of data from state budget offices and their designees.

[a]We did not obtain data for budget shortfalls and debt service on securitized funds for fiscal years 2000-01.

Information about how States have allocated their Master Settlement Agreement payments follows.

Health.—From fiscal years 2000 through 2005, States allocated about $16.8 billion of their Master Settlement Agreement payments to a variety of health care programs, including Medicaid; health insurance; cancer prevention, screening, and treatment; heart and lung disease; and drug addiction. Over this period, the amounts States allocated to health care ranged from about $1.9 billion in fiscal year 2005 to nearly $4.8 billion in fiscal years 2000–2001 combined.

In fiscal year 2005, the most recent year for which we collected actual data, 36 of the 46 States allocated some of their Master Settlement Agreement payments to health care. Of the 36 States, 5 States allocated two-thirds or more of their payments to health care; 19 States allocated one-third to two-thirds; and 12 States allocated less than one-third. Ten States did not allocate any of their payments to health care activities. In fiscal year 2005, Pennsylvania, Illinois, Michigan, and Maryland allocated larger amounts to health care than the other States. Pennsylvania allocated over $326 million of its payments to health care programs for adult health insurance, uncompensated care, medical assistance for workers with disabilities, and community medical assistance. Illinois allocated nearly $204 million of its payments to health care, citing Medicaid drugs as a key program that would receive funds. Michigan allocated over $185 million of its payments to areas such as elder pharmaceutical assistance and Medicaid support programs. Maryland allocated nearly $100 million of its payments to areas such as Medicaid; cancer prevention, screening, and treatment; heart and lung disease; and drug addiction.

Budget Shortfalls.—From fiscal years 2000 through 2005, States allocated about $12.8 billion of their Master Settlement Agreement payments to budget shortfalls. Over this period, the amounts the States allocated to budget shortfalls ranged from a high of about $5.1 billion, or 44 percent of the total payments in fiscal year 2004, to $261 million, or 4 percent in fiscal year 2005. In fiscal year 2005, only 4 of the 46 States allocated some of their Master Settlement Agreement payments to budget shortfalls. Of these States, only Missouri allocated more than one-third of its total payments—about $72 million—to budget shortfalls.

General Purposes.—From fiscal years 2000 through 2005, States allocated about $4 billion of their Master Settlement Agreement payments to general purposes, including law enforcement, community development activities, technology development, emergency reserve funds, and legal expenses for enforcement of the Master Settlement Agreement. Over this period, the amounts States allocated to general purposes ranged from $623 million, or about 5 percent of the total payments they

allocated in fiscal years 2000–2001 combined, to about $1.1 billion, or 8 percent in fiscal year 2003.

In fiscal year 2005, 27 of the 46 States allocated some of their Master Settlement Agreement payments to general purposes. Of these 27 States, 4 States allocated two-thirds or more of their total payments to general purposes; 2 States allocated one-third to two-thirds; and 21 States allocated less than one-third. Nineteen States did not allocate any of their payments to general purposes. Massachusetts, Tennessee, Connecticut, and Colorado allocated the largest amounts to general purposes in fiscal year 2005. Massachusetts allocated nearly $255 million of its payments to general purposes for its General Fund, Tennessee allocated nearly $157 million of its payments to its General Fund, and Connecticut allocated about $113 million of its payments to its General Fund. Colorado allocated about $64.5 million of its payments to general purposes, but did not specify which programs would receive funds.

Infrastructure.—From fiscal years 2000 through 2005, States allocated about $3.4 billion of their Master Settlement Agreement payments to infrastructure-related activities, including capital maintenance on State-owned facilities, regional facility construction, and water projects. Over this period, the amounts States allocated to infrastructure have ranged from $31 million, or about 1 percent of the total payments in fiscal year 2005, to about $1.2 billion, or 10 percent in fiscal year 2002.

In fiscal year 2005, 5 of the 46 States allocated some of their Master Settlement Agreement payments to infrastructure. Of these 5 States, North Dakota was the only State that allocated more than one-third of its total payments to infrastructure. North Dakota, Hawaii, and Kentucky allocated the largest amounts to infrastructure in fiscal year 2005. North Dakota allocated about $10.5 million of its payments to infrastructure for work on water projects. Hawaii allocated approximately $10 million of its payments to infrastructure, citing debt service on University of Hawaii revenue bonds issued for the new Health and Wellness Center as a primary program that would receive funds. Kentucky allocated $6.1 million of its payments to service debt on such things as water resource development and a Rural Development Bond Fund.

Education.—From fiscal years 2000 through 2005, States allocated about $3 billion of their Master Settlement Agreement payments to education programs, including early childhood development; special education; scholarships; after-school services; and reading programs. Over this period, the amounts States allocated to education ranged from between $280 million or 2 percent of the total payments in fiscal year 2004, to over $1.1 billion, or 9 percent, in fiscal year 2002.

In fiscal year 2005, 16 of the 46 States allocated some of the Master Settlement Agreement payments to education. Of the 16 States, only New Hampshire allocated more than two-thirds of its total payments to education; 4 States allocated between one-third and two-thirds to education; and 11 States allocated less than one-third. Thirty States did not allocate any of their payments to education-related activities. Michigan, New Hampshire, Nevada, and Colorado allocated the largest amounts to education in fiscal year 2005. Michigan allocated over $99 million of its payments to education for Merit Award scholarships and tuition incentive grants for higher education students; the Michigan Educational Assessment Program testing for K–12 students, nursing scholarships, the Michigan Education Savings Plan, and general higher education support. New Hampshire allocated $40 million of its payments to areas such as an Education Trust Fund, which distributes grants to school districts in the State. Nevada allocated about $33 million of its payments to education programs, citing a scholarship program for Nevada students attending Nevada's higher education institutions as a key recipient. Colorado allocated over $16 million of its payments to education, including its Read to Achieve program.

Debt Service on Securitized Funds.—From fiscal years 2000 through 2005, States allocated about $3 billion of their Master Settlement Agreement payments to servicing debt on securitized funds. This category consists of amounts allocated to servicing the debt issued when a State securitizes all or a portion of its Master Settlement Agreement payments. Over this period, the amounts States allocated for this purpose have ranged from $271 million, or about 2 percent of the total payments in fiscal year 2002, to about $1.4 billion, or about 24 percent, in fiscal year 2005. In fiscal year 2005, four States—California, Rhode Island, South Carolina, and Wisconsin—allocated 100 percent of their Master Settlement Agreement payments to servicing debt on securitized funds, while New Jersey allocated just under 100 percent. In addition, Alaska, Louisiana, and South Dakota, allocated more than half of their payments for this purpose. In fiscal year 2005, California and New York allocated the largest amounts to servicing debt on securitized funds.

Tobacco Control.—From fiscal years 2000 through 2005, States allocated about $1.9 billion of their Master Settlement Agreement payments to tobacco control programs, including prevention, cessation, and counter marketing. Over this period, the

amounts States allocated to tobacco control ranged from $790 million, or about 6 percent of the total payments in fiscal years 2000–2001 combined, to $223 million, or about 2 percent, in fiscal year 2004.

In fiscal year 2005, 34 of the 46 States allocated some of their Master Settlement Agreement payments to tobacco control programs. Of the 34 States, Wyoming allocated more than one-third of its payments to tobacco control, while 33 States allocated less than one-third. Twelve States did not allocate any of their payments to tobacco control-related programs.

Pennsylvania and Ohio allocated more than the other States to tobacco control—about $44 million and $37 million, respectively—in fiscal year 2005.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other members of the committee may have.

APPENDIX I: CATEGORIES OF STATES' ALLOCATIONS

To standardize the information reported by the 46 States, we developed the following categories and definitions for the program areas to which States allocated their payments.

Budget Shortfalls.—This category is comprised of amounts allocated to balance State budgets and close gaps or reduce deficits resulting from lower than anticipated revenues or increased mandatory or essential expenditures.

Debt Service on Securitized Funds.—This category consists of amounts allocated to service the debt on bonds issued when the State securitized all or a portion of its Master Settlement Agreement payments.

Economic Development for Tobacco Regions.—This category is comprised of amounts allocated for economic development projects in tobacco States such as infrastructure projects, education and job training programs, and research on alternative uses of tobacco and alternative crops. This category includes projects specifically designed to benefit tobacco growers as well as economic development that may serve a larger population within a tobacco State.

Education.—This category is comprised of amounts allocated for education programs such as day care, preschool, Head Start, early childhood education, elementary and secondary education, after-school programs, and higher education. This category does not include money for capital projects such as construction of school buildings.

General Purposes.—This category is comprised of amounts allocated for attorneys' fees and other items, such as law enforcement or community development, which could not be placed into a more precise category. This category also includes amounts allocated to a State's general fund that were not earmarked for any particular purpose. Amounts used to balance State budgets and close gaps or reduce deficits should be categorized as budget shortfalls rather than general purposes.

Health.—This category is comprised of amounts allocated for direct health care services; health insurance, including Medicaid and the State Children's Health Insurance Program (SCHIP); hospitals; medical technology; public health services; and health research. This category does not include money for capital projects such as construction of health facilities.

Infrastructure.—This category is comprised of amounts allocated for capital projects such as construction and renovation of health care, education, and social services facilities; water and transportation projects; and municipal and State government buildings. This category includes retirement of debt owed on capital projects.

Payments to Tobacco Growers.—This category is comprised of amounts allocated for direct payments to tobacco growers, including subsidies and crop conversion programs.

Reserves/Rainy Day Funds.—This category is comprised of amounts allocated to State budget reserves such as rainy day and budget stabilization funds not earmarked for specific programs. Amounts allocated to reserves that are earmarked for specific areas are categorized under those areas—e.g., reserve amounts earmarked for economic development purposes should be categorized in the economic development category.

Social Services.—This category is comprised of amounts allocated for social services such as programs for the aging, assisted living, Meals on Wheels, drug courts, child welfare, and foster care. This category also includes amounts allocated to special funds established for children's programs.

Tax Reductions.—This category is comprised of amounts allocated for tax reductions such as property tax rebates and earned income tax credits.

Tobacco Control.—This category is comprised of amounts allocated for tobacco control programs such as prevention, including youth education, enforcement, and cessation services.

Unallocated.—This category is comprised of amounts not allocated for any specific purpose, such as amounts allocated to dedicated funds that have no specified purpose; amounts States chose not to allocate in the year Master Settlement Agreement payments were received that will be available for allocation in a subsequent fiscal year; interest earned from dedicated funds not yet allocated; and amounts that have not been allocated because the State had not made a decision on the use of the Master Settlement Agreement payments.

The CHAIRMAN. Thank you very much. We'll have a 5-minute time limit on questioning. Dr. Land, let me ask you this—you must represent a part of the country where smoking is widely used, or perhaps used more frequently than in other parts of the country. What do your parishioners say about your involvement on this issue, when they've got a range of different kinds of moral issues that they're concerned about. Do they say, why are you interested in this smoking issue when there are many other negative activities that are going on in their communities or in the country or the world?

Mr. LAND. No, sir. They expect us to be able to walk and chew gum at the same time. They think our attention span is up to the task. As I pointed out at the beginning of my testimony, Southern Baptists have long had concern about tobacco use and indeed, we do have a lot of constituents in parts of the country where tobacco has been an important product but those resolutions are passed by majority vote of the constituents who elect their representatives. The Southern Baptist Convention, when it meets every June and passes these resolutions, is the largest deliberative parliamentary body in the world. Those 44,000 autonomous churches elect messengers who go to the convention and conduct business and they vote on these issues. They also voted to elect the trustees that elected me. I serve at the pleasure of the Southern Baptist Convention. There is somewhat of a generation gap. People older than myself tend to have somewhat different views toward tobacco than people younger than myself and since I'm now 60, a lot of the people who would be more ambivalent about this are older or have—you know, tobacco smokers tend to be a declining constituency because they die. When I first came to the Commission in 1988, we have several Sundays on the Denominations Calendar where we are charged to produce materials to help them observe these Sundays and one of those Sundays is Alcohol and Drug Abuse Sunday. The first one that I had the opportunity to choose the issue we were going to deal with, I chose nicotine for 1990 and this raised some eyebrows in 1988. They said, "Wow, you're going to take on tobacco?" And I said, "We absolutely are." We were braced for a large response, negative and we got very, very little. I would remind you that in 1984, the Southern Baptist Convention, in session, passed a resolution, overwhelmingly, that called for government to end subsidies to tobacco growth and to encourage individual Southern Baptists who were tobacco farmers, to find alternative means and alternative crops and to no longer grow tobacco. That was in 1984 and it was passed by the elected messenger to the Convention overwhelmingly.

The CHAIRMAN. OK. This is primarily because of the dangers to children. Am I right?

Mr. LAND. Well, we are particularly concerned about these deceptive advertising messages to children who do not have the maturity and the responsibility to make these decisions but it's also because it has obviously seeped into the conscious of people in the faith community as it has other people in this society, that this is a very dangerous product and I don't think there is any American who has reached maturity, who doesn't know people personally who have died from the use of this product. It really has seeped into the conscious. I smiled when I heard the reference to lard. I mean, it really is—people do understand that this is really a destructive product.

The CHAIRMAN. Thank you. Mr. Myers, let me come back to you for a quick response to Dr. Blum, who says there is no evidence that this bill will save lives. He says, it's deceptive, it's harmful to the public health, it's a Marlboro Protection Act. It should carry its own warning label. Pretty strong indictment of the legislation. Your response?

Mr. MYERS. I have great respect for Dr. Blum but I think it is not an accurate factual representation of what is in the bill. He said that the bill would strictly regulate new products but not apply the same standards to existing products. That's just wrong. Section 907 gives the FDA broad authority to regulate existing products as well as new products; in fact, it's the strongest regulatory standard ever proposed for any regulatory agency whatsoever.

He said it will inhibit the introduction of new products. That too, is wrong. What it will do is inhibit manufacturers from making health claims for new products before they have the scientific evidence from doing so. As we know, our experience shows that if you allow tobacco companies to make claims for products, not only will they mislead the public but they won't have any incentive to make actually less hazardous products. If anything, this bill will, for the first time, give tobacco companies and others, the incentives to make serious changes to those products.

He said it has no mandates to eliminate toxic gases. That's wrong. It provides the FDA with full authority to require changes in toxic materials, including gases, in them. We have to understand what the status quo is. The status quo is nobody has any authority to require any tobacco company to make any change in its product and as a result of that, the status quo is that the changes the tobacco companies make are more accurately what Dr. Henningfield described—those that make the product more addictive, more attractive without regard to its health hazards. He spoke about the past failed efforts. The problem is, we have relied on voluntary action in the past. So when he talks about advertisements about Carlton is the lowest, he ignores the fact that this bill would allow the FDA—a matter of fact, it would mandate that the FDA prevent exactly those kinds of claims, absent scientific evidence. Not only that the claim is truthful but that the claim is being made in such a way so that it won't discourage millions of people from smoking. He claims that it doesn't mandate the elimination of menthol. Well, that's one of those half-truth statements that is very important. It gives FDA authority to regulate menthol but to do it in a way based on sound science as opposed to making a political decision

without knowing what the impact would be automatically today of eliminating it.

Dr. Blum's experience in this field is unparalleled in terms of its length. But when you look at the terms of this legislation, it presents a very different picture when you look at its details than what was presented as the underpinning of his testimony.

The CHAIRMAN. Dr. Blum, my time is up, but I will give you an opportunity to respond if you don't get that opportunity with other questioners.

Senator Enzi.

Senator ENZI. Mr. Chairman, I won't be able to pass up the opportunity on that but I've got to tell you, I've got hundreds of questions—no, I started with hundreds of questions. Now I've got a lot more and I do appreciate that all of you volunteered to testify. I hope you also volunteered to answer questions that we won't have time to put in, in just 5 minutes.

Mr. Myers, to follow up just a little bit on what you said, before I give Mr. Blum a chance to unload——

[Laughter.]

Even if it is a new product and the FDA says that it's okay to sell it, isn't that putting an FDA stamp of approval on a product that is going to kill them? Or is it going to be made safe enough that it won't?

Mr. MYERS. You raise a very thoughtful and important question. The bill was carefully crafted; in fact, there are at least five different sections of the legislation that would authorize FDA to prohibit a manufacturer from saying that a product is FDA approved. If FDA found that that was necessary to protect the public health because the drafters of this legislation were concerned about the same issue. In fact, FDA doesn't approve most products. What FDA does is approve—well, whether or not there is adequate scientific evidence to make a claim so that will prevent the tobacco companies from misleading the public the way they currently do. And the only time the FDA actually gets in the process of approving whether a new product comes on the market, is when it is not substantially equivalent. So the issue you raise is a very important one. This legislation has tried in a very thoughtful way——

Senator ENZI. My time is pretty limited. I think you've made your point.

Mr. MYERS. To prevent the tobacco companies from doing exactly what you're——

Senator ENZI. Actually, from the FDA hearings that we've had, they can't control labeling, they can't control advertising. They can suggest.

Mr. MYERS. But this is——

Senator ENZI. Now, on a reform bill that we have, there would be some additional criteria on that, but any way you look at it, they'll be able to say, the constituents were approved or looked at. I wish I had time to ask Mr. Henningfield some more questions about some things like that. Another thing that will come into it, is who is going to pay the fees on this? We're looking at the medical device and drug user fee programs and trying to figure out how to get all of the pay for that sort of thing. Can we get the companies to pay for all of the testing? And I do suggest that we would have

to back up to the very beginning on the testing and test every single ingredient every time there is a change. Mr. Blum, you looked like you had a few comments you wanted to make on those, too.

Dr. BLUM. Part of the unloading process here, thank you, Senator Enzi. I think this bill creates a bridge on the River Kwai for the tobacco industry. It's what they want, at least Philip Morris does, because it will have government sanctioned cigarettes. We already know what Marlboro does. Marlboro kills. Whatever the market share is, it's 40 percent of the market—Marlboro is taking the lives of 40 percent of those 400,000 that die from tobacco smoke every year. What more is there to know? The definition of—research that we need to know more on is the definition of infinity. There are always going to be curious questions. But we already know what cigarettes do to you. All the other tobacco products put together do not cause the harm that cigarettes do and this regulation largely grandfathers in Marlboro. Sure, as Matt Myers said, it does grant the authority of the FDA to do certain things, to maybe consider these things and modify the product but it doesn't mandate. The only thing the bill mandates is candy flavorings, bigger warning labels or new and improved warning labels so if the deaf person can't hear you, you've got to yell louder. And it has more of the kinds of reliance on machine measurements, which Dr. Connolly, in his recent article in Tobacco Control, has said is bogus. So the science that the FDA is going be relying on is by those who study what kinds of statistics we're relying on anyway, through machine measurements of tar and nicotine are already unreliable. Where is the science standard going to come from? I don't think anybody knows that.

There is also the matter of ethics. If you were to conduct research to show whether or not a product is going to cause reduced harm, I don't know of any institutional review board at any university that would approve those subjects to take Cigarette A or Cigarette B or tobacco product A and tobacco product B and study those over the 20 and 30 years that it will take to see whether one product reduces harm over another.

This cigarette bill will not affect the sale of cigarettes in pharmacies. We're the only country in the world where cigarettes are sold alongside medications. As Paul Harvey said, "America is the only place where the sick people have to walk all the way in the back to get their medicines and healthy people get their cigarettes right up front."

Senator ENZI. I thank you and as I mentioned, I've got questions for everybody. I have particularly some numbered questions as the only accountant, I'm always fascinated by the numbers, so I apologize for not having an opportunity to ask them right now but I will put those in writing and would suggest that maybe the Federal Trade Commission ought to be involved in this, maybe as opposed to the FDA. They are the ones that really control false advertising or I hope control false advertising. And that's what we're talking about here, besides the need to do more testing and have more disclosure. But I just worry a lot about this FDA seal of approval, whether implied or actual, that's going to come about through this process. We've got to find some way. The oncologist that worked with my wife had the hospital attorney visit him because he said

that he wasn't going to treat people that smoked anymore for cancer because they were working against themselves and there's a little bit of a brouhaha going on over that. But we know that cigarettes kill. Now we've got to figure out how we can keep it from killing as many people.

The CHAIRMAN. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman. As we know, smoking kills some 400,000-plus Americans a year and we also know the tobacco companies know they have to replace those customers with young smokers and that's sort of been the thrust, it seems in all of this. We've sat through hearings for years, many of us and seen the sort of growing sophistication of the tobacco industry. It used to be Joe Camel. It used to be billboards near schoolyards, clever mailings, free samples, all the things they do. Dr. Huerta mentioned Camel No. 9 and I have a mailing here that this is—those of you that buy perfume can see that this looks a lot like it could be a perfume package, Camel No. 9. And you open this up, Camel No. 9 introducing our smoothest smoke sensation. Light and luscious. Are you ready to flaunt it? No. 9, take your No. 9 experience to the next level. This stylish, sexy cigarette case. If you look in really small print—and because I'm way older than the people they are appealing to, I have to use these cheap $6 glasses—an offer is on a Web site restricted to legal and tobacco consumers. But it says, just your smokes to the nines with a complimentary cigarette case. Take a pack at Camelsmokes.com and you'll be smoking in style in no time. Then again, light and luscious. You pull this out. I believe they can't actually send you a pack of cigarettes. That's the DMSA, I believe, but you open this up and it looks a lot like it. Then you strike gold with four coupons, $2 off, $2 off. Buy one pack, get one free, buy one pack, get one free. This is the kind of—and it's strains the imagination to think that this campaign is aimed at anybody other than 15, 16, 17-year-old girls, something that is a violation of the MSA, to be sure but maybe more importantly, pretty morally repugnant and a violation of what I think Dr. Land with his values and what all the public health people, all of whom find this pretty repugnant. Dr. Huerta, my question for you is about price. As you know, the 10 percent is pretty elastic—elastic economics, if you will, to the pricing of cigarettes. Ten percent increase in price generally brings a 7 percent decline in youth consumption. They are still finding ways, obviously, to make tobacco, the introduction of smoking to young people, they're finding a way to make it less and less expensive and more and more appealing until they're addicted and they may go beyond that.

The tobacco industry, I understand, spends about $10 billion on promotion, price promotion, obviously much of it to children, to recruit new people as the 400,000 people a year die. How should FDA, if this bill passes, how should FDA address things like this? How should FDA especially, more pointedly, address the whole issue of price and the kinds of price deals that the tobacco industry offers?

Dr. HUERTA. Thank you for the question. What the FDA, in my opinion, should do is base all their opinions on signs. And if the signs say that the tobacco companies are not allowed to make any claim, then FDA should not allow the companies to make that par-

ticular claim regarding marketing. Marketing—it's a whole chapter in the FDA regulation now, even we see that every day with the pharmaceutical companies that are doing this direct to consumer marketing practices on television and we are seeing that FDA is now taking a very active approach to these marketing techniques. So I would say that's a chapter that needs to be discussed among the experts of marketing but my feeling is that if the claim that the tobacco companies want to do is not based on science, they shouldn't be allowed to do it.

The CHAIRMAN. Thank you very much.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman. I have listened intently to everybody's testimony and I want to applaud you for bringing a lot to the table. There is only one major difference I have, it is that I am not yet convinced that all the things that you pointed out have to happen at the FDA. I have very few disagreements with some of the items that were highlighted by each of you and I'll try to go through some of those but let me ask first, just so I know.

If given the authority, would you outlaw tobacco today? Just a quick yes or no.

Matt.

Mr. MYERS. No, sir.

Senator BURR. Dr. Huerta.

Dr. HUERTA. No.

Senator BURR. Dr. Land.

Mr. LAND. No, sir.

Senator BURR. Right down the line.

Mr. HENNINGFIELD. No.

Mr. CONNOLLY. No.

Dr. BLUM. No. I'm not in favor of prohibition.

Senator BURR. I'm not going to ask you.

Ms. SHAMES. I can't——

Senator BURR. Dr. Huerta, you mentioned five things and I only got four of them but I think the four really do encompass what your message was. Magazine advertising—still going on, still affects children. In-store advertising—it certainly goes on, affects children. Outdoor signage, billboards gone but outdoor signage based upon the agreement in the MSA still exists, could influence children's decisions. Let me just simply ask you—and you mentioned no compliance. If we could address that in a way that you and I and Matt Myers and others said, you know, we have eliminated the ability to advertise to children. Can you live with that authority, staying at the Federal Trade Commission and the Department of Justice?

Dr. HUERTA. It seems to me that—of course, I'm a profound respectful person of the first amendment but there are limits for what you can—the way you can promote your products.

Senator BURR. Clearly to accomplish this without a constitutional challenge would require an agreement by the industry as well, to ban certain things. If we could accomplish that, are you comfortable that the Federal Trade Commission and the Department of Justice can, in fact, bring that degree of compliance and assurance to you and to me and to everybody else?

Dr. HUERTA. It's going to be difficult and would probably require a lot of discussion.

Senator BURR. Difficult to believe that they could bring that level of regulation? To enforce it?

Dr. HUERTA. Well, they are different forces playing here. I mean, the tobacco industry, obviously they want to sell their products and we want to protect the public so we meet you——

Senator BURR. Dr. Huerta, let me stop you. I'm talking about a direct, specific ban. Are you comfortable with a direct specific ban being administered by the Federal Trade Commission and the Department of Justice?

Dr. HUERTA. No. Bans are not good for society. That's what I can tell you.

Senator BURR. OK. Matt, are Phase 4 clinical trials important at the FDA for the safety and efficacy of drugs?

Mr. MYERS. For drugs?

Senator BURR. Yes, sir.

Mr. MYERS. We're not talking about—and I apologize to you. I'm not an expert on drug clinical trials so I need to be careful with regard to those issues.

Senator BURR. Sure.

Mr. MYERS. And that's not what we're talking about with regard to this legislation.

Senator BURR. Well, I appreciate you acknowledging that, but that's exactly my point—there are some that are very engaged in this but have absolutely no idea what the FDA is faced with, day in and day out. And Phase 4 clinical trials determine dosage. The safety and efficacy is already determined long before then but yes, Phase 4 trials are extremely important to the outcome for a patient.

Dr. Connolly, you went—put your props back up there, would you? I mean, I appreciate the fact that you brought something that visualizes the challenge. And the challenge is that we're way behind the curve from the standpoint of the degree that we make adults aware of the risk. Now, let's assume for a second that whether it was the half a pack size warning or whether it was the full back of the pack size warning, which I think is Brazil. If we codified that into law, would you feel comfortable if, in fact, the enforcement for that was part of the FTC and the Department of Justice versus the FDA?

Mr. CONNOLLY. No. I think the thing that you're forgetting is the product is linked with the marketing. Now, let me just—let me finish my point—you asked a question, sir. When you saw that blue pellet up there in Camel—that blue pellet is in the product. It's unregulated by FTC but that blue pellet, in part, is a very specific flavor that is tied to a Web site that is tied to a marketing claim that is tied to——

Senator BURR. Dr. Connolly, I appreciate your point but I'm asking specifically about the warning label. I don't disagree with you. I don't disagree.

Mr. CONNOLLY. We don't know. We're testing these—we're testing warning labels among children in Crete to determine if this is better than this and we think among the children, this is better. I wish we could test it——

Senator BURR. Dr. Connolly, my colleagues——

Mr. CONNOLLY. Back to the FDA with data and then let them make a reasoned choice on what works best—pictorials versus verbals. My impression would be, the FDA could make that decision, not the FTC. The FTC's most recent smokers report—the most recent one is 2001.

Senator BURR. Dr. Connolly, I know where we are today.

Mr. CONNOLLY. Right.

Senator BURR. Legally. I'm talking about if we codify in law, exactly what it has to say, are you comfortable with the FTC and the Department of Justice, in fact, enforcing it because I've got problems—Senator Kennedy has a bill right now that's addressing drug safety and labeling deficiencies at the FDA.

Mr. CONNOLLY. I'm very uncomfortable. You need joint regulation between FDA to regulate the product and regulate the marketing. Right now, we've got one arm tied behind our back. We're leaving the attorney generals to deal with consumer protection issues and the FTC but we're not dealing with public health issues in the product. What they're adding to the product can make this the most popular product with kids. We need combined regulation with both the FDA and with the consumer protection actions by the FTC and by attorney generals to address the issue of smoking among youth. If we let the blue pellets sit in the product, if we let them manipulate menthol levels, all the work and effort we do to restrain the claims, the marketing are for naught.

Senator BURR. Dr. Connolly——

Mr. CONNOLLY. We have to have a comprehensive approach in this Nation. It's about time we had a comprehensive approach, worried about our children and not about the economic interest of this industry.

Senator BURR. Dr. Connolly, I appreciate your passion on this.

Mr. CONNOLLY. Thank you very much, sir.

Senator BURR. And I'm not proposing or suggesting that there not be a comprehensive approach to this. You, as others, seem to connect all the pieces and they only end up at one place. I'm trying to determine whether, in fact, there are other places where those pieces can be done. In no way am I trying to diminish the scope of what we could sit at a table and talk about. I've got to tell you, though. It disturbs me—concerns me—as to what type of rational conversation we might be able to have if we got down to talk about where is the best fit. If, in fact, just the warning label has to be tied to everything else that you can't comprehend the—the warning label could be enforced at the Federal Trade Commission or the Department of Justice, yet you could have an agreement that the FDA looks at the toxicity of a product and that we've got an agreement that says, here's the epidemiology study that we're going to look at to determine whether something is reduced risk. I think there are agreements we can come to on that but I think there are also areas that you have highlighted, Dr. Huerta has highlighted that really don't fit in the FDA.

I thank the Chairman who has been very kind and I appreciate it.

The CHAIRMAN. OK.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. Thank you and good morning to all of you. I appreciate the testimony. I'm sorry that I wasn't present for all of it but I have read the testimony that has been provided.

My interest in this issue is really coming from the perspective of our kids. As much as I worry about the adults that make decisions, those are adults that are making decisions but I worry about the fact that every day, we've got some 4,000 American kids that are trying cigarettes for the first time and of those 4,000, how many of them go on to become the customers that we deal with later on in life. So I want to speak specifically to the issue of the children and why, after all that has been worked out through the MSA agreements, all that we have been trying to do in terms of education and getting into the classrooms, tell me—this is directed to you, Mr. Myers and Dr. Huerta—what else do we need to do? This legislation you obviously support. What else can we be doing to make sure that we're not growing new numbers of tobacco smokers through our children? Is there more that needs to be done, either within this legislation or elsewhere, to make a difference?

Mr. MYERS. Thank you and thank you for your longtime commitment to this issue, Senator Murkowski. One needs a comprehensive approach to this problem if we're going to really dramatically reduce tobacco use among our children. This bill provides key tools for that comprehensive approach but no one should kid themselves. It's not the panacea by itself. By eliminating the forms of marketing that have been identified as having a great impact on children, even after the Master Settlement Agreement, that allows a mother and father to sit down across the table with them and talk about tobacco with a much more even playing field. That's a critically important step.

By preventing the tobacco industry from implying that certain products are safer and therefore may be safer to start smoking—you can delude yourself as a young person into thinking that there is a safe way to start smoking. It gives us another tool to prevent the tobacco industry from luring our children. By doing this, Dr. Henningfield suggested looking at what the tobacco industry does with regard to nicotine and the impact of nicotine. We take into account the fact that most kids—literally 90 percent of all smokers—become long-term smokers before they're old enough to purchase the product legally. Many of them are addicted to the product and therefore, having a hard time to quit. We have not known how the tobacco industry has altered or controlled nicotine's impact. This bill would give us that tool at the same time to do so, which is vitally important as we move forward.

Ease of smoking is another area that Dr. Henningfield has talked about in his testimony that impacts how quickly kids start because if it's not to brusque, if it's not too hard when you start, when your lungs are still pure, what we have discovered is that more kids will move from that quick, experimental stage to becoming regular smokers. This bill would give FDA the authority to look at that issue and address that issue as well. So this bill has a number of key link tools that only by bringing those things together can you have a meaningful approach to kids.

And most importantly, it also, for the first time, gives a Federal agency the authority to look at what the tobacco industry is doing with its marketing and if they introduce new things that are not specifically covered, it gives us an administrative framework for addressing those issues up to the limit of the first amendment. It's as far as we can go in our Nation.

Senator MURKOWSKI. Let me ask you, Dr. Blum, you do not support this legislation but I understand that you are equally passionate about making sure that our kids are not the next customers. How do we address the kids? If this isn't the answer, what is the answer from the children's perspective?

Dr. BLUM. Thank you, Senator. I think that the Master Settlement Agreement had a hope as Ms. Shames alluded to that we would have had the resources to provide major multimedia counter advertising campaigns, such as Senator Kennedy proposed years ago and I justified before this committee. It's a shame that that money has been squandered and misused. So I also would see the possibility of perhaps a separate agency. But the reason why I oppose this bill is that literally from day one, if this bill is enacted, you would have the product that kills more people than all other drugs, food, medications—whatever else there is that the FDA regulates combined—and that product would be dithered with and torqued with and regulated when the elephant in the room would be Marlboro, would be sitting there, doing its damage every day. I think that it makes no sense whatsoever. It's good to talk about children but I think that it's the definition of infinity if we're going to try to regulate every single brand that comes out. They're going to come up with everything in the world to keep us on our toes, to constantly keep regulating. I think that the reason that we need to be here is to consider how do we reduce demand for this product, not how we regulate the product.

Senator MURKOWSKI. Thank you.

Mr. CONNOLLY. If I could add, Senator, we could research about 10 years ago, looking at the internal documents on a reformulation of Camel. At the time, Camel was smoked by old men. RJ Reynolds intentionally affected the nicotine level. They added more flavorings to make it more sugar-like and also affected the smoothness and they did rankings against Marlboro cigarettes. This was among 18-year-olds but in fact, it's what they did. They affected the smoothness of the product, they affected the nicotine yield, they added sugars so it would make it easier for a youngster to inhale. Now, the whole public health community is worrying about cartoon advertising when they were worrying about the product. I think if you want to address kids' use, we have to say, if you're going to reformulate and change the product, then tell us what you're doing with it. Why are you adding these sugars? Why are you affecting nicotine yield? And just to sit back and say, go ahead and have our children, with your product, and ban advertising. It's just a flawed public health strategy.

The CHAIRMAN. Senator Coburn.

Senator COBURN. Thank you, Mr. Chairman. Dr. Land, I remember as a young boy hearing an Evangelist by the name of Angel Martinez and his famous statement was, "as a believer, you

wouldn't go to hell for smoking. You'd just get to heaven sooner and smell like you'd been there."

[Laughter.]

And that has stuck with me through a number of years. I'm somewhat perplexed at where we find ourselves. I'm a big believer in prevention. As a matter of fact, I'm getting ready—March 15, to introduce a large prevention bill in this country. We spend almost $7 billion a year on prevention through 21 different agencies. We don't get much for it because it's not been focused properly, and I'm highly disturbed that less than $1.5 billion out of $50 billion has gone to fund prevention. The question I have for you is, why not pass a bill (rather than the FDA and all this other stuff) that says you'll get all the carcinogens out of your product by 9 years from now. You will be decreasing the nicotine level by "X" percent every year for the next 10 years. Why not go after it? We can't ban advertising without consent, based on the first amendment, but we certainly can say what you can and can't produce when it is such a great health hazard. So my question is—I know where Senator Kennedy wants to eventually go with this and I'm not necessarily opposed to getting rid of the addictive potential of cigarettes—but why not do it directly? Why don't we set it up? We know what to do. We know how to do it. Why are we not doing that? Why are we going through this? You know, the No. 1 reason for the Food and Cosmetic Act was for determining safety and efficacy. There is no safety in tobacco products of any type and the only thing they are efficacious at is addiction. And we're going to put that through an agency? Why not go for the gold. Why don't we go for the meat? Why don't we say, you've got this many years to get all 60 carcinogens out and you've got this many years by which you'll reduce the percentage and in the meantime, let's do some Federal tinkering, in terms of mandates, through incentives to States. If you don't spend some of your tobacco money, a larger percentage, on prevention and anti-smoking campaigns, then this will cost you this. And why don't we spend some of the $7 billion a year that we're now spending on prevention, to directly go after this? We can win this fight. Answer those questions for me. I don't care who answers them.

Mr. CONNOLLY. I think what you're doing is applying a scientific agency to make those very decisions. There is no reason why, under this legislation, that the FDA couldn't ramp the levels of nicotine down in 30 years to the levels in tomatoes.

Senator COBURN. We don't need FDA to do that. We can do it right here.

Mr. CONNOLLY. Well, I would argue that you've got a complex issue that takes time to weigh. Do you take the toxins out, the nicotine out, you take both and you give them——

Senator COBURN. You set up a separate commission. You say, here's your charge. Here's the 10-year goal. Go do it. We're going to compliment——

Mr. CONNOLLY. I think the bill adequately does that, Senator.

Dr. BLUM. Senator, I'd like to answer. One specific comment you made that might be in error and that relates to this bill, which talks about nicotine. We all know that's the addictive component—of nicotine but this bill only mandates that nicotine be adjusted in

one level and that is downward, yet the experience of the individuals who smoke is to compensate by inhaling more deeply and thus, we could regulate nicotine all we want but the fact is, not even to acknowledge that what science has found is that people who smoke are inhaling more deeply, putting themselves at far greater risk for emphysema, heart disease and lung cancer by smoking the low nicotine cigarettes is mind-boggling to me.

Senator COBURN. Well——

Mr. MYERS. Senator, could I just——

Senator COBURN. Let me make one point. There is wonderful new research about drugs that are coming out that hinder the addictive components of nicotine in the brain. So, the new treatments that are on the market for addiction, in combination with lowered carcinogens, this can help solve this problem.

Matt.

Mr. MYERS. Just quickly, Senator. Several years ago, we actually proposed that States be given incentives to spend more money on tobacco prevention. We don't see that it is an either/or. We think it is vitally important that we do everything we can to encourage States to do so. So if that's something you would like to work on, we would be delighted to work on it with you because we do think that more should be done to encourage States to do so.

And your notion is an intriguing notion about setting a 10-year goal for doing these sorts of things and a number of people have talked about that very idea in the past. The more experts you talk to who really look at this product, the more they tell you, just as Dr. Blum just did, is there are things that we don't know the answer to, which is one of the reasons for trying to give this to an agency with real scientific expertise, hold their feet to the fire, for them to come up with the kind of rigorous standards that can make a difference and I don't think anybody here today can tell you what they are. But in the past, when legislative bodies—not just in the United States but elsewhere, have thought they understood the issue without knowing all the detailed science and you know it better than most do, what we have found is that all it does is lead the tobacco industry into a pathway around it. So it is the reason that many of us have come to the conclusion that the best thing we can do is give it to an agency, give them a mandate, watch over them to make sure they do it and they do it in a way that, in the end, has the kind of public health, scrutinize them in the way you're talking about doing over the long-term.

Senator COBURN. The only problem with that theory is the Bureaucrats' Law of Washington—never do what is right when you can do what is safe. And that will mess up all your plans, I promise you, as I've seen many great plans messed up at the FDA. So that's a nice utopian goal but I'm here to tell you, that ain't going to work. The FDA is like a balloon. You push in one place, it goes out somewhere else. They are smart enough to get around anything—and they'll move around that, too. So the goal has to be everybody recognizing what the problem is. There's no question. We need to work on that end in terms of supply but the No. 1 thing is prevention. Prevention is the No. 1 thing and how do we counter what Senator Burr was talking about? If you could get an agreement where the first amendment rights were limited by agreement and

then we poured the money into prevention, we could make a big impact in this country, a big impact. We're not going to make any kind of impact with this for 5, 10, or 15 years. We could do that tomorrow. We could start saving 40,000 lives a year tomorrow if we would go with prevention and some type of agreement where we limited first amendment rights in terms of tobacco products.

Mr. Chairman, thank you. I've gone over my time.

The CHAIRMAN. Could I just ask Dr. Henningfield, who is an expert on this whole issue of addiction. Maybe you could make a comment?

Mr. HENNINGFIELD. I'd appreciate it. Being from Minnesota, I tend to wait and then you don't get in line.

The CHAIRMAN. You don't get any time, any floor time.

Mr. HENNINGFIELD. Prevention is vital. Prevention won't pay off in terms of death reduction for 20 to 30 years in a big way. We've got 50 million-plus tobacco users that we need to help earlier. The idea is intriguing of setting a standard and say 10 years or 9 years, to take all the carcinogens out. That sounds like a 10-year clock to prohibition. It's a legitimate thing to discuss. That really is a political/social discussion. But FDA does not design foods, drugs. Congress doesn't design foods, drugs. I work with WHO—they don't design foods, drugs. They say, these are the standards that you must achieve in light of today's science. As the science evolves, as the products evolve, you evolve the standards and hopefully, tighten up the standards. That, I think, is the regulatory approach to——

Senator COBURN. Let me respond to that, if I might. So we're going to tighten up the standards. There is no difference in that and in going to abolition. You're going to trust an agency to do what we don't have the courage to do as a Congress. That's what you're really saying to me. We don't have the guts to stand up and say, here's where we need to go. We can create a small commission and we can fund it and we can figure out a way to do that. We don't have the courage to do what is really necessary—take a combination of our ideas for an agreement on both advertising and warnings, and really invest in prevention. We don't have the courage to do that. We're going to shuffle this over and in 10 years, we're going to be back here talking about the same thing, because Marlboro will be Marlboro tomorrow.

Mr. HENNINGFIELD. Senator, I hope you will have the courage to stand up and argue for much more funding for prevention. I think it is atrocious that States haven't spent more money on prevention. I think we all agree with that. But you can give us the work in prevention too, an asset, so companies can't come out with Camel No. 9 or if they try to, we can say, what, when, how, why.

Senator COBURN. That's what Senator Burr is offering you.

Mr. HENNINGFIELD. The FTC is clueless. It can't——

Senator COBURN. But they are now. What makes you think the FDA is any better?

Mr. HENNINGFIELD. The FDA is——

Senator COBURN. On these same issues?

Mr. HENNINGFIELD. Well, the FDA's entire authority and history is health regulation, toxic regulation.

Senator COBURN. No, it's safety and efficacy. There is nothing safe and there is nothing efficacious about tobacco products and

we're going to ask an agency whose whole goal is safety and efficacy to approve our grandfather, what is obviously not safe and not efficacious.

Mr. HENNINGFIELD. Neither FTC nor DOJ nor anyone else discovered that light cigarettes were a sham. NCI, NIH, CDC and FDA discovered that. These are health organizations. The FTC is not a health organization. It doesn't have the culture, the experience to assess ingredients——

Senator COBURN. I want you to think bigger. I'm talking about doing the whole thing. I'm not talking about a little piece here and there. I'm talking about thinking outside of the box. Let's go after it. Let's create true prevention. Let's—sorry, Mr. Chairman.

The CHAIRMAN. Senator Reed.

Senator REED. Thank you, Mr. Chairman. Thank you for your testimony. One of the presumptions of an effective market is perfect information by buyers and sellers. So Dr. Henningfield, do you think buyers of cigarettes have perfect information about what's in the cigarette?

Mr. HENNINGFIELD. Not even close. I don't think they understand the vent holes. I don't think probably anyone here understands that the vent holes do something else. They increase the free-base nicotine fraction. CDC discovered that. It took CDC to jump in and say they not only are a sham but they increase free-base nicotine. So in order, if this is a product in the marketplace, in order to make it—the market—better, consumers need more information, like what's inside the cigarette, how is it designed to produce nicotine in higher effects? Wouldn't that sort of be a principle of an effective market? At least they know what they're getting into when they start smoking?

Senator REED. I think it is core and it's what we rely on the Food and Drug Administration to do, whether it's dog food, potato chips or anything else, to ask what, when, how, why—what are the effects?

Mr. HENNINGFIELD. Except for cigarettes.

Senator REED. Except for cigarettes. So the FDA—these arguments about they don't have the capacity and they can't be effective in terms of dog food seems to be disputed by—they actually do things like that. Is that true?

Mr. HENNINGFIELD. This is what they do on a routine, daily basis. One of the sad things about the data that Dr. Connolly showed about trends in nicotine is, all of us that are expert in this area are not sure why it's being done, how it's being done, what the effect is. FDA could do all of that. They could say why, what, when, how.

Dr. BLUM. Senator, could I add something? I'm Dr. Alan Blum.

Senator REED. Please, doctor.

Dr. BLUM. I served on an FDA advisory committee and again, I have great respect for the staff and it breaks my heart and I wasn't prepared to do this, to catalogue the list of abject failures of the FDA over the last 10 years. We all know about them, from antibiotics in animal feed that have resulted in resistance and contamination to women's hormones to antidepressants in children, cash donations to doctors from drug companies—it's all been botched and this is an agency that is now going to take over a product that

has no redeemable health value. It strikes me as an exercise in absurdity for this agency to be the one that the proponents of this bill want to entrust with the most irredeemably harmful consumer product in our society. I would love to see a separate agency or a separate Congress as Senator Coburn said, with the courage to tackle the elephant in the room, which is Marlboro. That's what's killing people. It's not little Camel No. 9's or whatever new little product come on the market that will be the definition of infinity.

Mr. CONNOLLY. Senator, let me——

Senator REED. Dr. Connolly, go ahead, please.

Mr. CONNOLLY. I disagree totally with what he said. I mean, if you read the history of the FDA, it's probably one of the most—greatest public health institutions known to our country. It prevented the adulteration of meat by throwing sugar in it. It stepped in and it stopped that in the early part of the last century. RJ Reynolds throwing sugar into tobacco products, to me is no different. It's adulteration of a very harmful product to make it even more attractive to kids. FDA dealt with HIV, fast tracking the research, did a wonderful job. FDA has done food labeling so our Nation's consumers are much, much more knowledgeable about foods. When Massachusetts—post the MSA, tried to get the ingredients in cigarettes, we were sued by a big tobacco—by six companies, by 4 p.m. and spent 6 years in Federal court, $20 million of their litigation, just trying tell adult consumers what's in their products so they could make a choice between one that could be more addictive and less addictive. If this industry has changed, they wouldn't be suing us to give adult consumers information about quitting. FDA has got a wonderful history and I can recommend some very excellent books to my close friend, Alan, to read about the history of FDA and I think this agency can do a miraculous job on an issue that this Congress, this Nation, has failed to address.

Senator REED. Dr. Henningfield.

Mr. HENNINGFIELD. Just to add to that, what FDA does is find the balance, it tries to find the balance. People, including Dr. Blum, have criticized the bill that will be too restrictive on new products, not restrictive enough—well, that's FDA's job to find the balance and it will make mistakes at times, as it has made in the past. Then it has mechanisms to be flexible and corrective. If you just say, Congress orders—this is the new label. This is the way it should be, that will be wrong in a while and you won't have a flexible way to address it. That's what FDA does every day.

Senator REED. Well, my presumption is that it is a process involving several institutions. No. 1, Congress lays out guidelines and an agency like FDA, when it comes to advertising, perhaps FTC, will implement those, subject to our approval, appeal, criticism, and changes. What I sense is that finding fault with the FDA is a way of stopping any type of progress with respect to regulating what is in cigarettes, the information consumers might have because I think, again, it's the classic situation of the perfect becomes the enemy of at least the barely adequate. And around here, barely adequate might mean progress. Mr. Myers, do you have any comments?

Mr. MYERS. Let me echo what Dr. Henningfield said. There is no simple solution, as much as we'd all like a simple solution. This bill

gives the FDA the authority to deal with Marlboro as well as with Camel 9. We're all going to have be vigilant to be sure that FDA does its job to protect the public to the extent possible but there simply hasn't been a more thoughtful, balanced approach presented to Congress to address this problem in the past. Otherwise, we have the status quo where it's Philip Morris who controls what goes in Marlboro. It's Philip Morris who controls what goes in the advertising to young people today. We need a Federal agency with a mandate to do it day in and day out and then all of us need to remain vigilant to make sure they do their job.

Senator REED. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. This has been enormously interesting and worthwhile discussion. Now let me ask the panel, what we have basically underlined in the legislation—we know that it is the tar and the chemicals that kill. But we know it's the nicotine that's addictive. So we know that people smoke and they get the nicotine because that is what is the addictive substance. We've given the FDA the authority to bring that nicotine level down. Some will say, "Well, by bringing it down, smokers are going to smoke a lot more and they're going to inhale a lot more tar and chemicals. Therefore, it's going to be just as dangerous for them." Are we saying that medically we don't know whether you can get nicotine down so low where, from a medical point of view, it is nonaddictive. These are all scientific questions. But aren't we all trying to get to the point where we're reducing the tar and the chemicals, which are the most dangerous and where we get the nicotine, which is the addictive substance. In this general kind of discussion, are we getting mixed up between these different subject matters in terms of what the legislation is attempting to do?

Mr. MYERS. I think you said it very well. The goal is to reduce the toxic substances with a real goal of reducing the number of people who die. That's the end measurement in this. The bill doesn't make a judgment about whether it's good or bad to raise or lower nicotine levels. What it does is say to the FDA, you need to take a look at the best available science and what its impact will be, with the ultimate goal of taking steps that will reduce the number of people who will die. It doesn't pre-judge whether that number goes up or goes down or what that number does and it defers to Congress to make that final decision in that respect. But the key here is it gives the agency the authority to take the steps to reduce the things that are killing people today.

The CHAIRMAN. What is the answer to the question that Senator Enzi mentioned, that the FDA regulation could give the appearance of an FDA seal of approval on the cigarettes that they allow to be sold?

Mr. MYERS. There are at least five provisions in this bill that give FDA the authority to prevent a tobacco company from explicitly or implicitly doing that. If that needs to be made clear, then we should make that clearer in that respect, I think everybody agrees. Equally important, there is a standard in the bill that addresses that issue and that is that FDA must look at the impact of any action, not just based on an individual smoker but on the population as a whole so that if an action has the impact, either by tobacco companies finding a way to give the impression that it's

FDA approved or some other mechanism, to actually increase tobacco use by encouraging starters, discouraging quitters, then FDA has the power to step in to prevent that. It's broadly based on the notion that the agency should have broad-based flexibility. Dr. Henningfield may want to add to that.

The CHAIRMAN. Please address that, and then address the point that, since the advertising budgets of the companies are virtually unlimited, no matter what the FDA has actually done, the companies' ads will distort it.

Mr. HENNINGFIELD. Well, the first thing is, what FDA is already good at, for better and for worse, is sitting back and letting the companies spend the money and say, "Prove it." And with this, Camel No. 9, it says it's new. FDA could sit back and say, "Is it new? Does that mean we need prior approval?" They can get into issues like that. They can look at—they can ask the company to do focus group testing on the intent of the marketing and the effect of the marketing and sit back and say, "We're not happy. Go do more." So the FDA has a lot of tools at its disposal that are embodied within the regulation. If I can just touch nicotine?

The CHAIRMAN. Go ahead.

Mr. HENNINGFIELD. Nicotine, like cocaine, like sedatives, like stimulants, it's not just the drug. It's how it's delivered. The National Institute on Drug Abuse that I used to be a part of made enormous progress. You look at the nicotine patch. It's minimally addictive. Same chemical. What Marlboro does is increase the freebase fraction, have other chemicals along with nicotine. They did research that showed that acetaldehyde worked synergistically with nicotine. So can we make a cigarette nonaddictive? Probably not, as long as there is nicotine. Can we make it less readily addicting? I believe we can.

Dr. BLUM. Senator, it took 10 years to get rid of Joe Camel. Everyone was jumping around with their necks cut off about the cartoon character and cigarettes. That did not even end as a regulatory measure. It was voluntarily withdrawn by RJ Reynolds. Meanwhile, Marlboro sales soared. You're all upset about Camel No. 9 but how many days, months, weeks or years will it take for more regulators to engage our taxpayer money in looking at each variation of a brand name that comes along? The most dynamic, creative expert marketing force in this country is Philip Morris. They have done wonders with any regulation. They have outwitted us. You know, three quick examples. This ad ran in the University of Alabama student newspaper last week. They know all about—the public knows all about what has been happening about smoking but that doesn't seem to block Philip Morris from coming into universities—over 35 universities and talking about how they have redefined not just cigarette marketing but marketing in general, to a one-on-one experience. And the job interviews are being held all this week. They are mailing to physicians. That's right—the Philip Morris Tobacco Company is mailing its Quit Assist booklet to physicians and asking them if they want more copies for their waiting room. They are promoting a youth anti-smoking—I call it anti-youth smoking program and we don't really—we say this is nonsense and of course, it is but this bill will not prevent this company from being as dynamic and creative as ever. I asked a college stu-

dent, why would you want to work for Philip Morris? He was interviewing for it and he said, "Oh, they don't just sell cigarettes. They help prevent smoking."

Mr. CONNOLLY. Senator, I would say that—two points. We don't know the answer. Is it toxicity or nicotine—which to take out. And I think the FDA is empowered to look at both issues. Tomatoes have .3 milligrams per gram of nicotine in them but no one is outside the building today eating bags of tomatoes. And maybe we want to go down that route but we have to look at it very, very carefully. If we go down that route, maybe bring in close products that reduce harm to replace the nicotine in Marlboros and turn Marlboros into lard. I think that's conceivable.

I brought some research we did on the safest cigarettes. We also asked consumers about the advertising claims. Do you think these claims are approved by government? Eighty percent of our respondents said, "Yeah, the Government has approved those claims." So the train has already left the station here. The Government—I mean the consumers think the Government is approving those claims so why not put them into—to look at those claims and regulate claims? I don't think this is going to impact whatsoever on the litigation front. If the industry continues to behave the way they have behaved, it will be continued action within the courts and FDA regulations are not going to impact on that.

Senator COBURN. Just one short answer. What would be wrong with the Federal Government having an advertising program saying that they didn't approve those claims? And that there is no government endorsement of the product? There is none. So we've not done that. So we've allowed that kind of response because we've failed to do what we should be doing.

Mr. CONNOLLY. If you pass this bill, Senator, you will ban those claims that are being made today for those 38 safer products. Their claims are being made today. We need this bill out there today to ban those unfounded, unsubstantiated claims. And then, based on science, if they do come up with a product that actually does reduce harm to the consumer, then the Federal Government should allow those claims. They shouldn't deny the consumer that information.

Senator BURR. Mr. Chairman, I have found this discussion to be fascinating and the reality is, the way the bill is written, there can't be higher nicotine because it bans it. As a matter of fact, it sets the ceiling at the current product and no product more harmful, which is the way it should be. More harmful should be considered, much less approved and yes, there is an FDA approval but somehow we suggest nobody in America will realize that when that new product comes out that suggests less harm, that they will consider that it has the stamp of approval from the U.S. Government because they are much smarter than we are, let me assure you. As a matter of fact, in 1938, when the FDA was created, there were drugs on the market then. Do you realize all of those drugs that were on the market then were never required to go through FDA approval? They are marketed today. They are not FDA approved. But to use your analogy, we would have to go out as a Federal Government and force those manufacturers of those compounds to now advertise that they're not FDA approved. Well, we know, what in fact, that would do to a compound that might be very useful to a

lot of people, that passed safety and efficacy a long time ago but when you put, "it has not been approved," boy, you kill the market for it. So part of the challenge that I've got is that I have to pick, choose from everything you're trying to do to figure out—just like the tobacco industry, which ones are they structuring so they can do this? Which ones are you structuring so that the outcome is predetermined? Because I think we have the—we're the only ones that have the challenge of balance, Dr. Henningfield.

Hold on. I mean, you guys have gotten a lot more time than I have and I'll ask a few questions. You said that the FDA's role is fair and balanced. It is not the FDA's role. The FDA's role is to make sure that the hurdle is never lowered and that the threshold for safety and efficacy is, in fact, something that every product that comes through has to meet. So I'm not sure where, in fact, there is balance on the part of the FDA. As a matter of fact, Dr. Coburn and I have worked for 13 years, as has Senator Kennedy and we've seen kids that came in—many of them cancer victims, patients. And you know what? Picking up the phone and trying to get the FDA to fast track something 10 years ago was unheard of, even if that was the only choice—the only option for that child to have a hope of overcoming cancer and the FDA said, "No, we don't do that. We have a threshold—a drug, a biologic, a device must meet that threshold and if it doesn't, it doesn't go through here. We don't approve it." And you know what? That's the standard that should be maintained. Now, let me say this. Can you create a new area of FDA that has limited responsibilities, authority, very well prescribed as to what it is we want them to look at, what it is that we want them to regulate? Sure, we can do that. We're the Congress of the United States. That may be what we need to do. But we've tried to go through a process today to determine, is this the most appropriate agency for everything that we're trying to do? And I would challenge you that it's not. That there are areas that can do it more effectively, with greater assurance that it's being done and there may be some things that at the end of the day, we need to sit down and say, maybe this is something only the FDA can do. But you know, even for some of the toxicology studies—I'd challenge you that probably CDC is a more appropriate place to do that. They do it every day. They respond in a different fashion. It doesn't encompass everything in one agency, which is what many want to do in this. But it can be just as effective.

Now, Dr. Henningfield, I've got to ask two real quick questions. Do you support granting sovereign control of the tobacco industry to an international organization and relinquish American control of the product?

Mr. HENNINGFIELD. No.

Senator BURR. Do you support sending taxpayer dollars to developing countries in order to subsidize their tobacco production?

Mr. HENNINGFIELD. Their tobacco production?

Senator BURR. Production, yes sir.

Mr. HENNINGFIELD. I think that's a question with complexity beyond my ability.

Senator BURR. Well, I've read the World Health Organization bill that you signed and I think it does exactly those two things. So I would ask you to go back and look at that. And Dr. Connolly again,

I want to—I really want to comment on your passion. There is no substitute for that and I appreciate it.

Mr. CONNOLLY. Senator, could I just respond?

Senator BURR. Yes.

Mr. CONNOLLY. By saying, I'd like to——

Senator BURR. But let me make my last point first and then I'll let you talk all you want to.

Mr. CONNOLLY. No, I don't want to—I just want to just correct the record, that's all, Senator.

Senator BURR. You know, I expected when I pulled the numbers up, that I'd find Massachusetts having used all their tobacco money for health and education. In fact, I found Massachusetts ranked No. 31. They used 23.4 percent for tobacco and education. North Carolina is the tobacco State. Our livelihood is in it—manufacturing, growth. We used 40.2 percent of the MSA money for education and for healthcare. We were No. 21. There were 20 States that did better than we did.

You know, in large part, I hope you—and I'm sure you have—displayed some of that passion back in Massachusetts as I will in North Carolina, to see if we can't use money that was targeted for this specific thing and to get it out of budget deficits and transportation dollars and everything else States love to spend it on.

Mr. CONNOLLY. Well, I didn't have the action but our Governor Romny, who wasn't a Democratic by the way, cut the budget. He maintained that—Governor DeVaugn—Patrick has increased the budget by $18 million 2 days—actually Wednesday, today, in his budget. So we will be ahead of North Carolina. We should be much higher. Just as acting as a Senate historian, the FDA bill was passed in 1906. What the FDA bill is grandfathered in from the homeopathic pharmacopoeia—all those substances that were either approved or not approved—nicotine was one of those substances. Purportedly for passage of the bill by the Senate in 1906, nicotine was withdrawn from the homeopathic pharmacopoeia so basically, unregulated by FDA. Cocaine was in the original 1906 FDA bill. It was in Coca-Cola. And what happened is FDA then took it out of Coca-Cola, put it into a schedule so a physician could still prescribe cocaine and then finally prohibited it. So I think it's a wonderful Senate—of this chamber and I think when one only has to go back to 1906 and empower the FDA to do what they've done for cocaine, to do for tobacco products and this Nation will be healthier for it. Thank you, Senator.

The CHAIRMAN. OK, well.

[Laughter.]

Dr. Land, did you have any final comments?

Mr. LAND. Well, I must confess, I experienced some frustration with the latter part of this process. It seems to me that we're trying to make the perfect enemy of the good here. The FDA, like all Federal agencies, like all man-made creations, has flaws but it has done an enormous amount to protect the American people over the years and I don't think—I would not want to be charged with the argument of trying to make the argument that this bill will not retard the ability of the tobacco companies to run their scam on the American people. Are there other things that can be done? Of course. And all of them together—the end product, the sum—the

end product will be more than the sum of the parts but this bill, we believe, will help protect the American people and will help to regulate what is too unregulated an industry. I will go back to what I said in my testimony—it just seems to me to be irrational that the FDA controls—has control over products that help people quit smoking but has no control over the product that they are trying to quit.

The CHAIRMAN. OK. We're running out of time here but I'll just give 30 seconds to anybody that wants a final comment.

Dr. HUERTA. Thank you, Mr. Chairman. When I do my radio talk shows on a daily basis, we talk about tobacco. Some listeners, they say, "Why don't you ban tobacco being so bad?" Well, nobody is in agreement with that in this room. So I see this bill as a positive way to change the environment and when you change the environment in a Nation, that is the first step for change for good. Remember our long fight against this industry. We fought this in the fifties and the sixties and the seventies, eighties and nineties—well, 2007 now and this will do the right thing to change the environment.

The CHAIRMAN. Thank you.

Dr. Blum.

Dr. BLUM. Thank you again, Mr. Chairman, for this hearing. I have to really claim to be the longest running person in this field in this room and I believe, unfortunately, that the bill is the wrong policy for the wrong agency at the wrong time. Tinkering with a product, with ingredients is the most resource and labor-intensive and the least effective, least proven, least relevant and biggest waste of time, money, attention and focus we can do.

The CHAIRMAN. You can see that we don't hear just one side at these hearings.

[Laughter.]

Senator COBURN. While we're at it, I'd just throw out one other drug that we ought to consider for FDA control. The FDA doesn't control alcohol but they control all the drug treatments for alcohol withdrawal and treatment. This rationalization—I'm not against the purposes that everybody in this room is trying to go for. But let's apply the same standard everywhere. You all have a lot more faith in the FDA than I have in the FDA and I have a law since January 2000, signed by Bill Clinton, that said the FDA will label condoms as to their efficacy. The science is proven on that. But, for the political correctness, the FDA has kept the information for that to themselves. So we consequently have no law and we have no label on condoms that are 80 percent ineffective—and this can cause cancer in women. Eighty percent ineffective. But yet we don't have it. So this is the same FDA that you are entrusting to do everything that you hope to do, but they don't control alcohol sales. They don't control advertising for alcohol and I would put forward to you, alcohol consumption in this country might be a larger problem, or equal, in terms of the illness and associated morbidities that Americans experience. Thank you, Mr. Chairman.

The CHAIRMAN. We're winding up but I really have to add my commendation of the Food and Drug Administration. I've been on this committee for a number of years, 45 years on it, and I've—particularly Senator Hatch and I—have spent a lot of time dealing

with the FDA. We've been very much involved in the re-authorization. There are a lot of challenges that are out there but we are the gold standard in the world, in terms of the Food and Drug Administration. Just while we're meeting here, the Chinese are in the process of adapting a Food and Drug Administration virtually identical to what we have here. It's been modeled in terms of the countries in Western Europe. We haven't always had the right answers, but we are in the life science century and the changes that have been brought on in terms of products that have made a difference in the lives, particularly of our senior citizens, have been close to miraculous. So I can also give my observations about some of the shortcomings of FDA and we're going to try and address some of those in the Enzi/Kennedy legislation; but we need to keep those shortcomings in perspective.

I want to thank all of our panel. We're going to keep the record open and we're going to keep you all busy with written questions. There will be more questions, but this has been very, very helpful to our committee. We're enormously grateful to all of you and we will stand in recess. Thank you.

[Additional material follows:]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR CLINTON

I would like to thank Chairman Kennedy and Ranking Member Enzi for convening today's hearing on the importance of providing the FDA with the authority to regulate tobacco.

We have a duty to safeguard our Nation's health and fight efforts to target tobacco products to women and children. I am proud to be an original cosponsor of *The Family Smoking Prevention and Tobacco Control Act*, and I am delighted that this bill has garnered such strong bipartisan support.

I'm also pleased to announce that today, Senator Hagel and I are reintroducing our lung cancer resolution, which seeks to draw attention to this terrible, smoking-related disease. This resolution passed the Senate last year, and I'm hopeful that the Senate will take quick action again.

It's hard to believe that it's been 7 years since the Supreme Court ruled that the FDA does not have authority over tobacco products.

I am fortunate to represent a State where tobacco control laws are amongst the best in the Nation. This past January, the American Lung Association ranked New York as the second highest in the Nation for its efforts. New York particularly received praise for its exceptional smoking prevention and cessation programs.

But, despite these laudable efforts, there has been a troubling increase in smoking-related diseases among women in New York in the last 30 years. Female smokers are 13-times more likely to develop lung cancer than women who don't smoke. And between 1983 and 2003, the annual number of cases of lung cancer and bronchus among women nearly doubled, increasing from 3,852 to over 6,000 in New York State in that 20-year period.

In fact, lung cancer is the leading cause of cancer deaths in our Nation, causing more deaths than breast cancer, prostate cancer, and colon cancer combined.

Each year, 178,000 women die annually from smoking-related diseases in this country, and over 35 million Americans—male and female—suffer from chronic lung diseases such as asthma, emphysema and chronic bronchitis.

Risk of infertility is greater among female smokers compared to nonsmokers, and there is a higher risk of pregnancy complications, premature birth, low-birth-weight infants, stillbirth, and infant death if a woman smokes during pregnancy.

There is strong evidence that tobacco advertisements cynically target advertising to adult and adolescent women. According to an analysis published by the Journal of the American Medical Association in 1994 and a 2001 report by the Surgeon General, the tobacco industry has targeted women with some form of this dangerous promotional strategy for almost a century, beginning in the 1920s. The latest example of this is chronicled in a recent *New York Times* editorial, entitled "Don't Fall for Hot Pink Camels," which discusses R.J. Reynolds's $25 million to $50 million investment in an advertising campaign behind the new female-friendly Camel No. 9.

In addition to targeting women, tobacco advertisements are also designed to appeal to our youth. This is unconscionable.

According to the 2004 Surgeon General's report on the Health Consequences of Smoking, there is a higher incidence of respiratory illness in children and adolescents who smoke compared to their nonsmoking peers. This report also concluded that the overall health of kids who smoke is worse than their nonsmoking peers.

I believe that tobacco use constitutes one of the largest threats to public health, a conclusion that is also expressed in the 2000 Supreme Court ruling.

In States such as New York, we've seen evidence that tobacco control efforts can help lower rates of smoking and tobacco use among kids. Between 2000 and 2004 in New York State, there was a widespread reduction in use of cigarettes and other tobacco products by students in both middle and high school. Frequent use of cigarettes among middle school students dropped by 55 percent, while high school students' frequent use decreased by 36 percent.

However, given the damaging effects of tobacco products on kids, I am still concerned that over 20 percent of high school students in my State smoke. And that nationally, 25 percent of children smoke by the time they finish high school.

The United States spends more on health care than any other industrialized nation and yet we struggle to provide adequate health care for all our citizens. We literally cannot afford the myriad of health problems that we know result from tobacco use: bladder, esophageal, laryngeal, lung, oral, and throat cancers, chronic lung diseases, coronary heart and cardiovascular diseases, as well as reproductive effects and sudden infant death syndrome.

That's why I support S. 625. This important legislation gives FDA the legal authority necessary to accomplish a collection of crucial tasks: preventing tobacco advertising aimed at children—preventing tobacco product sales to minors—and making tobacco products less toxic. These efforts are critical in improving our Nation's health and reducing the burden of health care costs.

I look forward to hearing the expert opinions from our panelists today, and I hope that with their input, we will remove any doubts that passing this legislation is critical to our Nation's health.

Again, I would like to thank both Chairman Kennedy and Ranking Member Enzi for holding this hearing and I look forward to working with my colleagues on the committee to ensure passage of this bill. Thank you.

STATEMENTS AND LETTERS OF SUPPORT

STATEMENT OF MATTHEW L. MYERS, PRESIDENT, CAMPAIGN FOR TOBACCO-FREE KIDS

WASHINGTON, DC. (February 15, 2007)—The bipartisan legislation introduced today to grant the U.S. Food and Drug Administration (FDA) authority over tobacco products presents the new Congress with a truly historic opportunity to protect our children, improve the Nation's health and save countless lives. There are few steps Congress can take that would make a bigger difference for our Nation's health. It is truly inexcusable that the most deadly product sold in America today is one of the least regulated products sold in America. By passing this legislation this year, the new Congress can end the special protection the tobacco industry has enjoyed for far too long and at such terrible cost in health, lives and money.

Along with our many public health, faith and other partners that have endorsed this legislation, the Campaign for Tobacco-Free Kids applauds U.S. Senators Edward Kennedy and John Cornyn and U.S. Representatives Henry Waxman and Tom Davis for their leadership in introducing this bipartisan legislation. The large num-

ber of original cosponsors in both houses of Congress and from both parties underscores the strong, bipartisan support for this legislation.

Throughout the coming debate, we should never forget what this legislation is all about: Reducing tobacco's devastating toll on our families. Tobacco use is the leading preventable cause of death in the United States. It kills more than 400,000 Americans and costs the Nation more than $96 billion in health care bills every year. Tobacco use kills more of our citizens annually than AIDS, alcohol, car accidents, murders, suicides and fires combined. Every day, another 1,200 Americans die from tobacco use and more than 1,000 kids become regular smokers. This deadly toll will continue to mount so long as the tobacco industry remains unregulated and free to engage in marketing that appeals to children, to deceive consumers and to resist even the most minimal steps to make their products less harmful.

Congress has debated the issue of FDA authority over tobacco for nearly a decade. It is time to finish the debate and take action to protect children and save lives.

STATEMENT OF JOHN KIRKWOOD, PRESIDENT AND CEO, AMERICAN LUNG ASSOCIATION, NEW YORK, NY

WASHINGTON, DC. (February 15, 2007)—The American Lung Association commends Senator Ted Kennedy (D-MA), Senator John Cornyn (R-TX), Representative Henry Waxman (D-CA) and Representative Tom Davis (R-VA) for the introduction of the *Family Smoking Prevention and Tobacco Control Act,* strong, bipartisan legislation that would give the U.S. Food and Drug Administration authority over tobacco products. Once enacted into law, this measure will end the special protection enjoyed by the tobacco companies for decades and seriously reduce the devastating impact of tobacco use in the United States.

Tobacco-related diseases are the leading preventable cause of death in the United States, causing more than 438,000 deaths each year. Each day, more than 1,140 kids become regular smokers—and one-third of them will ultimately die from their habit. The tobacco companies spend more than $15.15 billion a year marketing their deadly products—preying on our children, who make up the "replacement generation" of smokers.

In August 2006, U.S. District Court Judge Gladys Kessler correctly concluded that tobacco companies have engaged in a long-term, fraudulent scheme to mislead the American people about the health risks of smoking, the addictiveness of their products, and their tactics for marketing their products to children. In her decision, Judge Kessler wrote that the tobacco companies have "marketed and sold their lethal products with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted." Unless this important legislation becomes law, the tobacco companies will continue to aggressively market their products to children and lie about the health consequences of smoking.

The American Lung Association is committed to working with Congress to ensure that the legislation becomes law in 2007.

ABOUT THE AMERICAN LUNG ASSOCIATION

Beginning our second century, the American Lung Association is the leading organization working to prevent lung disease and promote lung health. Lung disease death rates continue to increase while other leading causes of death have declined. The American Lung Association funds vital research on the causes of and treatments for lung disease. With the generous support of the public, the American Lung Association is "*Improving life, one breath at a time.*" For more information about the American Lung Association or to support the work it does, call 1–800–LUNG–USA (1–800–586–4872) or log on to *www.lungusa.org.*

AMERICAN MEDICAL ASSOCIATION,
February, 15, 2007.

AMA APPLAUDS LEGISLATION TO GIVE FDA AUTHORITY OVER TOBACCO PRODUCTS

The American Medical Association strongly supports the regulation of tobacco products by the Food and Drug Administration (FDA). We applaud Representatives Henry Waxman (D-CA) and Tom Davis (R-VA) and Senators Ted Kennedy (D-MA) and John Cornyn (R-TX) for their bipartisan leadership in introducing the "*Family Smoking Prevention and Tobacco Control Act*" to give the FDA authority to regulate the manufacture, sale, distribution, and marketing of tobacco products. Passage of this legislation will end the cruel irony that cigarettes are the most important pre-

ventable cause of death and disease in the United States and one of the least regulated products in our society.

Every year, 440,000 Americans die from diseases caused by tobacco use, which kills more Americans than heroin, PCP, cocaine, alcohol and every other drug combined. Tobacco is responsible for more than $75 billion in health care costs and $92 billion in productivity losses each year.

Tobacco addiction usually begins in childhood or adolescence. Each day, 2,000 kids become addicted smokers and one-third will die prematurely as a result. Some of the provisions in this legislation would stop illegal sales of tobacco products to children; restrict tobacco marketing, especially to children; ban fruit and candy flavorings in cigarettes; and require more informative health warnings. The AMA urges Congress to protect the public health of Americans by passing legislation to authorize effective FDA regulation of tobacco products.

RON DAVIS, M.D.,
AMA President-Elect.

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association (AMA) is pleased to submit this statement for the record of the Senate Committee on Health, Education, Labor, and Pensions (HELP) hearing on "The Need for FDA [Food and Drug Administration] Regulation of Tobacco Products." On behalf of our physician and medical student members, we applaud Senators Ted Kennedy (D-MA) and John Cornyn (R-TX) for their bipartisan leadership in introducing S. 625, the *"Family Smoking Prevention and Tobacco Control Act,"* to give the FDA authority to regulate the manufacture, sale, distribution, and marketing of tobacco products. The AMA has a long history of supporting strong and effective FDA regulation of tobacco products. We firmly believe that Congress should act this year to protect the public's health by passing S. 625 and its House companion bill, H.R. 1108, introduced by Representatives Henry Waxman (D-CA) and Tom Davis (R-VA).

Cigarettes are one of the least regulated products in our society but cigarette smoking remains the leading preventable cause of death and disease in the United States. Passage of this legislation would address the lack of regulation of this product. We expect the FDA to carefully monitor and regulate thousands of products that we consume on a daily basis. There are recent examples of such oversight with peanut butter, spinach, eye drops and similar products. Our government should apply the same diligence to the monitoring of tobacco products that it currently dedicates to ensuring the safety of the food and drug supply. It is unconscionable that cigarettes remain virtually unregulated with their ingredients undisclosed a full 43 years after the first Surgeon General's report on smoking and health.

As physicians, we see daily the devastating consequences of tobacco use on our patients' health. Patients suffer from preventable diseases including cancer, heart disease, and emphysema that develop as a result of a single product—tobacco. The evidence is overwhelming concerning the health risks of using tobacco products, particularly when used over decades. Each year, 440,000 Americans die from diseases caused by tobacco use, including at least 38,000 who die from secondhand smoke. Smoking kills more people than alcohol, AIDS, car accidents, illegal drugs, murders, and suicides combined, with thousands more dying from chewing tobacco use. Millions more suffer from illnesses caused by smoking. In fact, former Surgeon General Richard Carmona, in releasing his office's 2004 report on "The Health Consequences of Smoking," stated that "smoking causes disease in nearly every organ in the body, at every stage of life."

In addition to the human toll, the financial consequences of tobacco use are enormous. The Centers for Disease Control and Prevention estimates that tobacco use causes over $96 billion in annual health care expenditures. This includes over $30 billion in total annual Medicaid costs (Federal and State), or 14 percent of all Medicaid costs.

Tobacco addiction usually begins in adolescence. Each day, approximately 4,000 kids will try a cigarette for the first time, and another 1,000 will become new, regular, daily smokers. As a result, one-third of these kids will die prematurely. Despite their assertions to the contrary, the tobacco companies continue to market their products aggressively and effectively to reach kids. Cigarette marketing and promotional expenditures have increased dramatically since the 1998 State tobacco settlement, reaching over $15 billion per year. Much of this increase was particularly focused on kid-friendly venues, such as convenience stores where kids hang out and from magazines that they read. Such marketing has also included fruit and candy flavorings in cigarettes. Research has shown that kids are three times more

sensitive to tobacco advertising than adults and are more likely to be influenced by cigarette marketing than by peer pressure.

Although there has been progress in recent years to treat tobacco-related diseases and encourage all smokers to quit, more needs to be done to preserve and protect the health of Americans. Congressional action to grant FDA authority to regulate tobacco products is long overdue. The AMA strongly supports S. 625/H.R. 1108, which we believe would finally end special protection for the tobacco industry and protect our children and the Nation's health instead. In particular, we believe the following provisions in the legislation are essential to ensure the effectiveness of the FDA in reducing the number of individuals who begin using tobacco.

Youth Access and Marketing. The bill would require the FDA, within 1 month after enactment, to republish the 1996 Rule, which was struck down by the U.S. Supreme Court in 2000. This rule would significantly restrict access to tobacco products by targeting marketing to children. The legislation would:

- ban all outdoor tobacco advertising within 1,000 feet of schools and playgrounds;
- ban all remaining tobacco brand sponsorships of sports and entertainment events;
- ban free giveaways of any nontobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase;
- ban free samples and the sale of cigarettes in packages that contain fewer than 20 cigarettes;
- require retailers to verify age for all over the counter sales and provide for Federal enforcement and penalties against retailers who sell to minors;
- restrict vending machines and self-service displays to adult-only facilities;
- limit advertising in publications with significant teen readership to black and white text only; and
- limit any outdoor and all point-of-sale tobacco advertising to black and white text only.

The FDA would have authority to take additional regulatory steps to restrict tobacco marketing and to prevent tobacco sales to children under the age of 18.

Health Information Disclosure. The bill would require detailed disclosure of ingredients and harmful smoke constituents by tobacco companies. It would also require that all documents relating to health, toxicological behavioral or physiological effects of current or future tobacco products be listed. FDA would have to publish a brand-specific list of harmful and potentially harmful constituents. These disclosure requirements would give the FDA the information it needs to require changes to tobacco products to reduce the harm they cause and to better educate the public about the dangerous chemicals in tobacco products and the health effects of tobacco use. It would also provide the public with much needed information in order to fully understand the toxic nature of the product. With tobacco companies offering their own version of smoking cessation programs, the public is misled about the inherent harm in this product which if used as intended causes disabling diseases and death.

Authority to Order Removal of Hazardous Ingredients. The FDA would have the power to establish performance standards, including reduction or elimination of ingredients, additives, constituents, including smoke constituents, or reduction in nicotine yields to any level other than zero. Thus, FDA could reduce nicotine to minimal levels, including nonaddictive levels, to protect the public health. This is especially important in light of a recent study conducted by the Harvard School of Public Health showing that tobacco manufacturers have intensified the concentration of nicotine in their tobacco and modified cigarette designs to increase the number of puffs per cigarette. As a result, the amount of nicotine that smokers typically inhale per cigarette rose by 11 percent from 1998 to 2005, making it much harder for smokers to quit.

This regulatory authority is also critical in protecting nonsmokers from secondhand smoke. The scientific evidence on the health risks associated with exposure to secondhand smoke is overwhelming. Secondhand smoke is a known cause of lung cancer, heart disease, chronic lung diseases such as bronchitis and asthma, and results in thousands of deaths annually in the United States. Sadly, secondhand smoke also contributes to over 1 million illnesses in children per year. As the Surgeon General concluded in his recent 2006 report, "The Health Consequences of Involuntary Exposure to Tobacco Smoke," "The scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke."

Health Warnings. The FDA would be granted the authority to revise the health warnings on both cigarettes and smokeless tobacco products, and in print advertisements, to make them more prominent and explicit. The warning labels on cigarette

packages could be increased from 30 percent up to 50 percent of the front and rear panels.

Standards for Reduced Risk Products. Any so-called "reduced risk" products could not be sold or distributed without prior FDA approval. In order to receive FDA approval manufacturers would be required to submit data and a sample product to the FDA. They would also have to demonstrate that the scientific evidence is adequate to conclude that the product, as actually used by consumers, will significantly reduce the risk of tobacco-related disease to individuals and that the product as marketed will benefit the health of the population as a whole. In addition, tobacco companies would be required to conduct and report to the FDA postmarket surveillance of approved products' actual usage. Providing the FDA with review and approval authority of "reduced-risk" claims is a critical safeguard in preventing deceptive industry marketing campaigns. It is ironic that on the same day that S. 625 was introduced, the *New York Times* reported on a new marketing campaign announced by a major tobacco manufacturer targeting women. The advertisements describe the product as "light and luscious," and show flowers surrounding packs of cigarettes, which are in hot pink fuchsia and minty green teal colors. This legislation would prevent such claims and advertisements without prior FDA approval, thereby protecting the health of our Nation's women.

In conclusion, congressional action to provide FDA with strong and effective regulatory authority over tobacco products is long overdue. Congress should act now to protect the public's health and save millions of lives by passing S. 625/H.R. 1108 this year. The AMA is committed to working with Congress to accomplish this goal.

STATEMENT OF JOHN R. SEFFRIN, PH.D., CEO, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, WASHINGTON, DC

The American Cancer Society Cancer Action Network℠ (ACS CAN) applauds the introduction today of *"The Family Smoking Prevention Tobacco Control Act"*, bipartisan legislation in the House and Senate that would grant the U.S. Food and Drug Administration (FDA) the authority to regulate the sale, distribution and advertising of tobacco products. Tobacco, which kills more than 400,000 Americans each year and remains the leading cause of preventable death in the country, is the only consumable product the FDA does not regulate.

"Congress has the opportunity to take a monumental step and grant the Food and Drug Administration the meaningful and long-overdue authority to regulate tobacco, which kills 440,000 people and costs our Nation $96.7 billion in health care bills every year," said John R. Seffrin, Ph.D. chief executive officer of the American Cancer Society and ACS CAN.

"The tobacco industry has demonstrated time and again that, if left to its own devices, it will falsely market its deadly products to our children, portraying this deadly addiction as glamorous and cool and luring 4,000 kids to try their first cigarette every day.

"The FDA has the scientific expertise necessary to effectively regulate tobacco products and the health-related claims made by the tobacco companies. As a science-based organization committed to decreasing the toll tobacco takes on our country, ACS CAN will continue to fight for American's right to know the contents of a product that when taken as directed, kills."

A joint statement from ACS CAN and its public health partners, the American Heart Association, American Lung Association and Campaign for Tobacco-Free Kids is also being released today.

STATEMENT OF AMERICAN CANCER SOCIETY CANCER ACTION NETWORK℠, AMERICAN HEART ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, AND THE AMERICAN LUNG ASSOCIATION

WASHINGTON, DC. (February 15, 2007)—Our public health organizations strongly support the bipartisan legislation introduced today in Congress to provide the U.S. Food and Drug Administration (FDA) with effective authority to regulate tobacco products. This legislation presents Congress with a truly historic opportunity to protect our children from tobacco addiction and save lives by addressing the Nation's No. 1 preventable cause of death. We applaud U.S. Senators Edward Kennedy (D-MA) and John Cornyn (R-TX) and U.S. Representatives Henry Waxman (D-CA) and Tom Davis (R-VA) for their leadership in producing strong bills that would end special protection for the tobacco industry and protect our children and the Nation's health instead.

We urge both the Senate and the House to quickly enact this long-overdue legislation into law and to reject all efforts to weaken it. Every day Congress fails to act, another 1,200 Americans die from tobacco use and more than 1,000 children become

new regular smokers. Each year in the United States, tobacco use kills more than 400,000 people and costs the Nation more than $96 billion in health care bills. The legislation introduced today would save countless lives and improve health for generations to come by reducing tobacco use and its devastating consequences, which include cancer, heart disease, chronic obstructive pulmonary disease (COPD) and diseases that affect virtually every organ in the human body.

Unbelievably, despite all the harm they cause, tobacco products are exempt from basic health and safety regulations that apply to other products, such as food, drugs, cosmetics and even dog food. The tobacco companies continue to take advantage of this lack of regulation to market their deadly and addictive products to our children, deceive consumers about the harm their products cause, make changes to their products without disclosing them (such as secretly increasing nicotine levels in cigarette smoke, as recent studies have shown), and resist any meaningful change to make their products less harmful. Until Congress grants the FDA authority over tobacco products, the tobacco companies will continue to get away with their harmful practices that addict children and make it difficult for smokers to quit.

The proposed legislation would grant the FDA the authority and resources to effectively regulate the manufacturing, marketing, labeling, distribution and sale of tobacco products. The FDA would have authority to:

- Restrict tobacco advertising and promotions, especially to children.
- Stop illegal sales of tobacco products to children.
- Ban candy-flavored cigarettes, which clearly are starter products for young new smokers.
- Require changes in tobacco products, such as the removal of harmful ingredients or the reduction of nicotine levels.
- Prohibit health claims about so-called "reduced risk" products that are not scientifically proven or that would discourage current tobacco users from quitting or encourage new users to start.
- Require tobacco companies to disclose the contents of tobacco products, changes to their products and research about the health effects of their products.
- Require larger and more informative health warnings on tobacco products.
- Prohibit terms such as "light," "mild" and "low-tar" that have mislead consumers into believing that certain cigarettes are safer than others.

These are common-sense measures that should have been enacted into law long ago. In 2004, the U.S. Senate voted 78–15 to pass FDA tobacco legislation as an amendment to a corporate tax bill, but it was killed in the conference committee.

Despite the tobacco companies' claims of reform, recent events underscore that their harmful practices continue today and show why the FDA tobacco legislation is so critical:

- On August 17, 2006, U.S. District Judge Gladys Kessler issued a final opinion in the U.S. Government's landmark tobacco lawsuit that found the major tobacco companies have violated civil racketeering laws and defrauded the American people by lying for decades about the health risks of smoking and their marketing to children. Judge Kessler also found that the tobacco companies' wrongdoing, including their marketing to children, continues today: "The evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity." However, Judge Kessler felt constrained by law in the remedies she could order and put the responsibility on Congress to take additional action: "In a democracy, it is the body elected by the people, namely Congress, that should step up to the plate and address national issues with such enormous economic, public health, commercial and social ramifications."
- Since Judge Kessler's ruling, two studies—one by the Massachusetts Department of Health and the other by the Harvard School of Public Health—have found that the tobacco companies have secretly and significantly increased the levels of nicotine in cigarette smoke since 1998. These findings indicate that as smoking rates decline, and more smokers try to quit, tobacco companies have sought to maintain addiction among smokers and to addict a new generation of replacement smokers. The tobacco companies can secretly increase nicotine levels because no Federal agency has regulatory authority over what they put in cigarettes.
- The tobacco companies have taken advantage of their unregulated status to introduce so-called "reduced risk" cigarettes with claims like "all of the taste . . . less of the toxins" and "reduced carcinogens, premium taste." However, no government agency currently has the authority to make sure these claims are scientifically proven and the products are marketed responsibly. These new products risk a repeat of the public health disaster caused by the marketing of "light" and "low-tar" cigarettes. Millions of smokers switched to these brands thinking they were safer or would help them quit only to find out decades later that neither is true and the to-

bacco companies knew this all along (as the National Cancer Institute concluded in a November 2001 report).

• The major cigarette companies have easily circumvented the minimal restrictions placed on their marketing by the 1998 State tobacco settlement and have since more than doubled their marketing to at least $15.1 billion a year—more than $41 billion every day, according to the Federal Trade Commission. Much of this marketing continues to appeal to children. A study published in the December 2006 issue of the peer-reviewed journal *Archives of Pediatrics and Adolescent Medicine* found that exposure to tobacco marketing and pro-tobacco depictions in movies, television and videos more than doubles the odds that children under 18 will become tobacco users.

AMERICAN DENTAL ASSOCIATION,
JANUARY 29, 2007.

Hon. TED KENNEDY,
Chairman,
Health, Education, Labor, and Pensions Committee,
SD–428 Dirksen Office Building,
Washington, DC. 20510.

DEAR MR. CHAIRMAN: We are writing to support your efforts to introduce and pass legislation to make Federal regulation of tobacco products an urgent priority for the first session of the 110th Congress. As associations and organizations involved in improving the Nation's oral health, we are committed to reducing and preventing oral cancer and other diseases that are related to tobacco use, especially spit tobacco. Approximately 30,000 new cases of oral cancer are diagnosed each year in the United States. According to the American Cancer Society, oral cancer occurs almost as frequently as leukemia and claims almost as many lives as melanoma cancer. When detected late, the overall 5-year survival rate is 50 percent.

Legislation providing the Food and Drug Administration (FDA) with the authority to regulate the manufacture, distribution, and sale of tobacco products is critically needed to protect the public health. FDA oversight is especially required to crack down on illegal sales of tobacco products to children and to restrict advertising and marketing that appeal to children. The tobacco industry is aggressively marketing as well a new generation of products with unproven claims that they are less harmful. This continued deception of consumers makes ever more urgent the need for FDA restrictions on advertising and marketing, especially to children.

Our organizations are especially supportive of legislative efforts to amend current law to strengthen and highlight spit tobacco warning labels. We were pleased to see that in previous legislation sponsored by you, you added a requirement for a new warning label to read, "Warning: This product is not a safe alternative to cigarettes." Our organizations are opposed to the use of smokeless tobacco as an alternative to cigarettes or as a smoking cessation technique. We encourage you to include this provision in your new legislation.

While virtually every other consumer product is regulated, tobacco products continue to be exempt from the most basic oversight. Tobacco companies are not required to test additives for safety, prevent misleading or inaccurate health claims, inform consumers what is in their products, or take any other action to make their products less harmful or addictive. In fact, besides containing 28 carcinogens, the level of addictive nicotine available in smokeless tobacco products is manipulated to increase the user's dependence on such products. Congress affords no other industry this degree of special protection, costing taxpayers billions of dollars each year to treat tobacco-caused disease through federally funded health programs including Medicare and Medicaid.

We applaud your efforts to address this situation legislatively and will work with you for its enactment.

Sincerely,

Academy of General Dentistry; Alabama Dental Association; Alliance of the American Dental Association; American Academy of Pediatric Dentistry; American Academy of Periodontology; American Association of Dental Editors; American Association of Dental Examiners; American Association for Dental Research; American Association of Oral and Maxillofacial Surgeons; American Association of Orthodontists; American Association of Public Health Dentistry; American College of Dentists; American College of Prosthodontists; American Dental Association; American Dental Education Association; American Student Dental Association; Arizona Dental Association; Arkansas State Dental Association; Association of State and Territorial Dental Directors; California Dental Association; Colorado Dental Association; Con-

necticut State Dental Association; District of Columbia Dental Society; Florida Dental Association; Georgia Dental Association; Hawaii Dental Association; Hispanic Dental Association; Illinois State Dental Society; Indiana Dental Association; International College of Dentists, USA Section; Iowa Dental Association; Kansas Dental Association; Kentucky Dental Association; Loma Linda University School of Dentistry; Loma Linda University School of Public Health; Louisiana Dental Association; Maine Dental Association; Massachusetts Dental Society; Michigan Dental Association; Minnesota Dental Association; Mississippi Dental Association; Missouri Dental Association; Montana Dental Association; National Dental Association; Nevada Dental Association; New Hampshire Dental Society; New Jersey Dental Association; New Mexico Dental Association; North Carolina Dental Society; Ohio Dental Association; Oklahoma Dental Association; Oregon Dental Association; Pennsylvania Dental Association; Pierre Fauchard Academy; Rhode Island Dental Association; School of Nursing at Loma Linda University; South Dakota Dental Association; Tennessee Dental Association; Texas Dental Association; Utah Dental Association; Virginia Dental Association; Washington State Dental Association; West Virginia Dental Association; Wisconsin Dental Association; Wyoming Dental Association.

PARTNERS FOR EFFECTIVE TOBACCO POLICY,
FEBRUARY 15, 2007.

DEAR SENATOR/REPRESENTATIVE: As members of Partners for Effective Tobacco Policy (PARTNERS), we are writing to strongly urge you to support the Kennedy-Cornyn and Waxman-Davis bills that would regulate tobacco products. PARTNERS is a coalition of more than 60 national organizations committed to reducing and preventing the staggering death and disease caused by tobacco use. Tobacco use kills more than 400,000 Americans annually and is the leading cause of preventable death in the United States.

Congress has failed to complete action on the strong legislation to address this epidemic that has been introduced in the last two Congresses. Moreover, there is overwhelming support of Americans for regulation of tobacco products by the Federal Food and Drug Administration (FDA). This support crosses all party, ideological, regional, State, income and educational lines—even a majority of smokers support FDA regulation of tobacco products.

Reflecting that support, FDA legislation in the last Congress enjoyed a broad, bipartisan group of 122 cosponsors in the House of Representatives and 28 in the Senate. It has the robust support of every major national health organization and of a broad cross-section of American faith leaders and organizations. In 2004, this legislation passed the Senate twice—once overwhelmingly; the second time by unanimous consent—but year, after year, it has languished in the House of Representatives.

Legislation providing FDA the authority to regulate the manufacture, distribution, and sale of tobacco products is critically needed to protect the public health. FDA oversight is especially required to crack down on illegal sales of tobacco products to children and to restrict advertising and marketing that appeal to children. The tobacco industry is aggressively marketing as well a new generation of products with unproven claims that they are less harmful. This continued deception of consumers makes ever more urgent the need for FDA restrictions on advertising and marketing, especially to children.

While virtually every other consumer product is regulated, tobacco products continue to be exempt from the most basic oversight. Tobacco companies are not required to test additives for safety, prevent misleading or inaccurate health claims, inform consumers what is in their products, or take any other action to make their products less harmful or addictive. Congress affords no other industry this degree of special protection, costing taxpayers billions of dollars each year to treat tobacco-caused disease through federally funded health programs including Medicare and Medicaid.

Now that strong, effective FDA legislation supported by the public health community has been reintroduced, we ask that you cosponsor it and work for its speedy enactment into law during the first session of the new Congress.

Sincerely,

American Cancer Society; American Heart Association; American Lung Association; Campaign for Tobacco-Free Kids; AARP; Alliance of the American Dental Association; American Academy of Child and Adolescent Psychiatry; American Academy of Family Physicians; American Academy of Nurse Practitioners; American Academy of Pediatrics; American Association for Respiratory Care; American College of Cardiology; American College of Chest Physicians; American College of Clinical Oncology;

American College of Obstetricians and Gynecologists; American College of Occupational and Environmental Medicine; American College of Physicians; American College of Preventative Medicine; American Dental Association; American Dental Hygienists' Association; American Medical Association; American Psychological Association; American Public Health Association; American Society of Addiction Medicine; American Society of Clinical Oncology; American Thoracic Society; Association of Maternal and Child Health Programs; Children's Defense Fund; Community Anti-Drug Coalitions of America; General Board of Church & Society of the United Methodist Church; Hadassah—the Women's Zionist Organization of America; Interreligious Coalition on Smoking or Health; March of Dimes; National African American Tobacco Prevention Network; National Association of County & City Health Officials; National Association of Local Boards of Health; National Education Association; National Hispanic Medical Association; National Latino Council on Alcohol and Tobacco Prevention; National Partnership for Women & Families; National Women's Law Center; Oncology Nursing Society; Oral Health America; Partnership for Prevention; Seventh-day Adventist Church; Society for Public Health Education; Trust for America's Health; United Church of Christ.

AMERICAN HEART ASSOCIATION AND
AMERICAN STROKE ASSOCIATION,
FEBRUARY 26, 2007.

DEAR SENATOR KENNEDY: The American Heart Association, on behalf of its more than 22 million volunteers and supporters, is pleased to endorse the provisions of the Family Smoking Prevention and Tobacco Control Act of 2007. If enacted into law, this legislation will finally ensure that the tobacco industry is properly regulated, that Americans are better informed about the dangers of smoking, and that our children are appropriately protected from this vigorously marketed product.

Smoking is a major cause of cardiovascular disease and stroke—the Nation's No. 1 and No. 3 killers. An estimated 180,000 Americans die each year from cardiovascular diseases caused by smoking. And it's not just smokers who are at risk: an estimated 35,000 people die from coronary heart disease every year caused by breathing secondhand smoke.

When the chemical cocktail created from smoking tobacco or breathing secondhand smoke hits the bloodstream, it can damage arteries throughout the body: the heart, brain, and other major blood vessels such as in the legs. Clots in arteries are more likely to form as a result, causing heart attack or stroke, and the capacity for routine physical activities markedly declines. Smoking also lowers the level of HDL or "good" cholesterol, raises heart rate and blood pressure, and replaces oxygen in the blood with carbon monoxide. In short, smoking wreaks havoc on the cardiovascular system, causing preventable disability and death for many Americans.

The health risks associated with smoking tobacco are undisputed. It is therefore alarming that tobacco products remain totally unregulated in America today. It is vital that Congress pass this legislation of the tobacco industry and its deadly products. We thank you for your leadership on this important health issue and look forward to working with you to advance this important legislation.

Very truly yours,

RAYMOND J. GIBBONS, M.D., FAHA,
PRESIDENT.

ANDREW B. BUROKER, ESQ.,
CHAIRMAN.

AMERICAN OSTEOPATHIC ASSOCIATION,
FEBRUARY 16, 2007.

Hon. EDWARD KENNEDY,
U.S. Senate,
317 Russell Senate Office Building,
Washington, DC. 20510.

Hon. JOHN CORNYN,
U.S. Senate,
517 Hart Senate Office Building,
Washington, DC. 20510.

DEAR SENATORS KENNEDY AND CORNYN: As President of the American Osteopathic Association (AOA), I write to express our strong support for the "Family Smoking Prevention and Tobacco Control Act" (S. 625). The AOA, which represents

the Nation's 59,000 osteopathic physicians, applauds your efforts to improve the health and wellness of your fellow citizens, especially children, by reducing their exposure to the dangers of tobacco products. The AOA advocates greater oversight of the tobacco industry and a more focused effort on preventing children from starting smoking in their formative years.

In 1990, the AOA House of Delegates adopted a policy that states,

> "The AOA strongly recommends that all Federal and State health agencies continue to take positive action to discourage the American public from using cigarettes and other tobacco products."

This policy was revised and reaffirmed in 2002. Additionally, the AOA has adopted and ratified policies that "endorse a ban on all advertising of tobacco."

By granting oversight authority of tobacco to the Food and Drug Administration (FDA), your legislation proposes important steps towards reducing the number of people who smoke or use other tobacco products. Additionally, if enacted, your legislation will contribute to a reduction in the number of children and teenagers who smoke by limiting their access and exposure to tobacco products. Ultimately, this will lead to a healthier population, a decrease in smoking related illnesses and diseases, and lower health care costs.

This important legislation has fallen short in previous Congresses. We are hopeful that it will receive a fair evaluation and once again be approved by the Senate during the 110th Congress. We look forward to seeing it enacted into law. Please do not hesitate to call upon the AOA or our members for assistance with this important issue. We stand ready to help. For additional information, please contact the AOA's Department of Government Relations at (202) 414-0140.

Sincerely,

JOHN A. STROSNIDER, D.O.,
PRESIDENT.

FAITH UNITED AGAINST TOBACCO,
FEBRUARY 26, 2007.

DEAR SENATOR/REPRESENTATIVE: We are writing to you as leaders of Faith United Against Tobacco, a faith coalition comprised of clergy and lay members throughout the country, to strongly urge you to support S. 625 and H.R. 1108, the Kennedy-Cornyn and Waxman-Davis bills that would authorize the U.S. Food and Drug Administration (FDA) to regulate tobacco. We in the faith community believe that our Nation's leaders, and particularly our Members of Congress, have a moral obligation to do all they can to protect Americans, particularly children, from tobacco addiction and disease. We are united on this issue.

Granting FDA authority to regulate tobacco products would prevent tobacco companies from adding even more deadly and addictive ingredients, prohibit candy-flavored cigarettes, prevent tobacco sales to underage children and limit advertising and promotion of tobacco products that lure children into a deadly habit. We find it incredible that the FDA can ensure the safety of everyday items like macaroni and cheese, but has no authority over tobacco, a product that kills over 400,000 Americans every year. No one wants too much government regulation, but FDA authority to regulate tobacco products will simply treat tobacco manufacturers like the manufacturers of other products—it will level the playing field and assure the protection of consumers and our children.

Over the last few years, Faith United Against Tobacco has been working with the public health community to draw attention to the need for FDA oversight of tobacco products. We have spoken out on this issue because we have spent too much time burying mothers, fathers, sisters and brothers who die because they became addicted to tobacco products when they were young. We know that the tobacco companies continue to spend billions of dollars marketing their deadly products to children and far too many high school students smoke.

Moreover, the evidence about tobacco industry's misdeeds and the harm caused by this unregulated product keeps mounting. On August 17, 2006, Federal Judge Gladys Kessler found the major tobacco companies to be racketeers who have lied—and continue to lie—to the American people about the health risks of their products and their marketing to children. Then, on the heels of this court decision, a report by the Massachusetts Department of Public Health found that tobacco companies have secretly and significantly increased the levels of nicotine in cigarette smoke between 1998 and 2004.

Now that strong, effective FDA legislation, S. 625 and H.R. 1108, has been reintroduced, we ask that you cosponsor it and work for its speedy enactment into law dur-

ing the first session of the new Congress It is time to protect our children and families.

If you have any questions or would like to reply to this request, please contact Vincent DeMarco, Coordinator for Faith United Against Tobacco at 410-591-9162 or *demarco@mdinitiative.org*.

James Winkler, General Secretary, General Board of Church and Society, United Methodist Church; Bishop Henry Williamson, Christian Methodist Episcopal Church; Dr. DeWitt Williams, Director, Health Ministries, North American Division, Seventh-day Adventists; Julie Taylor, Executive Secretary for Children, Youth and Family Advocacy, Women's Division, GBGM, United Methodist Church; Dr. Sayyid M. Syeed, National Director, Islamic Society of North America; Reverend William G. Sinkford, President, Unitarian Universalist Association of Congregations; Manmohan Singh, General Secretary, World Sikh Council—America Region; Rabbi David Saperstein, Director and Counsel Religious Action Center of Reform Judaism; Reverend Deborah L. Patterson, Executive Director, International Parish Nurse Resource Center; Dr. Walter L. Parrish, II, Executive Minister, American Baptist Churches of the South; Rev. Dr. A Roy Medley, General Secretary, American Baptist Churches USA; Peggy Matteson, President, Health Ministries Association; Dr. Richard D. Land, President, Ethics & Religious Liberty Commission, Southern Baptist Convention; Phil Jones, Director, Brethren Witness/Washington Office; Rev. Elenora Giddings Ivory, Director, Washington Office, Presbyterian Church (USA); Andrew Genszler, Director for Domestic Policy, Evangelical Lutheran Church in America; Matthew Ellis, Executive Director, National Episcopal Health Ministries; Reverend Bob Edgar, General Secretary, National Council of Churches of Christ in the USA; Reverend Ruben Cruz, Church Finance Council, Christian Church (Disciples of Christ) Reverend Michael H. Crosby, OFMCap., Coordinator Tobacco Program, Interfaith Center on Corporate Responsibility; Patricia G. Burkhardt, Legislative Officer, Church Women United; Barbara Baylor, M.P.H., Minister for Health and Wellness, United Church of Christ; Rev. David Adams, General Secretary, General Commission on United Methodist Men.

AMERICAN ACADEMY OF PEDIATRICS,
MARCH 6, 2007.

Hon. TED KENNEDY,
317 Russell Office Building,
Washington, DC. 20510.

Hon. JOHN CORNYN,
517 Hart Office Building,
Washington, DC. 20510.

DEAR SENATORS KENNEDY AND CORNYN: On behalf of the 60,000 pediatricians, pediatric medical subspecialists and pediatric surgical specialists of the American Academy of Pediatrics, I would like to express our support for H.R. 1108, legislation to protect the public health by providing the Food and Drug Administration (FDA) with certain authority to regulate tobacco products. This legislation is a good first step at curbing the devastating effects tobacco has on adolescents and young adults.

It is estimated that more than 3 million U.S. adolescents are cigarette smokers and more than 2,000 children under the age of 18 start smoking each day. If current tobacco use patterns persist, an estimated 6.4 million children will die prematurely from a smoking-related disease. Smoking and exposure to secondhand smoke among pregnant women cause low-birth weight babies, pre-term delivery, perinatal deaths and sudden infant death syndrome. Other effects may include childhood cancer, childhood leukemia, childhood lymphomas and childhood brain tumors. Well over 30,000 births per year in the United States are affected by one or more of these problems.

H.R. 1108 will lower tobacco use by restricting sales of tobacco products to children, regulating tobacco marketing, prohibiting unsubstantiated health claims about tobacco products, requiring disclosure of harmful ingredients in tobacco products, and mandating larger and more informative health warnings. By giving FDA this new authority to regulate tobacco products, we can lower tobacco use by our adolescents and young adults and reduce the life-threatening risks tobacco poses to our Nation's youth.

We look forward to working with you to move this legislation through Congress.

Sincerely,

JAY E. BERKELHAMER, M.D., FAAP,
PRESIDENT.

UNIVERSITY OF CALIFORNIA SAN FRANCISCO (UCSF),
MARCH 12, 2007.

Hon. EDWARD M. KENNEDY,
Chairman,
Committee on Health, Education, Labor, and Pensions,
317 Russell Senate Building,
Washington, DC. 20510.

DEAR SENATOR KENNEDY: I am writing to compliment you on the introduction of S. 625, the "Family Smoking Prevention and Tobacco Control Act." This legislation marks a critical point in our Nation's long effort to reduce the damage caused by tobacco and to protect our children and public health.

It has been 13 years since the Food and Drug Administration (FDA) announced its investigation into whether the evidences warranted FDA's assertion of jurisdiction over tobacco. That investigation was followed by regulations that would have addressed the serious problem of youth tobacco use. Unfortunately, those regulations never went into effect.

During the past 13 years, more than 5.2 million Americans have died from tobacco-related diseases and over 5 million kids became regular, daily smokers. The need for FDA jurisdiction over tobacco has never been stronger. This legislation as introduced would address the goals that the Food and Drug Administration sought to achieve during the time I was Commissioner, including reinstating the 1996 FDA rule, and would make a major contribution to the effort to reduce the number of people who die from using tobacco.

This is a strong bill and would significantly advance the public health.

Sincerely yours,

DAVID A. KESSLER, M.D.

PHILIP MORRIS USA,
FEBRUARY 26, 2007.

Hon. EDWARD M. KENNEDY,
U.S. Senate,
Washington, DC. 20510.

Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC. 20510.

DEAR CHAIRMAN KENNEDY AND SENATOR ENZI: Attached hereto is written testimony that I respectfully request be made part of the record of the hearing entitled "The Need for FDA Regulation of Tobacco Products" scheduled for February 27, 2007 before the Senate Committee on Health, Education, Labor, and Pensions.

As you know, Philip Morris USA strongly supports enactment of S. 625, The Family Smoking Prevention and Tobacco Control Act. Thank you for your consideration of these views.

cc. Senator Christopher Dodd, Senator Tom Harkin, Senator Barbara A. Mikulski, Senator Jeff Bingaman, Senator Patty Murray, Senator Jack Reed, Senator Hillary Rodham Clinton, Senator Barack Obama, Senator Bernard Sanders, Senator Sherrod Brown, Senator Judd Gregg, Senator Lamar Alexander, Senator Richard Burr, Senator Johnny Isakson, Senator Lisa Murkowski, Senator Orrin Hatch, Senator Pat Roberts, Senator Wayne Allard, and Senator Tom Coburn.

PREPARED STATEMENT OF MIKE SZYMANCZYK, CHAIRMAN AND CEO, PHILIP MORRIS USA, RICHMOND, VA

INTRODUCTION

On behalf of the nearly 12,000 employees of PM USA I am very pleased to submit these remarks, and to express our strong support for S. 625, legislation that would give the Food and Drug Administration (FDA) authority to regulate tobacco products. More than 4 years after we announced our full support for FDA regulation, Philip Morris USA remains committed to passage of comprehensive regulation of tobacco products. S. 625 can serve to create a uniform set of Federal standards for the manufacture and marketing of tobacco products. In addition, regulations promulgated pursuant to this legislation should provide clear guidelines and oversight of products that could potentially reduce the harm caused by tobacco use.

The Family Smoking Prevention and Tobacco Control Act is the result of many difficult choices and compromises by all those who have been involved in this process over the last several years. Nevertheless, the bill clearly provides the framework

for comprehensive FDA regulatory authority over tobacco products. We commend you for moving forward with this bipartisan legislation that provides important policy solutions to many of the complex issues involving tobacco products.

We applaud Chairman Kennedy and Senator Cornyn for the leadership they have shown on this issue. Likewise, we appreciate the leadership shown by Congressman Waxman and Congressman Davis in introducing identical legislation in the House of Representatives. We look forward to working with you and your colleagues in the House to enact this legislation that is intended to benefit adult consumers by reducing the harm caused by tobacco consumption, and to establish clear rules that will be applied to, and hopefully enforced uniformly, throughout the tobacco industry. Uniform enforcement of such rules by the FDA will be critical to reducing the harm for adult tobacco product consumers.

HARM REDUCTION—FIRST AND FOREMOST

We believe that adult consumers should be and will be a primary beneficiary of FDA regulation. S. 625 will serve to accomplish this goal by providing a new framework within which manufacturers can re-focus their efforts in reducing the harm of their products. As in many other industries, the companies that do the best job of exceeding their consumers' expectations, while meeting regulatory standards, will both benefit their consumers and achieve the best business results.

In spite of the controversy that continues to surround our industry and our company, we at Philip Morris USA spend most of our time running our factories, working with our suppliers, making our payroll and paying our taxes and continuing to look for ways to reduce the harm caused by smoking. We believe that comprehensive regulation of the tobacco industry makes sense for a number of reasons.

One of our highest priorities at PM USA is the development of cigarettes and other products that have the potential to reduce the harm caused by smoking. Of the thousands of compounds present in tobacco smoke, the public health community has identified a number of them that are harmful or potentially harmful to smokers. Accordingly, our basic strategy is to reduce smokers' exposure to as many of these compounds as we can by developing products that will also provide continued enjoyment to our adult consumers. It will take some time, but if we are successful in finding ways of both reducing potentially harmful compounds and reducing smokers' actual exposure to them under real-world conditions, we believe that the FDA under this legislation will be in a position to evaluate whether our product development efforts are actually reducing the risk of tobacco-related diseases among current smokers. Our goal, which we believe would ultimately provide both societal and shareholder value, is to design the best products we can, and then, ideally under the full regulatory oversight of the FDA, make them available to adult smokers who do not quit. It seems clear to us that we will not be able to make progress in this area unless two critical conditions are met: first, that manufacturers such as ourselves develop successfully and make available products that reduce smokers' exposure to harmful compounds compared to conventional cigarettes, and second, that current smokers are given a reason—through communication of truthful, nonmisleading information that avoids unintended consequences—to switch to these products. For people who continue to smoke, we believe that this is the best way to meaningfully reduce the overall harm caused by smoking.

We have extensive external and internal research programs that are focused on advancing our knowledge about tobacco smoke to support our efforts to develop new product designs. This includes work involving the compounds of smoke and smokers' actual exposure to them. We are continuing to devote substantial research and development efforts to develop and launch products that significantly reduce smokers' exposure to compounds that have been identified by public health authorities as harmful or potentially harmful.

We believe these product technologies show promise for the future, and that the FDA should be empowered as quickly as possible by enactment of this legislation to evaluate products and their potential for reducing the risk of contracting smoking-related diseases.

We respectfully urge our future regulators at the FDA to keep in mind that innovation in developing new products is crucial to the ultimate success of this legislation. In order to have any real impact, reduced exposure products must be acceptable to adult smokers. We see little benefit to consumers or society if harm reduction is not pursued in the context of cigarettes that adult consumers will enjoy smoking. As the 1998 Canadian Experts' Committee on this subject concluded, "[i]f smokers would not buy these products, product modification initiatives would fail."

Importantly, once the FDA concludes as a matter of science that a new product has the potential to offer reduced exposure or reduced risk, S. 625 grants the agency

an essential role in approving and overseeing any claims, explicit or implied, made about the product by the manufacturer regarding exposure or risk-reduction. Crafting appropriate claims regarding these products requires great care and attention. We are mindful of the critical need for manufacturers to work closely with the FDA on consumer messages.

Once again, as with determinations regarding the scientific issues of potential exposure and risk reduction, we believe S. 625 correctly charges FDA with deciding what communications to consumers are appropriate on this subject. On the one hand, in terms of public health, future FDA regulations should ensure that consumers are not mistakenly led to believe that a particular tobacco product may be an acceptable alternative to quitting. On the other hand, we do not believe future regulations should be utilized as a tool to suppress legitimate, accurate and objective information about product developments that individuals may find beneficial or important. The key here is for all FDA-approved communications to consumers to be truthful and not misleading, all within the context that there is no safe cigarette.

We are keenly aware that some members of the public health community are opposed to the very concept of developing and offering "reduced exposure" or "reduced risk" tobacco products. They are concerned that the availability of such products might discourage smokers from quitting or encourage people to start smoking. These advocates appear to believe that the only acceptable message for the government to communicate, irrespective of potential alternatives, is a directive not to consume tobacco products at all. Philip Morris USA strongly believes if products that could ultimately reduce the harm caused by smoking are developed, it would be wrong to deny adult smokers access to information about the potential benefits of such products. The "modified risk tobacco products" section of S. 625 sets out rigorous requirements that must be met before manufacturers could communicate about these types of products. We agree fully with the need for such rigorous requirements while urging future FDA regulators to take note of the Institute of Medicine admonition that "[the] regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, so long as steps are taken to ensure that consumers are not misled. . . ."

REDUCING YOUTH SMOKING—A CRITICAL PRIORITY

In 1998 PM USA created a Youth Smoking Prevention department with the objective of helping to prevent kids from smoking cigarettes. We are committed to this effort because we firmly believe that kids should not smoke.

S. 625 aims to help reduce youth smoking. Among other things, it would prohibit self-service transactions (except in adult-only facilities), establish a national minimum age of 18, require age verification for anyone younger than 27 years of age, and prohibit the sale of unpackaged cigarettes (so-called "loosies"). We commend the cosponsors of this legislation for taking these steps. We believe that by working together, we can all contribute to continuing the reduction in youth smoking rates that has occurred over the past decade.

A number of other provisions in the legislation deserve further discussion and comment.

SEC. 901—FDA AUTHORITY OVER TOBACCO PRODUCTS

S. 625 creates a new chapter within the Food, Drug, and Cosmetic Act to regulate tobacco products. Importantly, tobacco products will not be regulated as a drug or device. Moreover, the bill explicitly states that one of "the purposes of this Act" will be "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers." The bill limits the scope of FDA's authority to manufacturers of tobacco products, making clear that FDA does not have the authority to regulate tobacco growers. FDA will *not* be on the farm.

SEC. 903—MISBRANDED TOBACCO PRODUCTS

Pursuant to the legislation, tobacco products will be deemed misbranded if their label is false or misleading or they are not correctly labeled. Of real significance to America's tobacco growers and their families and communities, a tobacco product will be misbranded if the label does not contain an accurate statement of the percentage of the tobacco used in the product that is domestically grown and the percentage that is foreign grown.

SEC. 904—SUBMISSION OF HEALTH INFORMATION

The bill requires, within 6 months of passage, submission to the Secretary of documents any information concerning ingredients, compounds, paper, filter and other components of tobacco products as well as content, delivery and form of nicotine. Philip Morris USA fully supports this requirement with appropriate safeguards to protect our trade secrets, which this bill provides. We think the FDA should be able to give smokers confidence that the ingredients added to cigarettes do not increase the inherent health risks of smoking, including increasing the addictiveness. Further, we have no objection to disclosing the results of our own ingredients testing to the FDA so it can assess every ingredient we use. The same is true for other information that may be requested by the Secretary under this section including information related to research activities and findings, scientific information on reduced risk products and technology and marketing research.

SEC. 905—ANNUAL REGISTRATION

S. 625 requires the registration of every entity that owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of tobacco products. While these same requirements extend to foreign manufacturers of tobacco products, it will be critical for FDA to ensure the evenhanded application of the legislation to these foreign manufacturers, including through appropriate inspections.

SEC. 906—GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS

The section allows for regulations requiring good manufacturing practices (GMPs) with input from the public and interested parties and provides for a 3-year delay for compliance to ensure that manufacturers have ample opportunity to comply.

SEC. 907—PRODUCT STANDARDS

S. 625 grants the Secretary the authority to adopt performance standards for tobacco products if "appropriate for the protection of the public health." Although broad, the delegation of authority to the FDA to issue product standards is fully supported by PM USA. It will allow FDA to reduce harm by imposing mandatory design changes on tobacco products. These standards could include provisions to regulate nicotine yields and other constituents and components of cigarettes. It also will ban the sale of candy or fruit-flavored cigarettes.

We believe future FDA regulators should be very cautious and avoid doing what no one should want: to impose changes that are so radical that tobacco products are effectively banned, or consumers are driven away from the legitimate market toward illicit, completely unregulated products. In fact, the legislation explicitly directs FDA to consider whether a standard would create a significant new demand for contraband, including counterfeit, products, in determining what would, and would not, be "appropriate to protect public health." We urge future FDA regulators to fully consider the warning voiced by the FDA in the 1996 tobacco rule regarding this subject:

> Black market and smuggling would develop to supply smokers with these products . . . [which] would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.

In addition, a product standard may not have the effect of "banning all cigarettes" or reducing nicotine yields "to zero"; this power is explicitly reserved to Congress.

A word about nicotine is appropriate at this point. A recent Harvard University report asserts that Philip Morris USA and other tobacco companies have deliberately increased the amount of nicotine that smokers get from cigarettes over the past 7 years. The conclusion from the report, that there was a trend of more and more nicotine in cigarettes between 1997 and 2005, and that the cigarettes were designed to yield greater amounts year after year, is not true for Philip Morris USA. We have not changed the design of our cigarettes with the intention to increase nicotine yields in order to make the product more addictive. The data we submitted to Massachusetts shows that nicotine yields in Marlboro cigarettes were the same in 1997 as in 2006.

While current skepticism may stand in the way of arriving at a consensus on these data, we believe that enacting S. 625 will create a framework to address any public concerns.

SEC. 911—MODIFIED RISK TOBACCO PRODUCTS

Much of my earlier testimony is focused on the importance of harm reduction. These provisions are essential to that goal and must be implemented by FDA in a careful, thoughtful manner in order to be successful in achieving everyone's goal of reducing the harm caused by tobacco products. In its report, the IOM committee made two important, fundamental recommendations: (i) determinations about what is, and what is not, a reduced-risk or reduced-exposure product should be made by the government on a purely scientific basis and (ii) any claims made about such products should be strictly regulated to ensure that consumers are not misled. We believe S. 625 gives FDA the necessary level of authority and discretion to achieve both.

Significantly, the bill creates a special rule for certain products where the label, labeling or advertising contains an explicit or implied statement that the product contains a reduced level of a substance, or presents a reduced exposure to a substance if the Secretary makes such a finding based on a number of criteria. We believe the bill appropriately and reasonably empowers FDA to approve applications for products that make exposure-reduction claims for 5-year periods, utilizing criteria that appear to have been substantially derived from the Institute of Medicine Report.

SEC. 920—USER FEES

S. 625 requires the Secretary to require tobacco product manufacturers and importers to pay for providing, equipping and maintaining adequate service for regulating tobacco products. Philip Morris USA believes the collection of such user fees is reasonable, but again strict enforcement by the agency will be essential.

SEC. 102—REPROMULGATION OF FDA'S 1996 FINAL RULE

Within 30 days of enactment of S. 625 the Secretary is required to publish a final rule on the advertising of, and access to, tobacco products, which shall become effective no later than 1 year after the date of enactment. The rule will be identical in its provisions to the advertising and access regulations promulgated by the FDA in 1996. Prior to making any amendments to the rule, the Secretary would be required to publish a proposed rule.

In addition, under section 906(d) of the legislation, FDA would have authority to impose additional restrictions on the sale, distribution, advertising and promotion of tobacco products if the Secretary determines that the regulation would protect the public health. The bill specifies that marketing and advertising restrictions must be consistent with the first amendment.

The bill explicitly provides that FDA will not be permitted to prohibit the sale of any tobacco product to adults age 18 and over. Further, it does not permit the Secretary to require that tobacco products be available only by prescription.

The timing of these requirements raises a broader point. At the same time that we will be making the transition into the new regulatory environment, we understand that FDA will also be transitioning into its new role, including putting the necessary regulatory structures and resources into place.

As such, it will be critically important for FDA and the industry to work closely together in order to provide for a smooth transitional period, such as was accomplished with the State Attorneys General with respect to the transition into the MSA and with other government agencies that have been granted new or additional authority over tobacco products. For example, it will be important to work out reasonable timelines for the substantial new requirements that are contemplated by the legislation.

SEC. 201—CIGARETTE LABEL AND ADVERTISING WARNINGS

This section of S. 625 specifies nine new warning labels required to appear on cigarette packages and advertisements. The warnings must comprise at least the top 30-percent of the front and rear panels of the package, and at least 20-percent of the related advertisements. It will be unlawful for a manufacturer, importer, distributor or retailer to advertise any cigarette unless its advertising bears one of the required warning labels. Philip Morris USA fully supports these provisions.

CONCLUSION

I will conclude by reiterating a point made earlier: a comprehensive national tobacco policy should bring more, not less, beneficial competition to the U.S. tobacco industry. Viewed another way, none of the measures that would be advanced by enactment of S. 625 would give any one tobacco company a commercial advantage, not-

withstanding the assertions of some manufacturers. Tobacco companies know very well that the first amendment of the Constitution guarantees that the FDA could not impose a total ban on tobacco product advertising, which effectively ensures the continuation of vigorous competition in the market place.

The most significant restrictions placed on the tobacco industry in recent history were those contained in the Master Settlement Agreement ("MSA"). Those changes, which restrict billboard and transit advertising among other things, did not lock in any single company's market share. In fact, since the adoption of the MSA, there are examples of both new brands and pre-existing ones that have increased their market share.

History and the facts simply do not support the contention that the additional access, advertising or marketing restrictions contained in S. 625 will lessen competition, create a monopoly or lock in market share. Indeed, we believe that, with clear guidelines and oversight, there should be an opportunity for increased competition as both new and existing manufacturers work to develop and commercialize products that could potentially reduce the harm caused by tobacco use.

Thank you for allowing us to submit these views to the committee. Thank you for your leadership and commitment to this issue. Please know that we will work tirelessly to secure enactment of S. 625, which represents a truly historic opportunity to establish a comprehensive and coherent national tobacco policy.

STATEMENTS AND LETTER OF OPPOSITION

PREPARED STATEMENT OF HENRY O. ARMOUR, PRESIDENT AND CEO, NATIONAL ASSOCIATION OF CONVENIENCE STORES (NACS), ALEXANDRIA, VA

Good morning, Mr. Chairman and members of the committee. My name is Hank Armour and I am President and CEO of the National Association of Convenience Stores (NACS). NACS is an international trade association representing the convenience store industry. The industry as a whole includes about 140,000 stores in the United States, sold 143.5 billion gallons of motor fuel in 2005, and employs about 1.5 million workers across the Nation. It is truly an industry of small businesses; 60 percent of convenience stores are owned by one-store operators.

I know the industry not only from my time running the trade association, but prior to my tenure at NACS I owned a convenience store chain that operated primarily in the State of Washington. This topic is of great interest to our industry because more than one-third of in-store sales at convenience stores are tobacco products. Customers who come into our stores to buy tobacco also purchase other items that often have higher profit margins. Given that the annual per store profits in the industry average less than $40,000.00, it is not an exaggeration to say that if convenience stores are put at a competitive disadvantage in the sale of tobacco, it would threaten many of these businesses.

Before I relay the concerns we have with the way that the current legislation grants the Food and Drug Administration (FDA) the authority to regulate tobacco, I want to make our interest in this issue clear. NACS is not taking a position regarding whether or how the manufacturing of tobacco should be regulated. Our industry sells legal products and goes to great lengths to sell them responsibly. We spend millions of dollars each year in our industry on training and compliance programs, including efforts like the *We Card* program, internal stings to gauge our compliance, and the like. Selling tobacco products to minors is both against the law and bad for business. We are members of the communities where we have stores. We care about these communities and we make a large financial investment in trying to make sure we sell tobacco products responsibly.

Our concerns are limited to the parts of the legislation before the committee that directly impact the retail sale of tobacco products. It is, in fact, our view that these portions of the bill can be made more equitable and more effective. With that in mind, we have three main concerns about this legislation. First, the legislation does not create incentives for the behavior it is trying to promote or put responsibilities on the individuals who are best able to affect these behaviors—all of this undermines the effectiveness of the proposal. Second, the legislation federalizes an area of regulation where the States have already demonstrated effectiveness and is already guided by Federal performance standards. We believe this regime will be less effective than the current system. Third, the legislation treats different types of retailers inequitably, which will both create competitive imbalances and allow for loopholes that undermine the purposes of the bill. I will address each of these issues in turn.

LEGISLATION SHOULD PLACE INCENTIVES AND RESPONSIBILITIES IN THE RIGHT PLACES

It is a fundamental, equitable precept that an entity should be held accountable for behavior and acts which it can control and should not be penalized for actions over which it cannot exert effective control. NACS believes that everyone involved in the distribution of tobacco should do everything that can be reasonably expected of them to avoid the unlawful transfer of these products to minors. However, it is irrational and counterproductive to penalize any entity for things it cannot control.

The current legislation makes retailers responsible for things they cannot control. Socially responsible retailers can train employees regarding the laws prohibiting sales to minors, have a policy in place requiring compliance with the law, and take action if an employee does not follow the policy. Legislation ought to recognize these limits on the ability of retailers to prevent violations and ought to have incentives for retailers to take these steps and use best compliance practices. The current legislation does not do that. Instead, it makes retailers liable for every violation no matter how extensive the efforts they take to prevent violations. Legislation ought to provide socially responsible retailers with a "safe harbor" so that a violation would not cause a retailer to lose its right to sell tobacco if it has taken the steps it can to prevent a violation. The defense in the current legislation is inadequate because it is limited to situations in which the clerk relies upon a fake identification card and does not cover other errors made by the clerk (intentional or not), nor does it apply to situations when a minor uses a valid identification that belongs to someone else. The language in the legislation also requires the retailer to prove good faith on the part of the clerk, which introduces a complex and difficult-to-prove legal standard (particularly in light of the adjudication process).

The legislation also falls short by not having potential penalties for all of the individuals involved in an illegal transaction. A clerk who has been trained, for example, should face a penalty if he or she makes an illegal sale. The only defense for a clerk who has been trained should be that the clerk relied upon an identification which appeared to be valid.

Any legislation should also address the minor who makes an illegal purchase or illegally possesses tobacco products. Minors need to face a potential penalty for inducing an illegal transaction or they will have no incentive to stop them from trying to buy tobacco at every retailer who carries it—until they are successful. Some States have passed penalties for minors making illegal purchases and these laws have been quite successful. We do this for alcohol and other products. It makes no sense to allow teenagers to try to induce violations of law with impunity and face no countervailing incentive.

Without such a sanction this legislation will not be as effective in meeting its stated goals as it should be. Some socially responsible retailers may literally lose their businesses even if they have made substantial efforts to comply with the law—while teenagers will be able to smoke in public and attempt to buy cigarettes in the presence of FDA officials without any fear of sanction.

Similarly, the bill's provisions relating to labeling and advertising violate the principle of holding people accountable for only those things over which they can effectively exert control. Specifically, these provisions would hold retailers strictly liable for labeling violations, even if the retailer had nothing to do with the label.

In sum, the current system of retailer regulation in the legislation looks more closely calculated to move gradually and surreptitiously toward a system of prohibition of the product than to reducing consumption of tobacco products by minors.

STATE REGULATION MAKES SENSE AND WILL BE MORE EFFECTIVE

States have traditionally regulated the sale of tobacco products to make sure those products are not sold to people under the legal age. The same is true for alcoholic beverages and other products that are intended only for adults. In 1992, with the passage of the Synar Amendment, the Congress set performance standards to ensure that every State was effectively regulating retail tobacco sales. If States do not meet Federal performance measures, they can lose the funding they receive from the Substance Abuse and Mental Health Services Administration (SAMHSA).

Since passage of the Synar Amendment, youth smoking by high school students has declined from 31.9 percent to 23 percent among boys and from 29.8 to 22.9 percent among girls. This basic model is the right one to follow. There is room for the Congress to set standards for States to meet in their regulation of tobacco sales. But duplicating the extensive system of State regulation that already exists—and has shown results—does not make sense.

There are 300,000 retailers of tobacco products in the United States. The Food and Drug Administration does not have the resources to regulate these retailers in an even-handed manner. They may be able to contract with States to enforce the

law—though if that is the answer it is very difficult to understand why such a system would be preferable to setting standards for States—but it also ignores that much of the cost of regulating lies not in enforcement but in adjudication. Any system of regulation and enforcement needs to meet basic standards for due process. States already do this with respect to tobacco retailers and have an extensive infrastructure in place to try to ensure fairness. It would be exceedingly difficult for the FDA to provide due process for tobacco retailers. The financial burdens of hiring and deploying the necessary administrative law judges alone would be staggering.

Another due process problem with FDA regulation is geography. When FDA implemented a similar system in the 1990s, before it was struck down by the U.S. Supreme Court, retailers that wanted to challenge a violation had the choice of traveling to FDA's headquarters in Rockville, Maryland, for the hearing or participating by phone. Obviously, it is far more effective to appear in person than to participate by phone—we recognize this in the operation of our courts just as Congress does in the conduct of hearings like this one. But for many retailers around the country traveling to Rockville not only would mean a large expense, but it would be significant time away from running the business. For the 60 percent of the industry who are one-store operators, this is particularly burdensome.

There is also a long list of logistical issues with which the FDA would need to grapple in order to duplicate the State system of regulating retailers. The States have years of experience working with retailers and have a sense of who buys the products, who owns what outlet, where notices of violation should be provided, and the like. The FDA would have to recreate all of this information under the current legislation. Doing that would be costly and unnecessary.

LEGISLATION SHOULD TREAT RETAILERS EQUITABLY

The legislation, as currently drafted, would have adverse effects and loopholes that may not be readily apparent. With respect to prohibitions on sales to minors, for example, mail order and Internet sales are exempted. While such sales were a relatively small part of the market in the mid-1990s, when the FDA drafted its regulations on this topic, that is not true now. Internet sales of cigarettes, in particular, have exploded in the last decade. These sales constituted 14 percent of the market in 2005. A brief exploration of some of the more than 500 Web sites that sell cigarettes demonstrates that exempting these sales from age verification requirements would be a problem. Typically, these sites do nothing more than ask a customer whether he or she is 18 years of age and relies entirely on that representation to establish the customer's age. In fact, many sites give only one box to click in response to the question of whether the customer is 18—and that box says "yes." Even if a customer answers no, however, many sites still allow that individual to continue to purchase cigarettes.

Multiple delivery services offer their customers the option of having the delivery person check and verify identification upon delivery. There is no reason or justification, then, for treating Internet and mail order sellers any differently than other tobacco retailers with respect to age verification.

Native American tribes and reservation retailers also sell a large volume of tobacco products. We have been concerned about these sales for many years because the sales are often made without applying the legally required State taxes. The U.S. Supreme Court has weighed in on this issue many times and confirmed that States can impose taxes on reservation sales to everyone other than an enrolled member of the tribe. Yet many tribes across the Nation continue to illegally evade these taxes. This is also an age verification loophole. States are hindered in their efforts to enforce their laws against reservation retailers because of the tribes' assertion of sovereign immunity—notwithstanding the fact that the Congress through the Foreign Sovereign Immunities Act did away with immunity for every other sovereign in the world when it acts in a commercial, rather than governmental, capacity. If the Congress is going to pass legislation regulating the sale of tobacco, it cannot leave this gaping loophole in the law. It must make clear that Native American tribes and retailers are fully covered by the law and include a way for the law to be enforced against those retailers. Any other outcome leaves a gaping loophole in the law. There is nothing inherently safer about a cigarette sold by a Native American retailer than one sold at the local convenience store.

The signage and marketing restrictions in the legislation are also inequitable. The legislation would not allow for any signage, including simple displays of brands, if it could be viewed from outside the store. That restriction will disproportionately impact convenience stores. NACS has performed extensive studies of store security and published guidelines for its members recommending that convenience stores keep the entire store visible from outside. That visibility is the best deterrent to crime.

The result, however, is that while competitors such as grocery stores and drug stores may be able to place signage and other advertising inside their stores to let customers know they carry tobacco products, convenience stores will not. That creates a competitive imbalance in the marketplace and does not make sense in light of the stated goals of the legislation. These rules should be modified to cover all establishments in the same way.

Adult stores (other than tobacco shops), including bars and restaurants are also advantaged by this legislation. These businesses would be able to use color advertising in their stores while others would not have that opportunity. The assumption underlying this differential treatment—that minors do not enter these adult establishments—is factually wrong. Minors do enter these establishments and, if this legislation passes, more businesses will become "adult only" in name though not necessarily in practice. Again, this inequity should be remedied.

* * *

There are many other details in this legislation (and missing from it) that are of concern to NACS. If the FDA is going to regulate retailing of tobacco products and do it the right way, issues as diverse as where to send notices and how burdensome the recordkeeping requirements will be must be addressed. But the three principles I have laid out in this testimony are the primary problems we see and should be dealt with for this legislation to be fair and effective. We look forward to working with the members of this committee to address these issues.

PREPARED STATEMENT OF LAURIE COMSTOCK, ELK GROVE, CA

I am opposing the above S. 625—FDA Regulation of Tobacco Products.

I would like to tell you a little about my family's experience with tobacco products.

I am forwarding you a photo of my beautiful younger sister, Lois. She started smoking at the age of 13 (in 1968), and died on Oct. 16, 1999 at age 44 from lung cancer. She was my best friend. I miss her with all my heart and so does my entire family. She leaves behind her husband and two sons, who were 14 and 17 when she died. She suffered from lung cancer for 3 long years. She went through several surgeries, chemotherapy and radiation. In the end her cancer spread throughout her whole body and she was in excruciating pain. I was with her the last few weeks of her life. I promised her I would do everything I could to keep kids from starting to use tobacco and that I would spread the word about the dangers of tobacco and smoking. This bill is not the answer to keeping kids safe and would not help people to quit smoking.

We also lost our father to a tobacco-related disease when he was 39. I was 13 when he died, my two brothers were 9 and 11 and my sister was only 8. He died on Nov. 6, 1963, approximately 2 weeks before President John Kennedy was assassinated. In those days the public did not know as much about the dangers of tobacco and smoking cigarettes and cigars as we do now. Of course the tobacco industry knew even in those days how deadly their products were as is reflected in the Legacy.library.ucsf.edu tobacco documents that are online. Our dad started smoking in his teens.

We have lost many other family members, related both by blood as well as by marriage, to tobacco-related diseases. My mother is currently suffering from emphysema and my stepdad has heart problems, both because of their smoking.

In July 2001, I lost my favorite aunt to lung cancer, caused by smoking. I was staying at her house, taking care of her property and taking care of her dogs. I was sitting at her table and reading her San Diego Union Tribune Newspaper on July 18, 2001. The article I read, I could not believe. The title of the article was "Smoking Deaths an Economic Boon, Philip Morris study says." It goes on to say, "Sick smokers may burden a country's healthcare system, but dead smokers save governments money." That's the conclusion of a study on the financial cost of smoking that was commissioned by tobacco giant Philip Morris."

Even though this study was about the Czech Republic, this just is unacceptable and unbelievable. Every country and every family deserves to be protected from this despicable company and the tobacco industry. Yes, Philip Morris apologized, but I do not accept their apology. I have lost far too many loved ones because of the tobacco industry's deadly products. My family has been devastated and so have thousands of other families, thanks to the tobacco industry.

Philip Morris is the very company that is pushing for FDA Regulation. Philip Morris may have changed their name to Altria, but they certainly have not changed their ways. They claim that they don't want kids to start smoking, that it's an "Adult Decision" but that just causes kids to want to be adults and smoke even more. They think by smoking that they will be more mature and look more adult.

Don't believe the tobacco industry when they say they don't want kids to smoke. That is their future. The present smokers will either quit or die and without kids or young adults taking up smoking, this industry would no longer exist.

I used to be naïve enough to believe that FDA Regulation was the most important thing. I now realize just how wrong I was. By having weak FDA regulations, it gives the appearance that the Government is endorsing smoking by "regulating it." The tobacco industry will be able to say that cigarettes and tobacco smoking is now regulated by the Government, implying that smoking is somehow safer or the Government wouldn't be allowing it. They would also be able to use this as protection from punitive damages in lawsuits if they were allowed to bring FDA regulation to the jury's attention.

The Government should not be protecting the tobacco industry and their rights but should be protecting families from the devastation that this industry and their addictive and deadly products cause.

I ask this committee to really look long and hard at this bill and see why Philip Morris, a tobacco company, is pushing for this bill. There should be many red flags and it should be viewed with strong suspicion.

I ask this committee to look at the findings and orders of U.S. District Judge Kessler, after her finding the tobacco industry had violated the Federal Racketeering laws after the lengthy trial last year. Her orders really make sense. She found this industry had lied and deceived the public for over 50 years.

I ask you to disregard anything that Philip Morris (Altria) says or at least look at it with serious skepticism.

I believe that the big health agencies, American Cancer Society, American Lung Association and American Heart Association feel that even a weak bill is better than no bill at all. I strongly disagree with them.

We should not be negotiating with the tobacco industry on a bill to regulate them. That's like allowing the fox to guard the henhouse. The only thing that Philip Morris wants is the ability to continue to sell their addictive and deadly products. They definitely don't care about public health or they would get out of the tobacco business.

I ask this committee to look deep into your hearts and souls and do what's best for the public. Look at my sister's photo and think what if that were my child or grandchild or wife or mother. Please do not let my sister or father or the other smokers die in vain. Think of your own families.

Thank you for your time.

SMOKING OUT BIG TOBACCO

LAURIE COMSTOCK

Re: "Camel No. 9 smells of killer marketing," commentary, Feb. 21: No matter how much you dress it up, flavor it, decorate the packages with pink, fuchsia and teal flowers and designs, the truth is smoking all cigarettes, and using other tobacco products, addicts and kills people.

The words "light and luscious" should be "black and deadly" when used in advertising tobacco.

My younger sister started smoking when she was 13. She died from lung cancer at age 44. I miss her with all my heart and so does my entire family. She leaves behind her husband and two sons who were 14 and 17 when she died.

I have lost many other family members, related both by blood as well as marriage, to tobacco-related diseases. All of them started smoking as teens.

How many other people will die and how many more families will be devastated before this despicable industry is stopped?

The answer is not weak FDA regulation that Philip Morris (now part of Altria Inc.) approves of, but implementation of U.S. District Judge Gladys Kessler's orders when she found the tobacco industry had violated Federal racketeering laws after a lengthy trial last year.

The tobacco racketeers need to be held accountable for their crimes. Too bad prison is not an option.

PREPARED STATEMENT OF K.H. GINZEL, M.D., PROFESSOR EMERITUS OF PHARMACOLOGY AND TOXICOLOGY, UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES, WESTHAMPTON, MA

I am opposed to any Federal regulatory action that implies formal approval and indefinite continuation of the commercial trade of tobacco products (see Attachment 1 and 2). The mission of the FDA is to oversee, among others, drugs used for the treatment of diseases and to make sure they are effective and safe.

The inclusion of tobacco products by whatever classification would pervert this fundamental role of the FDA, especially as nicotine is increasingly recognized as an extremely harmful substance in addition to its addictiveness (see Attachment 3).

Age 18 as the age for the legal purchase of tobacco is unacceptable for the following reasons:

(1) The proposed regulation specifically prohibits the FDA from raising the legal minimum sale age for tobacco beyond age 18, as obviously demanded by Altria/PM to retain access to high school seniors, many of whom are over 18 and would therefore be able to legally buy tobacco products and pass them on to peers under 18.

(2) Although the majority of adult smokers started smoking under 18, 15 percent to 20 percent may start between 18 and 21. Hence, smoking would still be perpetuated at a significant level.

(3) Tobacco use, smoked or chewed, imposes a carcinogenic burden that is more dangerous for the growing organism than for the adult. Physical growth does not stop at 18 but continues at least until 21.

(4) The age at which the psychological maturity is attained for making an informed decision about using legal drugs with a high potential for addiction is at least 21, the age adopted for legal purchase of alcoholic beverages.

I am attaching the following documents:

(1) My position on tobacco as expressed in a letter to then-President Clinton and a Memo to the Presidential Task Force on National Tobacco Policy.

(2) BMJ posting on "The Future of Tobacco."

(3) Critical Review on Nicotine, just appeared as electronic version (publication in print early March).

The following two documents express my judgment as to how, in a civilized society, the true reality of the tobacco issue ought to be confronted and resolved.

Although they were created in 1997, they are as timely today as they were then.

September 8, 1997.

Hon. WILLIAM JEFFERSON CLINTON,
President of the United States,
The White House, 1600 Pennsylvania Ave. NW.,
Washington, DC 20500.

DEAR MR. PRESIDENT: It is puzzling beyond comprehension that not a single argument among those raised in recent weeks against the "tobacco settlement" or in favor of alternative solutions to the leading preventable public health scourge of our time, has truly confronted reality and proposed the obvious, the obvious being the phasing out of commercial production and sale of tobacco products. Tobacco farmers should be assisted in harvesting tobacco for the commercialization of a high-quality protein that could feed a protein-starved third world. Smokers who want to quit should be given help, while those who don't should be allowed to grow their own tobacco plants strictly for personal use. This is NOT PROHIBITION.

Are we so totally mired in the morass of ideological and political absurdities that we have lost the ability to think straight and act responsibly? For more than four decades American scientists have been at the forefront of accumulating incontrovertible evidence for the immense harm smoking inflicts on smokers as well as nonsmokers. At the same time U.S.-based tobacco corporations have occupied the field, deceived the public, and unashamedly pushed their deadly merchandise in the domestic and foreign marketplace. And essentially all we are laboring and fussing about now is how we can let them continue selling death with impunity, albeit in diminishing numbers. If this type of mindset had prevailed at the end of the second World War, we would probably have stopped our advance on the beachhead at Normandy, made peace with Hitler, and argued about the least offensive way to keep the concentration camps operating.

Mr. President, circumstances have now granted us one of those rare opportunities when politics must end and moral courage command our actions. If you can seize this unique moment, cut through all the sham to the bedrock of truth, and start the world on the path of liberation from the lethal addiction to tobacco and to the profits garnered from the suffering of its victims, you will have a place in history among the greatest benefactors of humankind.

Respectfully yours,

K.H. GINZEL, M.D.,
Professor of Pharmacology and Toxicology Emeritus,
University of Arkansas for Medical Sciences.

August 27, 1997.

MEMO

TO: PRESIDENTIAL TASK FORCE ON NATIONAL TOBACCO POLICY
FROM: K. H. GINZEL, M.D.

(The tobacco industry is an economic tyrannosaurus rex: enormous, ferocious, and destined for extinction. The world, and its economies, will survive the industry's gradual demise quite handsomely.—Kenneth Warner, The Global War, Seventh World Conference on Tobacco & Health, Australia, 1990.)

Ever since the first Surgeon General's Report on Smoking and Health appeared in 1964, the Federal Government has taken a duplicitous stance vis-a-vis tobacco use and its disastrous consequences for public health. Up till now one could euphemistically argue that the Government simply "condoned" the death of millions of Americans who succumbed to tobacco-related diseases during the past 33 years.

However, by adopting the proposed tobacco "settlement," the Government would formally endorse the continued sacrifice of old and new lives to the ravages of nicotine addiction. A case in point is the fact that a negotiated compromise intended to cut teens' smoking in half in a given number of years inescapably condemns the other half to the risk of disease and premature death. Hence, if there ever was pretense of innocence, from that moment on innocence would irretrievably be lost and liability for inflicted injury would no longer be limited to industry alone.

Thanks to many years of untiring tobacco control advocacy, activism, and litigation, we have finally arrived at a juncture of profound significance and unparalleled opportunity. Numerous compelling reasons converge to mandate that the Federal Government, empowered by the Commerce Clause of Article 1, Section 8 of the Constitution, act responsibly and ban the commercial manufacture and worldwide marketing of tobacco products by U.S.-based corporations. Sales would have to be phased out over a specified period of time, during which current consumers can either seek help for quitting tobacco use or be permitted to start growing their own tobacco plants for strictly personal use (This would NOT be PROHIBITION. Tobacco farmers should be assisted in changing to alternative crops or in harvesting tobacco for the extraction and commercialization of a high-quality protein that is only found in tobacco plants. Tobacco giants, which are already highly diversified, will be able to switch to non-tobacco commodities without undue hardship. According to Kenneth Warner, the total economic impact of changing to a non-smoking society would be negligible, if not beneficial.

If this prescription sounds too Utopian, a reality check may be in order.

Let everyone try to invoke cogent and logically impeccable arguments as to why the industrial manufacture and global marketing of tobacco products by U.S. corporations must continue.

(1) Is it to continue because 50 million Americans still smoke and need to be provided with cigarettes? (After all nicotine replacement medication can be purchased over the counter and smokers could still grow their own tobacco).

(2) Is it because smokers' alleged freedom of choice to continue smoking—they surely did not exercise choice when they started smoking as teens—deserves greater protection than their health, as well as the health of those involuntarily exposed to their smoke?

(3) Or is it because tobacco sales at home and abroad not only yield huge profits for the tobacco industry and substantial tax revenues for governments, but also make possible generous corporate donations to influential Members of Congress?

(4) Or, finally, is it because the premature death of smokers could help reduce payments from pension funds, and Social Security and Medicare expenditures?

The issue of a black market for cigarettes, now faced especially by countries like Canada with high taxes on cigarettes, would largely disappear once U.S. production has ceased. Europe is now looking at America's evolving tobacco policy and is likely to follow its example.

If any of the reasons considered above are deemed sufficient to justify the continued marketing of such a deadly product, this would suggest that our society places a higher priority on corporate profit than on the health and happiness of people. If, however, the converse is true and no valid arguments can be found in support of the status quo, the time for action has clearly arrived. This is a propitious moment in history that, if not seized upon now, will probably not return until tobacco has claimed many more millions of victims.

THE FUTURE OF TOBACCO

In addressing "The Future of Tobacco," Nigel Gray suggests two alternative approaches. One is the prohibition of tobacco, the other concentrates on finding other nicotine delivery systems to compete with tobacco. He dismisses the first option because of the notorious failure of the alcohol prohibition in the United States in the 1920s. Indeed, a "Prohibition" patterned after the former would not be a practicable solution.

However, a fundamentally different kind of "prohibition" not only deserves serious consideration but also follows compellingly from the extraordinary new stance Philip Morris, the most successful U.S.-based multinational cigarette maker, has recently adopted. After more than half a century of blatant denial, PM is suddenly fully embracing the death and destruction its products inflict (philipmorris.com Web site). Yet, despite PM's agreement with "the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers," it still conducts "business as usual," continues to advertise and sell its cigarettes at home and abroad. *<and persists in harvesting the world's childen as customers indispensable for securing future profits.>** The perfunctory warning labels about the risks of smoking can in no way compete with the massive pictorial impact of insidious advertising imagery that uniquely affects the young mind. *<This duplicitous behavior is totally incongruous with any honest and civilized approach to trade, especially as public health on a national and global scale is concerned.>* I am not aware of any product other than cigarettes that, after being found defective and endangering life, was not withdrawn from the market, either voluntarily by the manufacturer or by regulatory or legal fiat of government.

The stage appears to be set to examine if the sale of a product that kills half of its long-term users and whose manufacturer now unreservedly endorses its multiple risks and dangers can any longer be tolerated by society. As one ponders the realities of the free enterprise system, one is inevitably led to appreciate the role that Government must play on behalf of its people. In their wisdom, the Framers of the Constitution granted Congress the right to regulate commerce, empowering the U.S. Government in the "Commerce Clause" of Article 1, Section 8, of the Constitution to stop the interstate trade of dangerous merchandise, an authority that could conceivably be exercised in the case of tobacco. Such action must be clearly distinguished from prohibition, since individuals would still be able to grow tobacco strictly for personal use.

The second alternative considered by Nigel Gray aims at a nicotine delivery device not based on tobacco. Although this would greatly reduce the burden of toxic and carcinogenic exposure of the user, the fact that nicotine itself is a tumor promoter and can be converted in the body to the tobacco-specific nitrosamine, NNK, one of the most potent lung carcinogens known, would argue against its extended use as a substitute for tobacco. However, sebacylcholine, an agent that is chemically different from nicotine but duplicates certain effects of nicotine, should be tested as a potential substitute (K.H. Ginzel, A hypothesis on the peripheral origin of smoking satisfaction and its implication for nicotine replacement. Proc. 7th World Conference on Tobacco and Health, Perth, Western Australia, 1990, pp. 426–427).

JOURNAL OF HEALTH PSYCHOLOGY

CRITICAL REVIEW: NICOTINE FOR THE FETUS, THE INFANT AND THE ADOLESCENT?

K.H. GINZEL, GERT S. MARITZ, DAVID F. MARKS, MANFRED NEUBERGER, JIM. R. PAULY, JOHN R. POLITO, ROLF SCHULTE-HERMANN AND THEODORE A. SLOTKIN)

ABSTRACT

The recent expansion of Nicotine Replacement Therapy to pregnant women and children ignores the fact that nicotine impairs, disrupts, duplicates and/or interacts with essential physiological functions and is involved in tobacco-related carcinogenesis. The main concerns in the present context are its fetotoxicity and neuroteratogenicity that can cause cognitive, affective and behavioral disorders in children born to mothers exposed to nicotine during pregnancy, and the detrimental effects of nicotine on the growing organism. Hence, the use of nicotine, whose efficacy in treating nicotine addiction is controversial even in adults, must be strictly avoided in pregnancy, breastfeeding, childhood and adolescence.

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*(Note: The two statements added here between < and > in the above paragraph had been eliminated by the BMJ Editor from the published version of my RESPONSE).

KEYWORDS: ADOLESCENCE; CARCINOGENESIS; FETOTOXICITY; NICOTINE REPLACEMENT THERAPY; PREGNANCY; TERATOGENICITY

INTRODUCTION

With the prospect of causing one billion deaths in the 21st century, cigarette smoking has entrapped the planet in a pandemic of tobacco-related morbidity and mortality of unprecedented proportion (Ginzel, 2001). Since addiction to nicotine is at its core, one should expect that efforts be focused on helping smokers to overcome their addiction to nicotine. Instead, nicotine, as in "Nicotine Replacement Therapy" (NRT), is becoming a more and more heavily promoted tool for smoking cessation.

In support of NRT, it is claimed that the main cause of the health damage inflicted by smoking is the cigarette smoke with its contingent of over 4,000 substances, many of which are toxic or carcinogenic, but not the nicotine to which the smoker is addicted. Therefore, it is argued, if the addiction to cigarette smoking is too powerful to respond to treatment, providing nicotine via NRT or even smokeless tobacco in place of cigarettes is the correct course of action. This argument is then further strengthened by portraying nicotine as largely innocent, on par with caffeine, thereby ignoring the abundant evidence that nicotine itself can imperil health due to a host of adverse effects independent of its addictiveness.

But even if the toxicity of nicotine were accepted as a given, would medicinal nicotine from NRT not be preferable to nicotine contaminated with the bulk of poisons in cigarette smoke? Although this question may suggest an affirmative answer, it actually hides the need for uncompromised quitting as the only truly lasting solution. There are at least two points to consider. For one, the satisfying experience of a deep inhalation of cigarette smoke correlates with a sudden, steep spike of the blood nicotine level. The generally much gentler and more protracted rise following ingestion of NRT or smokeless tobacco can neutralize the unpleasantness of withdrawal symptoms during quitting attempts but it fails to eliminate the urge to smoke, prompting a relapse to smoking. The unsuccessful quitter then smokes either in alternation or even concurrently with NRT. Despite the inevitable increase in nicotine exposure that this practice entails, it was officially endorsed by the "the new rules" (see later). Second, for both the addict and the counselor, the true labor of quitting is comfortably postponed or suspended by resorting to a simple pill or patch. By making "quitting" look so effortless, the health concerns and attitudes toward smoking will have lost their urgency.

When the concept of treating nicotine addiction with nicotine first emerged in the early 1980s, pharmaceutical companies seized upon the opportunity to develop and market several nicotine preparations for this purpose. Available today are nicotine chewing gum, transdermal patch, lozenges, nasal spray and inhaler, which enjoy increasing popularity among cessation specialists and smokers who are trying to quit. However, a critical commentary questions the overall utility and success rate of NRT as an aid to smoking cessation (Polito, 2006). Also, according to a new meta-analysis, the long-term benefit of NRT is modest, while existing treatment guidelines, based on only 6–12 months of followup, overestimate the lifetime benefit and cost-efficacy of NRT (Etter & Stapleton, 2006).

Despite the lack of evidence for long-term effectiveness, NRT use continues to grow. In the United Kingdom the Committee on Safety of Medicines (CSM) and the Medicines and Healthcare Regulatory Authority (MHRA) have issued new rules, extending the use of nicotine in smoking cessation to the most vulnerable recipients, the unborn child, the neonate and children as young as 12 (Action on Smoking and Health, 2005). Yet, in the only two trials conducted in pregnancy, NRT patches had no greater effect on smoking cessation than placebo (Coleman et al., 2004). Neither did NRT prove effective in a study of 120 adolescent smokers (Moolchan et al., 2005).

Whether or not successful in achieving quitting, the recommendation to use NRT in pregnancy and childhood raises the most serious concerns because of potential long-term consequences of nicotine action for this target group. In addressing these concerns, we first review the current state of the science on nicotine's pharmacological profile with its diverse impact on body functions, in particular its implication in carcinogenesis, and then zero in on those effects of nicotine that specifically impinge upon the developing and growing organism, the primary objective of this article.

A BRIEF SYNOPSIS OF NICOTINE ACTION

More than 100 years ago nicotine was first used as a tool in physiological research. When nicotine was found to duplicate several effects of acetylcholine (ACh),

one of the principal neurotransmitters in the central and peripheral nervous systems, this type of "cholinergic" transmission was designated "nicotinic."

The transmission occurs across a synapse between a presynaptic nerve ending from which ACh is released and the adjacent postsynaptic neuronal cell body or effector cell that carries specialized receptors normally stimulated by ACh but also responsive to nicotine. Nicotinic cholinergic transmission via nicotinic cholinergic receptors (nAChRs) is a vital process indispensable for the normal functioning of the living organism but vulnerable to impairment by nicotine. This is one target for nicotine in the mature nervous system. Yet in the developing nervous system, very early in gestation, nAChRs are expressed prior to the formation of the neurons, which later establish synaptic contact with the nAChRs. By modifying the function of these receptors, nicotine can interfere with the normal developmental role of ACh (Falk, Nordberg, Seiger, Kjaeldgaard, & Hellstrom-Lindahl, 2005). These effects occur in the range of amounts of nicotine derived from smoking or equivalent sources.

Nicotine also exerts multiple effects on the afferent portion of the nervous system. In lowest effective doses it stimulates vagal sensory nerve endings in the lungs, producing reflexly a generalized relaxation of the skeletal musculature and an activation of the electroencephalogram (EEG) correlated with mental alertness. This intriguing combination, experienced and valued by the smoker, is likely to contribute to nicotine's addictive property (Ginzel, 1987).

Recently an entirely new dimension was added to the wide spectrum of nicotine action. Neuronal nicotinic acetylcholine receptors, nAChRs, expressed on many different nonneuronal cell types throughout the body, including lymphocytes, macrophages, dendritic cells, adipocytes, keratinocytes, endothelial cells and epithelial cells of the intestine and lung, appear to be implicated in inflammatory conditions and diseases as diverse as ulcerative colitis, chronic pulmonary obstructive disease, Parkinson's and Alzheimer's disease (Gahring & Rogers, 2006).

Among the classical effects of nicotine are those on heart and blood vessels mediated via nAChRs in the peripheral autonomic nervous system. Nicotine affects adult heart rate and rhythm and accelerates fetal heart rate. More recently, a key role of the inner lining of blood vessels, the endothelium, in maintaining adequate blood flow to organs was discovered. In the human brachial artery, the endothelium-dependent dilatation was found to be impaired by nicotine from cigarette smoke as well as from NRT nasal spray (Neunteufl et al., 2002). After a mere 30-minute exposure to environmental tobacco smoke (ETS), a substantial reduction in the coronary flow velocity reserve, indistinguishable from that seen in habitual smokers, was observed in healthy young nonsmokers (Otsuka et al., 2001). The underlying mechanism was found to be the inhibition by nicotine of the self-regulatory coronary vasodilatation in response to nitric oxide released by endothelial cells. Since this effect of nicotine reaches its maximum already in the small amounts present in ETS, the difference between passive and active smoking as to their effects on blood vessels is greatly narrowed. Heart disease from smoking only one to four cigarettes per day is probably due to this mechanism (Bjartveit & Tverdal, 2005). By increasing platelet aggregation and low density cholesterol (LDL) while lowering high density cholesterol (HDL), nicotine favors clot formation that may lead to heart attacks and strokes. Nicotine, especially in the presence of a high cholesterol diet, stimulates the growth of vascular smooth muscle cells and promotes plaque formation and atherosclerosis (Jeremy, Mikhailidis, & Pittilo, 1995). The American Heart Association (2006) has questioned the suitability of NRT for patients with heart disease and for pregnant smokers.

Nicotine has a whole spectrum of other effects at different stages of fetal and adult development, which should not be ignored by those administering or receiving NRT. Some of these are: an increase in airway resistance; a decrease in fetal respiratory movements; a decrease in alphal-antitrypsin associated with an increase in elastase favoring the development of emphysema; gastrointestinal vasoconstriction combined with a reduction in prostacyclin leading to stomach ulcers; a depression of the immune response; and multiple effects on hormones, especially a lowering of estrogen due to an increase in its metabolism leading to an earlier onset of menopause, osteoporosis and cardiac problems (U.S. Department of Health and Human Services, 1988).

NICOTINE AND CARCINOGENESIS

One of the reasons for protecting the developing and growing organism from exposure to nicotine is the prominent role nicotine plays in both "initiation" and "promotion," the two cardinal stages in carcinogenesis. Nicotine can be transformed to one of the most potent lung carcinogens, the tobacco-specific nitrosamine, NNK. As

an initiator, NNK is a prime candidate among the many carcinogens in cigarette smoke responsible for starting the process toward cancer in active and passive smokers (Hecht, 2004; Hecht, Hochalter, Villalta, & Murphy, 2000). NNK and its metabolites are found in the first urine of infants born to smoking mothers, supporting the hypothesis that in utero exposure to tobacco carcinogens could be carcinogenic later in life (Lackmann et al., 1999). Transplacental carcinogenesis associated with smoking during pregnancy may involve, in addition to nicotine and NNK, other carcinogens from cigarette smoke. Reduced detoxification capabilities and increased susceptibility to DNA damage render the fetus especially vulnerable to carcinogenic risk (Whyatt et al., 2001). NNK and metabolites have also been recovered from elementary school children and adults exposed to ETS (Hecht et al., 2001), attesting to the fact that even the relatively small amounts of nicotine in ETS can be transformed to NNK in the recipient. Added to this are the minute concentrations of NNK in ETS that had been formed earlier in stored and burning tobacco. Nicotine ingested from NRT can also undergo transformation to NNK (Hatsukami et al., 2004). Fetal pulmonary neuroendocrine cells as well as lung cancer cells express nAChRs that bind NNK and nicotine which, in turn, stimulate the growth of these cells (Minna, 2003). The fact that human lung cancer cells of all histological types carry nAChRs suggests that nicotine itself may also play a direct role in the pathogenesis of lung cancer (Minna, 1993).

Tumor growth occurs when the critical balance between cell proliferation and programmed cell death (apoptosis) in normal healthy tissues is disturbed. At blood concentrations achieved by smoking, ETS exposure, or NRT, nicotine activates via nAChRs the cellular signalling pathway Akt, a protein kinase, which stimulates cell proliferation and inhibits apoptosis (Tsurutami et al., 2005). Activated Akt has been identified in all lung cancer samples taken from smokers. By this mechanism nicotine promotes unregulated growth and tumor formation, an effect that is not limited to the lungs but can also occur in cancers of other organs. Nicotine in NRT can be expected to act in a similar way (Heusch & Maneckjee, 1998).

Nicotine from cigarettes or NRT might also confer a proliferative advantage to already existing tumors. At concentrations even lower than those in smokers' blood, nicotine stimulates proliferation of endothelial cells and the formation of new blood vessels (angiogenesis), a basic requirement for tumor growth and metastasis (Villablanca, 1998). Furthermore, through activation of protein kinase C, nicotine accelerates migration and invasion of human lung cancer cells (Xu & Deng, 2006). All these actions define nicotine as an effective tumor promoter. As smoking-related promotion is now being recognized as the primary etiologic mechanism in carcinogenesis dominating over smoking-related initiation (Hazelton, Clements, & Moolgavkar, 2005), nicotine, implicated in both processes, ought to be a major aim for intervention instead of a tool advocated for use in smoking cessation.

New research using human tissues raised the question whether nicotine is "potentially a multifunctional carcinogen" (Campain, 2004), since it produces concomitant genotoxic and antiapoptotic effects, first steps in the neoplastic process. In human gingival fibroblasts nicotine induced rapid DNA damage at in vitro concentrations equivalent to those found to occur in the plasma of tobacco users (Argentin & Cicchetti, 2004). Genotoxicity observed in human tonsillar tissue and lymphocytes as well as in upper aerodigestive tract epithelia also suggests a direct tumor-initiating effect of nicotine (Kleinsasser et al., 2005; Sassen et al., 2005).

Smoking is now recognized as the second most significant cause of cervical cancer after human papilloma virus (International Agency for Research on Cancer, 2003). Nicotine which accumulates in cervical mucus after active and passive smoking and smokeless tobacco use (McCann et al., 1992), and which is also highly concentrated in the cervical mucus of women who use nicotine patches (*Cancer Weekly*, 1995), was found not only to promote rapid tumor growth and its lympho-angiogenic spread but also to inhibit an anti-proliferative factor (Lane, Gray, Mathur, & Mathur, 2005).

Although the preceding experimental data focus largely on adult cancer incidence implicating nicotine as a causative factor, similar scenarios can be expected to play out over time following fetal or childhood exposure to nicotine. Transplacental carcinogenesis associated with smoking during pregnancy may also involve, in addition to nicotine, other carcinogens found in cigarette smoke.

NICOTINE IN PREGNANCY AND CHILDHOOD

Nicotine also acts as a neuroteratogen. There is now abundant evidence that normal fetal development can be disrupted more specifically by nicotine than by any other component of cigarette smoke. Nicotine, which impacts the brain during critical stages of its intrauterine development in experimental animals, is in the off-

spring of smoking mothers also the most likely cause of the deficits in learning and memory, and the emotional and behavioral problems seen in childhood and later in life (Levin & Slotkin, 1998; Slikker, Xu, Levin, & Slotkin, 2005; Slotkin, 1998). In this context, a higher incidence of attention deficit hyperactivity disorder (ADHD), lower adult intelligence and mental retardation have been reported (Drews, Murphy, Yeargin-Allsopp, & Decoufle, 1996). Higher order sensory function depends in part on the activation of nAChRs in the sensory cortex by its natural transmitter acetylcholine. When nicotine, even if only transiently, usurps these receptors in the developing sensory cortex during a critical period, it can permanently alter sensory-cognitive function (Metherate, 2004). Just published new findings provide experimental evidence that nicotine exposure in pregnancy is responsible for auditory-cognitive deficits in the offspring. Children with cognitive hearing deficits have difficulty in understanding speech and verbally presented information in noisy settings, and may be unable to tell the difference between similar sounds (Liang et al., 2006). Prenatal nicotine also primes the adolescent brain for depression (Law et al., 2003), and for nicotine addiction in future years (Abreu-Villaa, Seidler, Tate, Cousins, & Slotkin, 2004; Kandel & Davies, 1994; O'Callaghan et al., 2006).

Significantly lowered levels of catecholamines found in umbilical cord blood in response to hypoxemia during parturition may explain the increased perinatal morbidity and mortality associated with smoking during pregnancy (Oncken et al., 2002). A blunted catecholamine response to hypoxic stress with a greater risk of death to offspring was also observed in rats receiving nicotine throughout gestation. Prenatal nicotine exposure can also have a permanent impact on lung development and function with potential long-term health consequences (Fauroux, 2003). Nicotine crosses the placenta and activates nicotinic receptors located at a wide range of lung cells. In rat experiments, in doses equivalent to those ingested by smoking mothers, nicotine causes what appears to be a faster aging of the lungs in the offspring, characterized by enlarged alveoli, fewer alveoli, a smaller surface area for gas exchange and microscopic emphysema (Maritz & Windvogel, 2003). NRT use during pregnancy and breast-feeding when the neonate lungs are still developing should be avoided (Alm, Lagercrantz, & Wennergren, 2006). Prenatal nicotine exposure can permanently alter lung development and airway function (Sandberg, Poole, Hamdan, Arbogast, & Sundell, 2004). Prenatal and postnatal nicotine exposure have been causally implicated in Sudden Infant Death Syndrome (SIDS) (Cohen et al., 2002; Huang, Wang, Dergacheva, & Mendelowitz, 2005; McMartin et al., 2002; Milerad, Vege, Opdal, & Rognum, 1998; U.S. Department of Health and Human Services, 2006). NRT use during the first 12 weeks of pregnancy increased the risk of congenital malformations (Morales-Surez-Varela, Bille, Christensen, & Olsen, 2006).

A well-known consequence of smoking during pregnancy is the incidence of low birth weight (LBW) babies, but even in the absence of LBW, nicotine that reaches some 15 percent higher levels on the fetal side of the placenta than on the maternal side, affects fetal brain development and newborn neurobehavior (Lambers & Clark, 1996). Nicotine concentrates in fetal blood, amniotic fluid and breastmilk. Breast-feeding by smoking or ETS exposed mothers continues the delivery of nicotine to the baby (Dahlstrom, Ebersjo, & Lundell, 2004). Postnatal exposure to cigarette smoke also appears to act through nicotine: in a study of 4,399 children aged 6 to 17 years, even the lowest exposure, as monitored by the levels of cotinine, the main metabolite of nicotine, in blood, urine, saliva and hair, was found to significantly impair, in a dose-related manner, the children's reading, math and reasoning scores (Yolton, Dietrich, Auinger, Lanphear, & Hornung, 2005).

NICOTINE IN ADOLESCENCE

According to recent human and animal research, adolescents are more susceptible to developing nicotine dependence than adults, because a single drug exposure can lead to lasting neuronal changes associated with learning and memory (Fagen, Mansfelder, Keath, & McGehee, 2003). The earlier the exposure to nicotine, the greater is the impact on the neuronal circuitry of the still developing brain causing irreversible effects on hippocampal structure, function, learning and memory (Slotkin, 2002). This experimental finding was borne out of a study of 5,863 students, where a single experience with cigarettes reported at age 11 was found to significantly increase the risk of becoming a smoker as an adolescent even after 3 intervening years of nonsmoking. This dormant vulnerability, termed "sleeper effect" (Fidler, Wardle, Brodersen, Jarvis, & West, 2006), must be made widely known to help prevent preteens from early experimentation with cigarettes or other tobacco products. Early exposure to nicotine can also make children more vulnerable later to stress or depression, prompting them to try some form of nicotine again.

Adolescent smokers have only recently started to receive NRT. Some of them reported simultaneous use of NRT and cigarettes. Nonsmoking teens have also tried NRT and some have even indulged in regular use (Klesges, Johnson, Somes, Zbikowski, & Robinson, 2003). The easy availability of NRT poses a special risk for the curious and adventurous young. Like smoking, NRT has the potential of priming the brain for nicotine addiction and leading to illegal drug use.

A review of teen smoking cessation approaches reveals their complexity and the lack of an effective solution (Mermelstein, 2003). What appears to be missing from the majority of interactions with young people is a totally honest confrontation and a truthful dissection of the tobacco problem in its entirety (Ginzel, 2002).

THE NEW RULES

Against this background, it is with much concern that we confront the recently proposed rules issued by the Committee on Safety of Medicines (CSM) and by the Medicines and Healthcare Regulatory Authority (MHRA) for the use of NRT in the UK (Action on Smoking and Health, 2005), likely to set a precedent for other countries to follow. According to these new rules, all forms of NRT can be used by pregnant smokers; different forms of NRT can be used alternatively or concurrently; NRT can be used while still smoking (!) and can be prescribed for up to 9 months if needed; and all forms of NRT can be used by young smokers aged 12 to 17 years as well as by patients with cardiovascular disease if so advised.

These new rules differ fundamentally from past recommendations. Molyneux (2004) states that the effectiveness of NRT in adolescents and children who smoke has not been established, and he also urges smokers not to smoke while using NRT. NRT, especially by transdermal patch, delivers more nicotine to the fetus than smoking does. Nicotine concentrations in fetal rat brain are 2.5 times higher than the mother's blood nicotine level when on continuous nicotine feed; a similar ratio can be expected in pregnant women using the patch (Sarasin et al., 2003). Smokers who use NRT may have nicotine concentrations up to three times higher than the approved dose (Chan, Jeremy, Stansby, & Shukla, 2004). The U.S. Surgeon General's Report of 2001 on Women and Smoking states: Because of uncertainties over the safety of nicotine replacement during pregnancy, FDA has assigned a Pregnancy Category C warning to nicotine gum ("Risk cannot be ruled out") and a Pregnancy D warning to transdermal nicotine ("Positive evidence of risk") (U.S. Department of Health and Human Services, 2001, p. 557). Since many of tobacco smoke's harmful effects on the unborn baby can be attributed to nicotine, NRT or smokeless tobacco products are not a safe alternative to smoking during pregnancy (Cohen et al., 2005). No data are available on long-term effects of NRT use on fetal outcomes (Oncken, Bert, Ockene, Zapka, & Stoddard, 2000). The uncertainty of benefit and the risk of NRT use in pregnancy and by teens are echoed throughout the literature dealing with this topic. The risk of oral NRT use also received new emphasis by the recent finding that nicotine causes concomitant genotoxic and antiapoptotic effects in human gingival fibroblasts, potentially the first step in the neoplastic process (Argentin & Cicchetti, 2004).

It is obvious that the smoker whose body is busy dealing with the nicotine contingent in inhaled smoke ought not to be burdened with additional amounts of nicotine delivered from NRT but should be resolutely supported to overcome the addiction to nicotine altogether. This cannot be achieved by recommending or prescribing nicotine through NRT. The ultimate goal must be total cessation of smoking and nicotine intake in any form. NRT simply substitutes one form of nicotine for another but is neither safe nor as effective as other cessation aids (Hutter, Moshammer, & Neuberger, 2006; Marks, 2005, 2006; Moshammer & Neuberger, 2006). Originally, the tobacco industry opposed the makers of NRT, but now both industrial enterprises seem to be finding common ground as tobacco and NRT have begun reinforcing each other and keeping the addiction to nicotine alive.

CONCLUDING COMMENTS

Prescribing or simply recommending an over-the-counter purchase of one form or another of NRT is unquestionably quicker and less engaging for the health professional than any in depth one-to-one counsel that tries to inspire mind and heart of the mother-to-be so as to make her cherish and protect the new life she has been entrusted with; it is also easier than a straight talk with a teen or preteen about a future eclipsed by addiction, disease and premature death, exploring the real reasons that made them light up in the first place (Ginzel, 2002). It is easy not only for the counselors to prescribe NRT, it is also easy for the clients to receive it: they may conveniently assume that this is all that needs to be done, and the urge to smoke may go away in due course. While there is compelling experimental and clin-

ical evidence that nicotine harms the developing fetus in several ways, evidence is lacking that NRT aids smoking cessation in pregnancy. There are pregnant women today who would have quit but are wearing nicotine patches, persuaded by the safety assurances about NRT use. Moreover, new evidence reveals that offering a remedy for a risky behavior inadvertently promotes it by suggesting that the risk is manageable (Bolton, Cohen, & Bloom, 2006).

If the new UK rules, which extend and multiply a regimen ill-conceived from the start were followed and also adopted by other countries, they would perpetuate nicotine addiction rather than diminish it. And so would a recently proposed policy of extended, or even indefinitely continuing (!), use of the so-called "clean nicotine" of NRT (Gray et al., 2005). This could actually set us on a path eventually leading to the end of tobacco control as we know it. Tobacco control must be nicotine control. Without nicotine control, nicotine addiction and nicotine's multifarious and insidious impact on the user would persist and spread at the peril of the unborn, the next generation and public health in general.

Some 4,000 years ago the code of Hammurabi decreed the penalty of death for anyone who would harm a child. In an editorial in the *New York Times* in March 1985, William G. Cahan of the Memorial Sloan Kettering Cancer Center identified smoking as the most prevalent form of child abuse. Will nicotine now join this deplorable distinction?

ABBREVIATIONS

ACh, acetylcholine; ADHD, attention deficit hyper activity disorder; CSM, Committee on Safety of Medicines; ETS, environmental tobacco smoke; FDA, Food and Drug Administration; MHRA, Medicines and Healthcare Regulatory Authority; nAChRs, nicotinic cholinergic receptors; NNK, tobacco specific lung carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone; NRT, nicotine replacement therapy; SIDS, sudden infant death syndrome.

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COMMENT OF STEPHEN L. HANSEN, M.D.

Prof. Ginzel has it just right. This is a politically achievable goal of tremendous public health import. Polls support de-legalization of the sort envisioned here. Let's unify around this approach for the long run—people are ready for tobacco to go.

PREPARED STATEMENT OF MICHAEL S. GIVEL, PH.D., PROFESSOR OF POLITICAL SCIENCE, UNIVERSITY OF OKLAHOMA, NORMAN, OK

FDA LEGISLATION REQUIRES SIGNIFICANT CHANGES TO CURB CIGARETTE USE

Mr. Chairman and distinguished members of the committee, thank you for the opportunity to allow me to submit this written testimony with respect to proposed Food and Drug Administration legislation and regulation of tobacco. I respectfully

request that my written statement be included as part of the committee's official record.

My name is Michael Steven Givel and I am an associate professor of political science at the University of Oklahoma. My area of research expertise includes public policy, health policy and tobacco policy. I have been involved in tobacco policy research for about 10 years and prior to that was involved for 2 years with Synar youth enforcement program administration in the State of Missouri. I have published extensively in scientific peer-reviewed journals with respect to the issue of Federal tobacco policymaking, including two recent scientific articles on the Global Settlement and past attempts by the U.S. Food and Drug Administration (FDA) to regulate tobacco products. I will preface my written testimony today with comments regarding the adequacy of the proposed FDA legislation to actually reverse the use of the Nation's consumption of tobacco products.

The very long title I of this bill with the various requirements for cigarette product performance, labeling, and monitoring standards represents a long-term goal by some for an alleged "safer" cigarette. Unfortunately, there is no wide scientific consensus or proof that has definitively and conclusively shown that a reduction of some ingredients or product modifications will make a lit cigarette safer. In fact current scientific evidence and research has provided little conclusive evidence as to what tobacco ingredients and in what combination and in what levels is specifically linked to particular morbidities and mortalities.

For example, even if the FDA were to lower nicotine levels as is proposed for title I of this bill, this will not make cigarettes, as some claim, non-addictive or "safer." In fact, lowering of nicotine levels will lead smokers to compensate to maintain their current level of nicotine consumption. This will result in these smokers consuming higher levels of harmful ingredients including tar leading to continuing high levels of disease and death.

Supposedly safer cigarettes coming on to the market with FDA approval will also maintain the current market brands of cigarettes that cause significant disease and death. Given that there is no scientific evidence conclusively linking varying amounts of ingredients with specific morbidities and mortalities, testing of the new brands, which would be very long-term lasting numerous years would be highly problematic and questionable. In the meantime, the current market would be maintained.

Another glaring example of the problem with this idea of supposedly safer cigarettes in title I is the provision to ban all additives except menthol. Why is there this significant disparity in standards in banning additives that are all known to unduly entice smokers to smoke particular brands? This is illustrative of how uncertain actual agreement is on what constitutes a supposedly safer cigarette.

In fact, if there were such a thing as a safer cigarette, the shorter title II of this proposed bill requiring stronger warning labels would not be necessary. Either a cigarette is safer or there is no need for larger warning labels, but not both. While much of title I can not currently be justified, at a minimum, in order to mitigate one very severe problem with title I, I would recommend that this committee remove by amendment the provision that allows the use of menthol as an additive.

This legislation also provides a significant litigation shield (along with provisions of title II, discussed below) that can be presented to future juries that there are now supposedly stricter product standards (along with larger and clearer warning labels). With this litigation shield consumers would have lesser basis to obtain monetary damages, particularly punitive damages. Thus this bill, which is based on a far from settled notion that cigarettes can supposedly be made safer stymies the lawful right of plaintiffs to obtain full justice in lawsuits. I recommend that this committee ensure that clear language in this law require that this legislation can not be used to justify undue lesser legal damages, particularly punitive damages, in product liability and tort lawsuits.

Title II of this bill does approximate current scientific public health recommendations for warning labels, except the strongest labeling requirements also require graphic color pictures depicting four major diseases due to smoking. These diseases include: heart disease, stroke, lung cancer in smokers, and lung cancer in non-smokers. The current legislation makes this a discretionary requirement. This is an important public health consideration as recent research indicates that the strongest approach to cause smoker cessation or smoker consideration of cessation occurs when all diseases are graphically shown on large warning labels. I recommend that this committee make color graphics tied to the four major diseases related to smoking a mandatory and not discretionary requirement.

The legislation also substantially preempts State and local control in the following areas: tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified risk tobacco

products. In addition, section 906 (3) (ii), of this bill preempts State authority to restrict the minimum age of sale of tobacco products to no one older than 18. This is an unprecedented advance of Federal power at the expense of State and local governments. Several States, which have enacted innovative regulatory requirements in such areas as adulteration of cigarette products would have their legislative autonomy and authority significantly superceded by this legislation. I recommend to this committee that the clause preempting State and local rights be removed.

Title III addresses another important issue with respect to smuggling calling for stronger labeling and tracking of tobacco products. However, this can be easily circumvented with counterfeit labels and packaging as has been done in the past so this is a very weak provision. This provision needs to be reconsidered with respect to more aggressive anti-smuggling policies such as stepped up border enforcement efforts and equivalence in tobacco tax policies and rates that do not encourage smuggling from the United States to bordering countries like Canada or visa versa.

Finally, due to the glaring deficiencies in various key premises of this legislation, unfortunately this proposed law will not significantly reduce tobacco use in the United States. Instead, it will ironically create a stable and thriving adult tobacco market through the FDA regulatory framework into the far future that unduly sanctions tobacco products as "safe" while removing greater legal liability and State and local authority to pass more stringent legislation. There is no conclusive evidence that this legislation will significantly save lives or reduce disease. What this legislation will do is convince current and new smokers into believing that cigarettes are supposedly safer with a likelihood of even stabilizing or increasing consumption to the detriment of the public health.

I strongly urge this committee to either defeat this bill or in the alternative significantly amend and correct this bill so that true progress can be made in reducing tobacco consumption.

Thank you for this opportunity to allow me to present my written testimony to this committee.

PREPARED STATEMENT OF WILLIAM T. GODSHALL, M.P.H., EXECUTIVE DIRECTOR, SMOKEFREE PENNSYLVANIA, PITTSBURGH, PA

Smokefree Pennsylvania is a nonprofit organization founded in 1990 whose goals include protecting people from the involuntary exposure to tobacco smoke pollution, reducing tobacco marketing to youth, increasing cigarette prices, preserving civil justice remedies for injured tobacco victims, and increasing tobacco prevention and cessation services.

Smokefree Pennsylvania strongly opposes the introduced version of S. 625, the "Family Smoking Prevention and Tobacco Control Act" that would authorize the U.S. Food and Drug Administration (FDA) limited regulatory jurisdiction over tobacco products.

In sum, Smokefree Pennsylvania opposes the current text of S. 625 because it would:

- mislead the public into believing FDA regulation reduces tobacco products risks,
- protect cigarettes from market competition by less harmful smokeless tobacco products,
- increase Philip Morris' 51 percent cigarette market share, as well as Marlboro's market share,
- increase inaccurate public beliefs that smokeless products are as hazardous as cigarettes,
- encourage FDA to set cigarette emission standards based upon inaccurate machine tests,
- increase inaccurate public beliefs that certain cigarettes are less hazardous than others,
- mandate counterproductive and/or ineffective warning labels on tobacco products,
- fail to adequately inform consumers of comparable risks of different tobacco products,
- prohibit harm reduction marketing of lower risk smokeless products to smokers,
- do very little, if anything, to reduce cigarette-caused disease, disability and death,
- allow tobacco manufacturers and others to promote cigarettes as FDA approved,
- severely limit the FDA's authority to issue effective tobacco product regulations, and
- reduce cigarette manufacturer liability by misleading potential jury pools.

REDUCING HEALTH RISKS OF FUTURE TOBACCO PRODUCTS

Effective regulations gradually phase out the most hazardous products, and encourage the development of and transition to lower risk products. Effective product regulations also adequately inform consumers of relative and comparable product risks. In sharp contrast, S. 625 protects the most hazardous tobacco product (cigarettes), the largest cigarette company (Philip Morris) and the largest cigarette brand (Marlboro) from market competition from far less hazardous noncombustible tobacco products by misleading consumers to incorrectly believe that smokeless tobacco products are just as hazardous as cigarettes, and by prohibiting truthful harm reduction marketing claims by smokeless tobacco products that are directed towards already addicted cigarette smokers.

Cigarettes kill 50 percent of addicted smokers, and up to 63,000 American nonsmokers annually (from secondhand smoke and fires). In contrast, smokeless tobacco kills about 1 percent of addicted users, and ZERO nonusers. Swedish smokeless (snus) and other new low nitrosamine noncombustible tobacco products pose even fewer risks. Smokers who switch to smokeless products can sharply reduce their disease and death risks.

But S. 625 perpetuates the myth/fraud that noncombustible tobacco products are just as hazardous as cigarettes by requiring larger labels on smokeless packs and advertisements that state: "This product is not a safe alternative to cigarettes," and by failing to inform smokers (e.g., via labels on cigarette packs and advertisements) that smokeless tobacco products pose fewer morbidity and mortality risks than cigarettes. If U.S. Congress is sincere about truthfully informing consumers about the health risks of different tobacco products, this misleading warning MUST be removed from smokeless tobacco products.

S. 625 also could be improved if FDA was encouraged to approve clean nicotine products (e.g., skin patches, gum, lozenges, inhalers) for nicotine maintenance instead of just for temporary use as a smoking cessation aid. Shiffman et al. found that 36.6 percent of nicotine gum users consumed the product for longer than 6 months, despite the product warning urging discontinued use after 12 weeks. Clean nicotine products are far less hazardous than relapsing to cigarettes, and should be approved for nicotine maintenance.

Although Section 911 of S. 625 includes provisions for FDA to approve the marketing of "modified risk tobacco products," it is highly unlikely that any product would be approved since any manufacturer applying for FDA approval for a modified risk product would need to demonstrate that the product wouldn't discourage smokers from quitting tobacco use and wouldn't result in use by nontobacco users. Besides, the Campaign for Tobacco Free Kids, American Cancer Society and other proponents of S. 625 have repeatedly alleged that the marketing of smokeless tobacco products for harm reduction discourages smokers from quitting and encourages youth to begin using those products.

In contrast, Section 911(g)(2) of S. 625 would allow a cigarette manufacturer to apply for and receive FDA approval for "an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke." This clause could very likely result in the FDA approving the marketing of a "reduced exposure" cigarette even if the cigarette is as hazardous as other cigarettes. Even worse, the marketing of an FDA approved "reduced exposure" cigarette is likely to confuse smokers into believing that the product is less hazardous than other cigarettes.

CIGARETTE MACHINE TESTING METHODS ARE INACCURATE, AND ONLY SERVE TO MISINFORM

Effective product regulations also protect consumers from health frauds. Although S. 625 eliminates cigarette brand descriptors "Light," "Low-Tar" and "Mild," (which arguably is the deadliest consumer fraud of the 20th century), consumers of these products would barely notice this change because these brands would remain on the market in their easily recognized package designs and colors (minus one word). Marlboro Lights, which has the largest market share of any cigarette, would simply become known as Marlboro Gold, while Marlboro Ultralights would simply become known as Marlboro Ultras or Marlboro Silver. Meanwhile, S. 625 does nothing to warn smokers that the brands previously named "Lights" and "Ultralights" are just as hazardous as other cigarettes.

But far more troublesome, S. 625 authorizes the FDA to establish cigarette emission standards for various smoke constituents based upon inaccurate smoking machine testing methods similar to the notorious FTC smoking machine tests that were partly responsible for creating the 35-year-old consumer fraud that duped

smokers into believing that Low-Tar, Light and Ultralight cigarette brands were less hazardous than other cigarettes.

Although a recent study by the Harvard School of Public Health concluded that cigarette companies have increased the nicotine yields of cigarettes by about 10 percent during the past decade leading some news reports to claim that cigarettes are now more addictive, that same study also concluded that (during the past decade) nicotine yields of Light brands were about 25 percent less than those of Full Flavor brands, and that nicotine yields of Ultralight brands were about 30 percent less than those of Light brands. But in fact, all cigarettes are similarly and quite adequately addictive. The fundamental problem with the Harvard study is that it relied upon another inaccurate smoking machine testing method somewhat similar to the defective FTC testing method.

Hammond *et al.* recently evaluated the accuracy of the International and Canadian cigarette machine testing methods, and concluded that neither of those machine testing methods are accurate, and that NO machine testing method should be relied upon for establishing government regulatory standards for cigarette smoke emissions.

Besides, cigarette smoke contains more than 50 carcinogens and 3,000 other constituents. So even if an accurate FDA machine testing method is devised (which doesn't appear viable), an FDA product standard that reduces or removes one, two or a few chemicals or carcinogens from cigarette smoke would not reduce the overall health risks of cigarettes.

Any FDA product standard for cigarettes almost certainly would be perceived by smokers and the public as making cigarettes less hazardous, which could discourage smokers from quitting and could encourage youth and ex-smokers to begin smoking.

S. 625 also authorizes the FDA to reduce nicotine levels in cigarettes, and some supporters of S. 625 have advocated mandatory nicotine levels reductions in cigarettes. Yet, there is broad scientific consensus that smokers of cigarettes with purportedly lower nicotine yields simply puff more intensely, take more puffs and/or smoke more cigarettes in order to obtain a similar level of nicotine that they are accustomed to receiving, which is known as "nicotine compensation." As such, smokers of purportedly lower nicotine yield cigarettes inhale greater quantities of smoke, which increases their disease risks.

Thus, it would be counterproductive for public health if the FDA mandated reductions in nicotine, because doing so could make cigarettes even more hazardous. If the FDA were to require any changes in nicotine content (assuming that an accurate machine testing method could be developed), it would be better for public health to require higher levels of nicotine in cigarettes, because smokers would inhale less cigarette smoke.

CONSTITUTIONAL CONCERNS ABOUT S. 625

Another concern with S. 625 is that some of its tobacco advertising restrictions are virtually certain to be struck down by the Supreme Court for violating a manufacturer's first amendment right to advertise to its adult customers. That is precisely why in 2001 the Supreme Court (in *Lorillard Tobacco Co.* v. *Reilly*) struck down a Massachusetts regulation that prohibited outdoor tobacco advertisements within 1,000 feet of a school or playground. And yet, a similar 1,000 foot outdoor advertising restriction is contained in S. 625.

DENYING FDA AUTHORITY TO EFFECTIVELY REGULATE TOBACCO PRODUCTS

Effective product regulations also allow regulatory agencies unfettered authority to issue regulations that reduce use of and access to the most hazardous products. But S. 625 prohibits the FDA from issuing many of the most effective regulations that could reduce cigarette usage, especially among youth, including prohibiting the FDA from:

- increasing the minimum age to purchase cigarettes beyond 18 years;
- eliminating cigarette sales from any type of retail outlet;
- requiring prescriptions to buy cigarettes (as FDA requires for other hazardous drugs);
- removing nicotine from cigarettes; and
- eventually removing cigarettes from the market.

While these restrictions limiting the FDA's authority to regulate tobacco in S. 625 are not necessarily opposed by Smokefree Pennsylvania, our organization is nevertheless concerned that their inclusion in S. 625, along with the many truly counterproductive provisions that were previously cited, have severely compromised this legislation.

The following report compares the health risks of different tobacco products and recommends the only viable tobacco product and policy harm reduction strategy for smokers who are not ready or willing to quit tobacco use; providing truthful comparable product risk information, and encouraging switching to a smokeless tobacco product. *http://www.harmreductionjournal.com/content/3/1/37.*

TOBACCO HARM REDUCTION: AN ALTERNATIVE CESSATION STRATEGY FOR INVETERATE SMOKERS

BRAD RODU [1] AND WILLIAM T. GODSHALL [2]
(HARM REDUCTION JOURNAL 2006)

ABSTRACT

According to the Centers for Disease Control and Prevention, about 45 million Americans continue to smoke, even after one of the most intense public health campaigns in history, now over 40 years old. Each year some 438,000 smokers die from smoking-related diseases, including lung and other cancers, cardiovascular disorders and pulmonary diseases.

Many smokers are unable—or at least unwilling—to achieve cessation through complete nicotine and tobacco abstinence; they continue smoking despite the very real and obvious adverse health consequences. Conventional smoking cessation policies and programs generally present smokers with two unpleasant alternatives: quit, or die.

A third approach to smoking cessation, tobacco-harm reduction, involves the use of alternative sources of nicotine, including modern smokeless tobacco products. A substantial body of research, much of it produced over the past decade, establishes the scientific and medical foundation for tobacco-harm reduction using smokeless tobacco products.

This report provides a description of traditional and modern smokeless tobacco products, and of the prevalence of their use in the United States and Sweden. It reviews the epidemiologic evidence for low health risks associated with smokeless use, both in absolute terms and in comparison to the much higher risks of smoking. The report also describes evidence that smokeless tobacco has served as an effective substitute for cigarettes among Swedish men, who consequently have among the lowest smoking-related mortality rates in the developed world. The report documents the fact that extensive misinformation about ST products is widely available from ostensibly reputable sources, including governmental health agencies and major health organizations.

The American Council on Science and Health believes that strong support of tobacco-harm reduction is fully consistent with its mission to promote sound science in regulation and in public policy, and to assist consumers in distinguishing real health threats from spurious health claims. As this report documents, there is a strong scientific and medical foundation for tobacco-harm reduction, and it shows great potential as a public health strategy to help millions of smokers.

I. BACKGROUND

According to the Centers for Disease Control and Prevention (CDC), about 45 million Americans continue to smoke [1], even after one of the most intense public health campaigns in history, now over 40 years old. Some 438,000 smokers die from smoking-related diseases each year, including lung and other cancers, cardiovascular disorders and pulmonary diseases [2].

There is clear evidence that smokers of any age can reap substantial health benefits by quitting. In fact, no other single public health effort is likely to achieve a benefit comparable to large-scale smoking cessation. Surveys document that most smokers would like to quit, and many have made repeated efforts to do so. However, conventional smoking cessation approaches require nicotine-addicted smokers to abstain from tobacco and nicotine entirely (as discussed later, use of nicotine replacement medications is limited to 10–12 weeks, per labels required by Federal regulations). Many smokers are unable—or at least unwilling—to achieve this goal, and so they continue smoking in the face of impending adverse health consequences. In effect, the status quo in smoking cessation presents smokers with just two unpleasant alternatives: quit or die.

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[1] Professor of Medicine and Endowed Chair, Tobacco Harm Reduction Research, School of Medicine, University of Louisville, KY, USA.
[2] Founder and Executive Director, Smokefree Pennsylvania, Pittsburgh, PA, USA.

There is a third choice for smokers: tobacco-harm reduction. It involves the use of alternative sources of nicotine, including modern smokeless tobacco (ST) products, by those smokers who are unable or unwilling to quit tobacco and nicotine entirely. The history of tobacco-harm reduction may be traced back to 1974, with the publication of a special article in the *Lancet* by British tobacco addiction research expert Michael A.H. Russell [3]. Citing the "high dependence-producing potency and the universal appeal of the effects of nicotine" on smokers, Russell likened "harsher restrictive measures" and "intensification" of anti-smoking efforts to "flogging a dead horse harder." Russell believed that "the goal of abstinence and the abolition of all smoking is unrealistic and doomed to fail."

Six years later Russell's research group compared nicotine absorption rates from various tobacco products, which led them to suggest that nasal snuff use could serve as an effective substitute for cigarette smoking [4]. This article was cited shortly thereafter by a short letter in a leading American medical journal [5]. Russell et al., published followup studies on nasal snuff in 1981 [6] and on an oral ST product in 1985 [7]. Lynn Kozlowski, a prominent American smoking and nicotine addiction expert at Penn State University, noted in 1984 and 1989 that ST products conferred fewer risks to users and therefore might serve as effective substitutes for cigarettes [8, 9]. In 1994 oral pathologist Brad Rodu and epidemiologist Philip Cole from the University of Alabama at Birmingham made quantitative comparisons of the risks from oral ST use and smoking in a series of studies [10–13]. Some of that work was summarized in a 1995 ACSH publication [14].

A substantial body of research over the past decade has been transformed into the scientific and medical foundation for tobacco-harm reduction, the substitution of safer sources of nicotine, including tobacco products, by those smokers who are unable or unwilling to achieve nicotine and tobacco abstinence. In 2001 the Institute of Medicine, a subsidiary of the National Academy of Sciences, provided a now widely accepted definition of a harm reduction product as "harm reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants" [15]. The purpose of this report is to review the evidence for tobacco-harm reduction.

II. THE STATUS QUO: CIGARETTE SMOKING

A. Prevalence

At first glance, the United States (U.S.) appears to be the quintessential example of the slow but substantial decline of cigarette smoking in the developed world. Smoking prevalence in the United States has decreased since at least the mid-1960s, following landmark reports from the Royal College of Physicians of London in 1962 and the U.S. Surgeon General in 1964. Smoking among men was 52 percent in 1965 [16], dropping to 23 percent by 2004 [1]. Prevalence among women declined from 34 percent in 1965 to 19 percent in 2004. In 1965, only 44 percent of American adults had never smoked and 14 percent were former smokers; by 2004, those percentages had increased to 58 percent and 21 percent respectively.

But declining prevalence overshadows the fact that, with population growth, the absolute number of smokers in the United States remained relatively constant at 45 to 50 million over the entire period. Heavily-addicted, or inveterate, smokers are resistant to conventional cessation strategies emphasizing tobacco and nicotine abstinence. Today's smoking population has a higher proportion of heavy smokers than in the past, and the National Cancer Institute (NCI)-funded Community Intervention Trial for Smoking Cessation underscores the challenges facing them [17]. Perhaps the most intensive cessation trial ever conducted, this 4-year effort had no effect on cessation among heavy smokers. The published report called the intervention "disappointing but consistent with the findings of most other community studies . . .", and it described heavy smokers as "more resistant to change. Reaching these smokers may require new clinical programs and public policy changes."

B. Health effects

Cigarette smoking remains the single most important avoidable cause of death in the developed world. The CDC reports that smoking is responsible for 438,000 deaths in the United States annually [2], a figure which has changed little over the last 15 years.

Cigarette smoking was responsible for a large proportion of the increase in cancer mortality in the second half of the 20th Century, a trend with important social consequences, including the widespread misperception that the United States was being consumed by a "cancer epidemic" caused by environmental pollution and industrial chemicals. In fact, the "epidemic" consisted almost exclusively of one disease, lung cancer, and was due to one lifestyle factor, cigarette smoking. A retrospective anal-

ysis of mortality statistics revealed that, if lung cancer is excluded, the mortality rate from all other forms of cancer combined has declined continuously since 1950 [18].

The first reports linking lung cancer to cigarette smoking were published over 50 years ago [19, 20]. In 2006 there will be 175,000 new cases of lung cancer in the United States, with a 5-year survival rate of just 15 percent [21]. The CDC estimates that smoking causes 142,000 deaths per year from lung cancer [2]. Smoking is a risk factor for other malignancies, including cancers of the oral cavity and pharynx, larynx, esophagus, stomach, bladder, kidney, pancreas, uterine cervix and leukemia [2].

According to the CDC, smoking causes 132,000 deaths per year from cardiovascular diseases, including heart attacks, strokes, atherosclerosis and aortic aneurysms [2]. Smoking also causes 103,000 deaths per year from pulmonary diseases such as pneumonia, influenza, bronchitis and chronic airway obstruction [2].

While many Americans are aware that cigarette smoking causes cancer, cardiovascular and respiratory diseases, most are not aware that it also increases risks for neurological disorders, reproductive complications, cataracts and other eye diseases, premature aging of the skin, osteoporosis and other orthopedic and rheumatologic problems, psychiatric disorders and surgical complications [22]. Recent studies have also linked smoking to the development of type 2 diabetes [23–25].

C. Stagnation

As Russell noted 30 years ago, "There is little doubt that if it were not for the nicotine . . . people would be little more inclined to smoke than they are to blow bubbles or light sparklers" [3]. Nicotine fulfills all the criteria of an addictive agent, including psychoactive effects, drug-reinforced behavior, compulsive use, relapse after abstinence, physical dependence, and tolerance. Nicotine stimulates specialized receptors in the brain which produce both euphoric and sedative effects. It has been known for many years that nicotine shares many features of drug dependence with opioids, alcohol and cocaine. This includes similar disappointing patterns of relapse [26].

It is for this reason that most attempts at smoking cessation are not successful, despite the fact that the majority of smokers are aware that smoking is harmful to their health, and so would like to quit. It is clear that most smokers would rather quit on their own, and 90 percent of successful quitters use self-help methods because of limited access to and cost of formal cessation programs [27].

Formal cessation programs have existed for decades and have grown more complex and sophisticated, but relapse rates remain very high. According to a 2006 National Institutes of Health (NIH) Consensus Conference on Tobacco Use, "70 percent [of smokers] want to quit and 40 percent make a serious quit attempt each year, but fewer than 5 percent succeed in any given year" [28]. The conference press release went on to make an astounding admission, "Effective tobacco cessation interventions are available and could double or triple quit rates . . ." This means that fewer than 15 percent of existing smokers, no more than 7 million, would be successful with maximum application of existing cessation strategies. The consensus statement failed to answer a vital question: What can be done for the remaining 40 million adult smokers? The rest of this report will review the scientific rationale and evidence for tobacco-harm reduction as an alternative for these smokers.

III. SMOKELESS TOBACCO USE

A. Introduction

The tobacco plant is native to the Western hemisphere, and the use of tobacco in smokeless forms (placed in the mouth or inhaled as a powder through the nose) predates the arrival and exploration of the West by Europeans. According to the historian Jan Rogozinski, the most common manufactured tobacco product in Europe until the early 1800s was a compressed plug or cake [29]. This product was relatively simple to produce and was amenable to transport and storage. The plug could be cut into large pieces for chewing, grated into smaller pieces for smoking, or ground into a fine powder for nasal inhalation. Smokeless forms were the favored method of use because a day's supply could be carried and conveniently used in industrial and agricultural work settings.

ST was the dominant form of tobacco used in the United States until early in the 20th century [29]. Developments in tobacco cultivation, curing and manufacturing, along with the invention of the safety match, resulted in the increased popularity of cigarettes. In addition, at the beginning of the 20th century tobacco spit inaccurately was believed to transmit tuberculosis, so bans on public spitting and spit-

toons resulted in a decline in ST use. The transmission of tuberculosis now has been understood for decades, and it does not include expectoration [30].

Use of all types of ST traditionally has been most prevalent in Southern States and in rural areas throughout the United States.

B. Types of ST

As described below, ST is currently used by only a small proportion of American tobacco users. This is one reason that most Americans, including smokers, know almost nothing about ST products, or—even worse—are completely misinformed about even basic product characteristics. Thus, it is important to understand what these products are and how they are used.

ST products are not burned but instead are placed in the cheek or between the lip and gum. ST is used in many countries around the world, including those in the Middle East and on the Indian subcontinent. However, ST products in those regions are considerably different from those used in the West. For example, in India ST products are made by individual farmers and small companies with little control over fermentation and curing, which affects the production of potential carcinogens called tobacco-specific nitrosamines (TSNAs) [31]. In India ST is often combined with betel leaf (*Piper betle*), sliced areca nut (*Areca catechu*) and/or powdered agricultural lime [32], additives that enhance the toxicity as well as the psychotropic effect of tobacco [33, 34]. In addition, Indian ST users often smoke concurrently, which complicates efforts to assess the health effects of ST use [35, 36].

This report will focus on ST products used in Western societies, mainly the United States and Sweden. But ST is not a homogeneous category, even in these countries. Three traditional types of ST are used in the United States: powdered dry snuff, loose leaf chewing tobacco and moist snuff, and it is important to understand the differences among them with respect to their manufacturing and characteristics, the populations that consume them, and the consequential health risks, especially mouth cancer.

Powdered Dry Snuff

Dry snuff is made from fermented, fire-cured tobacco that is pulverized into powder. Nasal inhalation of dry snuff was widely practiced in Europe in the 17th and 18th centuries but declined thereafter [37]. Manufacturers in Germany and the United Kingdom still provide an array of flavored dry snuff products for a small number of contemporary users in those countries. In the United States powdered dry snuff, also called dental or Scotch snuff, is sold in small canisters. Since the early 1800s it has been used primarily by women in Southern States [29,38], who place the powder on the gum or between the gum and cheek. However, use of dry snuff is declining, and sales have fallen 67 percent in the past 15 years [39].

Figure 1

Loose Leaf Chewing Tobacco

Loose-leaf chewing tobacco consists of air-cured leaf tobacco from Pennsylvania and Wisconsin that is shredded, coated with sweet flavoring solutions and packaged in foil-lined pouches. It is consumed primarily by men in the United States, commonly in conjunction with outdoor activities. Chewing tobacco is typically used in large volumes, resulting in the archetypical golf ball-sized bulge in the user's cheek and large quantities of saliva that users usually expectorate. Consequently, the popularity of this product has waned, with consumption declining gradually over the past century, dropping by about 44 percent in just the last 15 years [39].

Figure 2

Moist Snuff

Moist snuff consists of fire- and air-cured dark tobaccos that are finely cut or ground. It is packaged in round containers, and the user compresses a "pinch" between the thumb and forefinger and places it inside the lip. Much less bulky than loose leaf chewing tobacco, moist snuff produces less saliva, but expectoration is still common. It is now the most popular form of ST in the United States; sales of this product increased by 66 percent over the past 15 years [39].

In addition to the United States, there is a long tradition of moist snuff use in Scandinavia, especially in Sweden, where "snus" (the generic term for moist snuff in Swedish, pronounced "snoose") is essentially the only type of ST product in use [40]. There are differences in how American and Swedish moist snuff products are manufactured. Traditional American products undergo fermentation, which imparts characteristic flavors but in the past resulted in higher concentrations of unwanted bacterially mediated by-products, especially TSNAs and nitrite. In Sweden, moist snuff is subjected during manufacturing to a heat treatment akin to pasteurization, yielding virtually sterile products containing very low levels of TSNAs. However, manufacturing refinements over the past 25 years have resulted in lower TSNAs in both Swedish and American products. A 1997 report by the Swedish National Board of Health and Welfare reported that TSNA concentrations in both Swedish and American ST brands had declined substantially [41]. The report concluded:

"Recent data suggest that the differences [in TSNA levels reported in American and Swedish ST] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks—at least where TSNA content is concerned."

A separate section of this report will discuss how the high prevalence of snus use in Sweden has played an important role in the low prevalence of smoking, especially among men.

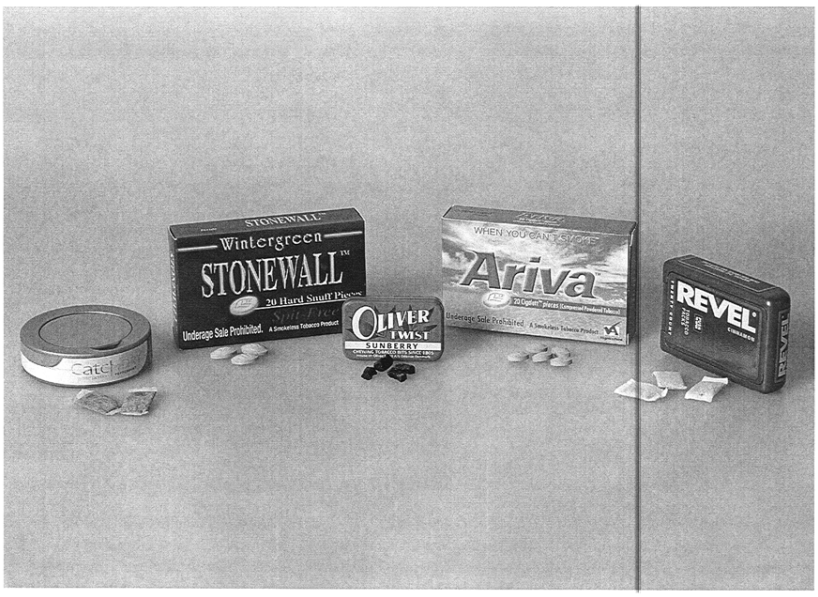
Figure 3

Modern ST Products

Over the past few years several ST products have emerged that are not easily classified into one of the previous groups. In fact, one reason for the popularity of moist snuff is that manufacturers have gradually refined the products in this category to be more user-friendly. The traditional pinch of moist snuff is difficult to keep in place, and the resultant migration is esthetically displeasing. Modern moist snuff products are sold in pre-portioned pouches similar to teabags, but much smaller. Because these products remain stationary in the mouth and generate very little juice, they can be used discreetly with no expectoration. There is a recent trend among manufacturers to offer even smaller pouches that are dry, with a wide range

of non-tobacco flavors. Other products in this category consist of small pieces of leaf tobacco and pellets of compressed tobacco that dissolve completely. These products all share one important characteristic: they are of sufficiently small size that can be used invisibly, and without expectoration.

Figure 4



C. PREVALENCE

The prevalence of ST use has not received nearly as much attention as that of smoking, but adult prevalence has been documented by the National Health Interview Survey (NHIS). For adults, NHIS defines current ST users as those individuals who have used ST at least 20 times in their lives and are using ST every day or some days. In 1991 the prevalence of current ST use among adult men in the United States was about 5.6 percent (4.8 million), which declined to 4.4 percent (4.4 million) in 2000. In 1991 about 0.6 percent (533,000) of adult women in the United States were current users, and prevalence declined to 0.3 percent (324,000) by 2000 [42, 43].

In 2000 the prevalence of ST use was higher among men age 18–44 years (6 percent) than among those age 45+ years (3 percent). Men in the Southern United States had the highest prevalence (7 percent) and those in the Northeast had the lowest (2 percent). As with smoking, prevalence of ST use was higher among men with a high school education or less. Finally, higher male prevalence was seen in rural areas (9 percent), compared with urban areas (3 percent) [43].

In the United States the number of male smokers is tenfold higher than the number of ST users, so it follows that concurrent use of both products is common among ST users, but rare among smokers. About 25 percent of men who use ST report concurrent smoking, whereas concurrent use occurs in fewer than 5 percent of men who smoke [44]. Cigarette consumption is considerably lower in combined users compared with exclusive smokers [45–47].

D. HEALTH EFFECTS

1. Oral leukoplakia

Oral leukoplakia is an ominous sounding term used frequently in discussions about ST use. The term literally means "white plaque," and it is used to describe areas of the mouth lining that become thickened by ST use or smoking. The World Health Organization has determined that leukoplakias resulting from ST use are considerably different from those resulting from smoking. The distinctions are based

on the frequency of occurrence, the location in the mouth, and how often these leukoplakias result in mouth cancer [48, 49].

The condition is rare, occurring in less than 1 percent of the general population, primarily in long-time smokers 40 to 60 years old [50, 51]. Smoking-related leukoplakias most commonly involve the undersurface of the tongue and throat area, locations that account for 75 percent of oral cancer in the United States [51, 52].

Oral leukoplakias occur in up to 60 percent of ST users [53, 54], within 6 months to 3 years of starting ST use [55, 56]. They primarily occur at the site of ST use and are largely a result of local irritation [55, 57]. The frequency of appearance depends on the type of ST that is used. Moist snuff, which is more alkaline than chewing tobacco, more often leads to leukoplakia [56]. However, moist snuff in preportioned pouches causes fewer cases of leukoplakia than does the loose form [58].

There are distinct differences in how often ST and smoking leukoplakias show pre-cancerous changes called dysplasia. Dysplasia is seen infrequently in ST leukoplakias (less than 3 percent) [49, 59–61]. Furthermore, even when dysplasia is present in ST leukoplakia, it usually is found in earlier stages than in leukoplakias due to smoking [62, 63] where it is seen in about 20 percent of cases [64].

ST leukoplakias only rarely progress to cancer. For example, one prospective study found no case of cancer in 1,550 ST users with leukoplakia who were followed for 10 years [65], and a second study reported no case of oral cancer among 500 regular ST users followed for 6 years [66]. A retrospective study of 200,000 male snuff users in Sweden found only one case of oral cancer per year, an extremely low frequency [67]. In comparison, a followup study reported that 17 percent of smoking leukoplakias transformed into cancer within 7 years [68].

In conclusion, oral leukoplakia occurs commonly in ST users, but it primarily represents irritation and only very rarely progresses to oral cancer.

2. Oral cancer

ST use has been associated with oral cancer for many decades. It is widely perceived—both by laypersons and medical professionals—that the association is strong and applies to all ST products. However, epidemiologic studies dating back to the 1950s provide convincing evidence that most ST products increase oral cancer risks only minimally.

Rodu and Cole reviewed 21 epidemiologic studies published from 1957 to 1998 [69]. Unlike previous reviewers, these authors derived relative risk (RR) estimates for cancers of the mouth and associated upper respiratory sites related to use of chewing tobacco, moist snuff, dry snuff and a fourth category in which the type of ST was unclear or undetermined (ST unspecified). This study found that use of chewing tobacco and moist snuff were associated with only minimally elevated risks, while use of dry snuff conferred somewhat higher risks.

Chewing tobacco has been studied at least once in each of four decades from the 1960s to the 1990s. The data clearly show that chewing tobacco use is associated with only slightly elevated cancer risks; RRs for all anatomic sites are under 2 with confidence intervals including 1 (i.e. the risk elevation was not statistically significant) (Table 1). The first study evaluating the risk of chewing tobacco appeared in 1962 [70]. There were two studies in 1977 [71, 72], two in 1988 [73, 74], and four studies from 1993 to 1998 [75–78].

Table 1.—Chewing Tobacco and Cancer of the Mouth and Upper Respiratory Sites

Anatomic Site	RR (95 percent CI)	Studies	Cases/Controls
Oral cavity	0.6 (0.3–1.3)	2	283/296
Pharynx			
Oral cavity + pharynx	1.1 (0.8-1.6)	4	2113/4454
Larynx	1.3 (0.9–1.8)	1	387/2560
Oral + pharynx + larynx	1.7 (1.2–2.4)	2	362/457
All sites	1.2 (1.0–1.4)	8	3145/5245

As with chewing tobacco, summary RRs are only slightly elevated for moist snuff, with three RRs at or below 1 and the highest RR at 1.2 (Table 2). RRs for moist snuff were reported first in 1977 [71]. Another study appeared in 1988 [74], and five additional studies were published from 1993 to 1998, as this ST type came under intense scrutiny [75–79].

Table 2.—Moist Snuff and Cancer of the Mouth and Upper Respiratory Sites

Anatomic Site	RR (95 percent CI)	Studies	Cases/Controls
Oral cavity	1.1 (0.8–1.6)	2	482/995
Pharynx	0.7 (0.4–1.4)	1	138/641
Oral cavity + pharynx	0.7 (0.4–1.2)	3	1682/3931
Larynx	1.2 (0.9–1.7)	2	544/3201
Oral + pharynx + larynx			
All sites	1.0 (0.8–1.2)	5	2846/4926

Two of the seven studies on moist snuff were Swedish, both appearing in 1998 [78, 79]. These studies have received considerable attention among tobacco researchers, particularly in Europe, because they are viewed as showing no oral cancer risk for Swedish products. They formed the basis for the Swedish government's decision in 1999 to recommend that the European Union (EU) oral cancer warning labels be removed from ST products. An EU directive in 2001 accomplished that objective and specified a new warning, "This tobacco product can damage your health and is addictive" [80]. Notably, the other five studies contributing to the summary RRs for moist snuff were American, and they reported RRs very similar to those of the Swedish studies.

Summary RRs for dry snuff use are higher, ranging from 4 to 13, although the confidence intervals for these estimates are wide (Table 3). The first study appeared in 1962 [70], followed by studies in 1981 [81], 1988 [73], and 1994 [76], spanning a period of 32 years.

Table 3.—Dry Snuff and Cancer of the Mouth and Upper Respiratory Sites

Anatomic Site	RR (95 percent CI)	Studies	Cases/Controls
Oral cavity			
Pharynx			
Oral cavity + pharynx	4.0 (2.7–5.9)	3	298/947
Larynx			
Oral + pharynx +larynx	13 (8.0–20)	1	93/393
All sites	5.9 (1.7–20)	4	391/1340

RRs for ST-unspecified range from 1.5 to 2.8, and most are statistically significant. For all sites the summary RR is 1.9 (CI = 1.5–2.3), which is intermediate between the low risks reported for chewing tobacco (1.2, 1.0–1.4) or moist snuff (1.0, 0.8–1.2) and the higher risk for dry snuff (5.9, 1.7–20) (Table 4). The intermediate risks for this ST category probably reflect the use of either the lower- or higher-risk products among different groups within the studies. Eight studies provided RRs for ST-unspecified, five of which appeared between 1957 and 1969 [82–86]. Additional studies appeared in 1992 [87], 1993 [75] and 1998 [88].

Table 4.—ST-Unspecified and Cancer of the Mouth and Upper Respiratory Sites

Anatomic Site	RR (95 percent CI)	Studies	Cases/Controls
Oral cavity	2.8 (1.9–4.1)	4	581/798
Pharynx	2.3 (1.2–4.4)	3	169/472
Oral cavity + pharynx	1.5 (1.1–2.0)	3	655/2718
Larynx	1.8 (0.3–9.3	1	23/100
Oral + pharynx +larynx			
All sites	1.9 (1.5–2.3)	7	1428/3681

Tables 1 to 4 are adapted from [69].

Prior to the 2002 analysis by Rodu and Cole, the distinctive risk profiles of moist snuff and chewing tobacco on one hand, and dry snuff on the other, had gone unnoticed. In fact, the low oral cancer risk associated with chewing tobacco had been discussed briefly in only one article [89]. No distinction in risks had been made previously between dry snuff and moist snuff, even though these products are considerably different with regard to tobacco content and processing, as noted earlier.

The majority of epidemiologic studies regarding ST and oral cancer have limitations, many of which are typical for case-control studies, and some important for understanding unique oral cancer risks. Most of them did not control for confounding by two strong determinants of oral cancer, cigarette smoking and alcohol use. Posi-

tive confounding by smoking would occur if ST users smoke more than do nonusers of ST. This would result in artificially high-risk estimates for oral cancer among ST users. On the other hand, negative confounding is plausible and would occur if smoking rates are lower among ST users than among nonusers of ST. This would result in artificially low risks for oral cancer among ST users.

Only three studies [78, 79, 81] controlled for alcohol use, where only positive confounding is likely. Thus, control for alcohol consumption in all studies probably would have reduced, somewhat, many of the estimates of mouth cancer risk associated with ST use.

However, even with these limitations, the results of these studies are reasonably consistent with regard to mouth cancer risks from long-term use of moist snuff and chewing tobacco. In their review Rodu and Cole concluded that "the abundance of data now available indicates that commonly used ST products increase the risk of oral and upper respiratory tract cancers only minimally."

Since the 2002 review four epidemiologic studies, one from Sweden and three from the United States, have been published [90–93]. In all of these studies ST use was not associated with a significant increase in mouth cancer risk. In 2004 a group of epidemiologists concluded that the evidence linking ST use and oral cancer was "not decisive" [94]. These investigators commented that many claims in the media "overemphasize the risk of oral cavity cancer [from ST use], reaching beyond the scientific data."

In 2005 the American Cancer Society (ACS) reported that ST users did not have significantly increased risks for oral and pharyngeal cancer in either the first or the second Cancer Prevention Study [92]. Despite this finding, the ACS Web site continues to focus on ST as a cause of mouth cancer, erroneously stating that "risk of cancer of the cheek and gums may increase nearly 50-fold among long-term snuff users" [95]. A later section of this report will discuss this type of misinformation.

3. Other cancers

As noted above, cigarette smoking is associated with increased risk for several cancers in locations not in contact with cigarette smoke. In comparison, numerous epidemiologic studies have not demonstrated that ST use is associated with risk of cancer at any site outside the mouth. In 2004 Waterbor et al. assessed the epidemiologic research literature and summarized the evidence regarding ST use and cancers in various locations [94]. Table 5 shows the conclusions of Waterbor et al. with respect to cancer risks associated with ST use, compared with the established risks for smoking.

Table 5.—Risk of Cancer in Various Sites Associated with ST Use and Smoking

Cancer Site	Risks from ST Use*	Risks from Smoking**
Pharynx	No relationship	RR = 5–11
Larynx	No relationship	13–15
Lung	Inadequate	13–23
Stomach	Not persuasive	1.4–2.0
Kidney	No association	1.3–3.7
Esophagus	Not persuasive	7–8
Pancreatic cancer	Inconclusive	2.3
Bladder cancer	None	2.2–3.3

* From [94].
** Among current smokers (men and women), used by the CDC for national estimates of smoking-attributable mortality [96].

4. Cardiovascular diseases

Over the past 15 years, eight epidemiologic studies have examined the risk of cardiovascular diseases among ST users. Six of the studies found that ST users had no increased risk for heart attacks or strokes [47, 90, 97–100]. The other two reported modestly positive associations, with ST users having RRs of 1.2 and 1.4 [92, 101], which are lower than those of smokers. In 2003, Asplund completed a comprehensive review of the cardiovascular effects of ST use [102]. He concluded that, in distinct contrast to smokers, ST users do not exhibit any significant differences from nonusers of tobacco with regard to the following measures of cardiovascular health: heart rate, blood pressure, cardiac output and maximal working capacity, levels of hemoglobin and hematocrit, leukocytes, antioxidant vitamins, fibrinogen, components of the fibrinolytic system, C-reactive protein and thromboxane A2 production. In addition, ST users did not show important smoking-associated vascular changes, including increased thickness of blood vessels and atherosclerotic plaque

development. In summary, most of the medical and epidemiologic evidence documents that ST users do not have elevated risks for cardiovascular diseases.

Two studies based in Sweden have examined the impact of ST use as a risk factor for adult-onset diabetes. One of these studies found that current ST users had a slightly elevated risk (Odds ratio = 1.5, CI = 0.8–30) [103], while the other reported that the risk of diabetes in ST users was not significantly increased [104].

IV. SCIENTIFIC RATIONALE FOR HARM REDUCTION WITH ST

A. Nicotine maintenance

1. Nicotine background

Nicotine has been characterized as powerfully addictive. But nicotine itself poses little or no health hazard. For example, it does not cause emphysema or cancer [105, 106], and there is no evidence that it plays a direct role in the development of cardiovascular diseases [106, 107]. A report from a meeting at the United Nations Focal Point on Tobacco or Health concluded that "long-term nicotine use is not of demonstrated harm, with the possible exception of use during pregnancy" [108].

The U.S. Food and Drug Administration (FDA) has acknowledged the safety of nicotine replacement therapy (NRT) by allowing its sale without prescription. Long-term use of NRT has not been associated with any medical risks and is considered far less hazardous than relapsing to smoking cigarettes [109, 110], prompting authorities in the United Kingdom (U.K.) to liberalize NRT regulations there recently. The new guidelines allow NRT use by patients with cardiovascular disease, by confirmed smokers ages 12 to 17, by pregnant smokers, and concurrently by those who continue to smoke [111].

Nicotine gum was introduced in the United States in 1984 as a prescription product to assist in smoking cessation. The gum is considered to pose no consequential health hazard, and it was granted over-the-counter status by the FDA in 1996. The gum gives the user only a limited degree of control over the amount of nicotine absorbed because its nicotine content is low and only slowly released [112]. Depending on State and local excise taxes and cigarette consumption, the gum may be competitive on a per-unit basis for the smoker. However, it is available only in large quantities, making the purchase price far more expensive than that for cigarettes, a major economic disincentive. In fact, cost is the reason most frequently cited by smokers for never using NRT [113].

The nicotine patch was introduced in the United States in 1992 and was available without prescription by 1996. It continuously delivers nicotine through the skin for up to 24 hours. Although the patch is intended to preclude smoking, the rate of nicotine delivery is so low that smoking while wearing the patch is not uncommon. The patch's major limitation is its inadequate nicotine delivery, but it is not a technical problem. A high-dose nicotine patch has been evaluated and may provide complete nicotine replacement even for heavy smokers [114].

Many smokers overestimate the health risks of NRT products. A 2001 survey of 1,046 adult smokers found that 53 percent incorrectly believed nicotine causes cancer and 14 percent didn't know [115], and a 2002 survey found that half of all smokers are concerned about negative side effects of using NRT [116]. A similar problem exists in the United Kingdom, where recent research found that 69 percent of smokers believe NRT is as harmful as cigarettes.

Misconceptions are not limited to persons without medical training. Twenty-two percent of general medical practitioners in the United Kingdom are concerned that NRT is just as harmful as cigarettes, 40 percent believe that nicotine may cause cardiovascular disease and stroke, and one-quarter believe it may cause lung cancer [117].

In summary, poor nicotine delivery, high cost and misconceptions about health risks are the principal reasons that the long-term quit rate among users of non-prescription nicotine medications is only 7 percent, according to a recent meta-analysis [118].

2. Long-term use of nicotine medications

The FDA specifies that nicotine medications should not be used for more than 10 to 12 weeks. This restriction is based not on health considerations, but on a concern about prolonging nicotine addiction. Considering the limitations of nicotine medications, it is remarkable that some smokers continue to use the products beyond the 3-month period specified by the FDA. About 20 percent of those who quit smoking with nicotine gum used it for more than 1 year when it was available only by prescription [112]. A cessation study that provided free gum but encouraged weaning

after 2 months use reported that 37 percent of smoke-free subjects at 1 year were still using nicotine gum [119]. Using a liberal definition of continuous use, a recent study found that as many as one-third of current nicotine gum users have used the product for longer than 6 months [120]. That study also reported that, among persons who start to use nicotine gum, 7 percent will use it for longer than 6 months and 1 percent will continue use for over 2 years. The equivalent figures for nicotine patch were 1.7 percent and 0.05 percent respectively.

3. Nicotine concentration and availability from ST products

ST products contain nicotine at far higher concentrations than nicotine medications, and at levels that are generally acknowledged to be addictive [121, 122]. Bioavailability of nicotine from ST products is dependent on the pH of the product, since unprotonated nicotine (in more alkaline products) is absorbed more efficiently and more rapidly across the mucous membranes of the mouth than protonated forms of the drug from more acidic products. The pH-dependent absorption kinetics of nicotine is a very important reason why ST is not consumed like foods. The pH of stomach contents is very acidic, which strongly inhibits the absorption of nicotine [122]

The nicotine absorption profiles of ST products, which have been known for many years [105, 123], show both advantages and disadvantages when compared with those from smoking. Nicotine absorption from ST is somewhat slower than that from cigarettes, although the peak nicotine levels obtained in venous blood are similar [105]. In addition, elevated serum nicotine from ST use persists for much longer than that from smoking [105]. This may explain the observation that unit consumption of ST products among former smokers was much lower than prior unit consumption of cigarettes [124, 125]. In the end, ST users and smokers consume similar quantities of nicotine daily [126].

B. Comparison of risks from ST use and smoking

The established health risks associated with ST use are vastly lower than those of smoking. In the past 25 years, almost 80 peer-reviewed scientific and medical publications have acknowledged the differential risks between the two tobacco products (see *Additional File 1*).

In 1980 Michael A.H. Russell and co-workers proposed that powdered nasal snuff might serve as an effective substitute for cigarettes because it delivers nicotine effectively without the risks of tobacco combustion [4]. This article was cited shortly thereafter in a brief letter in the New England Journal of Medicine [5]. Russell et al. published followup studies on nasal snuff in 1981 [6] and on an oral ST product in 1985 [7]. Lynn Kozlowski, a prominent American smoking and nicotine addiction expert at Penn State University, noted in 1984 and 1989 that smokeless forms of tobacco conferred fewer risks to users and therefore might serve as effective substitutes for cigarettes [8, 9, 127]. Starting in 1994, University of Alabama at Birmingham researchers Brad Rodu and Philip Cole provided a quantitative assessment of the difference in risks for the two products. Using established risk estimates from accepted sources, Rodu and Cole documented that ST use confers only about 2 percent of the health risks of smoking [10–12]. In addition, they established that the average reduction in life expectancy from long-term ST use was about 15 days, compared with a reduction of about 8 years from smoking [11].

In 1994 Rodu noted that ST use posed a lower risk for mouth cancer than smoking [10]. In 2001 this was confirmed by a comprehensive report on tobacco-harm reduction by the Institute of Medicine, which stated that "the overall [oral cancer] risk [for ST use] is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk" [15].

By the late 1990s some influential organizations acknowledged the differential risks of ST use and smoking. For example, in 1997 experts meeting at the United Nations Focal Point on Tobacco or Health concluded that "it is now evident that the risk of death and disease is related to not only the amount but also the nature of tobacco exposure; for example, daily cigarette smoking is far more dangerous than occasional use of Swedish snuff" [108]. That same year a scientific panel convened by the Swedish National Board of Health and Welfare concluded that "the health risks related to smokeless tobacco are with great probability lower than those related to smoking" [41].

In 2002 the Royal College of Physicians of London, one of the oldest and most prestigious medical societies in the world, issued a report called "Protecting Smokers, Saving Lives," which stated,

"As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10–1,000 times less hazardous than smoking, depending on the product."

The report continued with an even bolder statement, acknowledging that some smokeless tobacco manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community" [128].

In 2004 a study funded by the NCI assembled an international panel of experts (including epidemiologists from the NIH and the ACS) to compare the risks of ST use with those of smoking. The study authors reported that, "In comparison with smoking, experts perceive at least a 90 percent reduction in the relative risk of low-nitrosamine smokeless tobacco use." The authors concluded that "This finding raises ethical questions concerning whether it is inappropriate and misleading for government officials or public health experts to characterize smokeless tobacco products as comparably dangerous with cigarette smoking" [129].

Phillips et al. have provided perhaps the most detailed and direct comparison of risks from use of Swedish or American ST products and from smoking, using a spectrum of risk estimates for ST use ranging from well-substantiated and plausible to highly speculative and implausible [130]. They estimated that, compared with smoking, ST risks "in the range of 1 percent or 2 percent, and possibly less, are most consistent with the epidemiologic evidence. Perhaps most important, our calculation shows that comparative risk estimates as high as 5 percent, let alone 10 percent or more, cannot be justified based on the evidence."

C. Evidence that ST is an effective substitute for cigarettes

1. Survey data

There is limited evidence from governmental and other surveys that some smokers have quit by substituting ST products for cigarettes, and most of the published information on this subject is dated. The 1991 NHIS survey revealed that 33.3 percent (about 1.8 million) of adult current ST users were former cigarette smokers [42].

The 1986 national Adult Use of Tobacco Survey, conducted by the CDC Office on Smoking and Health, found that 7 percent (1.7 million) of male ex-smokers had used ST to help them quit smoking cigarettes. That same survey found that only 1.7 percent of male ex-smokers (404,600) had used organized programs to help them quit smoking [131].

The 1998 NHIS survey revealed that 5.8 percent of daily snuff users reported quitting smoking cigarettes within the past year, that daily snuff users were three times more likely to report being former cigarette smokers than never snuff users, and that daily snuff users were four times more likely to have quit smoking in the past year than never snuff users [132].

According to the 1987 NHIS survey, 23- to 34-year-old U.S. men who had smoked cigarettes and subsequently used snuff were twice as likely to have quit smoking (95 percent CI 1.2–3.5) than were cigarette-only users [133].

Cohen-Smith and Severson surveyed 51 female and 59 male ST users in the Northwestern United States, 98 percent and 90 percent of whom respectively were either current or former cigarette smokers. They found that 52 percent of women and 59 percent of men used ST in place of cigarettes while quitting smoking [134].

2. Clinical trial data

One clinical trial, an open-label, nonrandomized pilot study, has been conducted assessing the efficacy of an ST product in helping cigarette smokers become smoke-free. The investigators used a low-intensity approach, consisting of a 20-minute lecture about the health effects of all forms of tobacco use, followed by information about and samples of pre-portioned single-dose tobacco packets available throughout the United States. The investigators used exhaled carbon monoxide levels to validate participant self-reports regarding smoke-free status at the conclusion of the original study after 1 year [125] and after 7 years of followup [135].

Of 63 subjects starting the study, 16 had successfully quit smoking by switching to ST after 1 year, and 12 were still smoke-free after 7 years. At enrollment, the average cigarette consumption of the successful participants had been 1.5 packs per day. One year later average consumption of ST was 2.3 packages per week among the 13 successful quitters using ST (3 were tobacco-free). Four additional participants had used ST to reduce their cigarette consumption by at least 50 percent.

3. The Swedish tobacco experience

For the past 100 years, cigarette smoking has been the dominant form of tobacco consumption in almost all developed countries. One notable exception is Sweden, where smoking rates, especially among men, have been considerably lower than those of comparable countries for decades. (An ACSH article provides historical background on Swedish snus [136]). Over the past 50 years Swedish men have had the lowest rates of smoking-related cancers of the lung, larynx, mouth and bladder in Europe [137], and the lowest percentage of male deaths related to smoking of all developed countries [138, 139].

A 2004 study revealed that if men in the (15-country) EU had the smoking prevalence of Sweden, almost 200,000 deaths attributable to smoking would be avoided each year [140]. In contrast, women in Sweden smoke at rates much more similar to women in other European countries, and this is reflected in similar rates of smoking-related illnesses. The 2004 study found that only 1,100 deaths would be avoided in the EU at Swedish women's smoking rates.

As Fagerström pointed out in a recent study, per capita consumption of nicotine from tobacco in Sweden is quite high and on par with other countries such as Denmark, the United States and Austria [141]. The difference between Sweden and the other countries is how nicotine is consumed. In Denmark, the United States and Austria, almost all nicotine consumption is derived from tobacco combustion. In contrast, ST use, in the form of snus, accounts for almost 50 percent of all contemporary nicotine consumption in Sweden. Snus use in Sweden is much more common among men than among women; over 60 percent of nicotine consumption among Swedish men is from snus. This is not a new phenomenon; for over a century, Swedish men have had among the world's highest per capita consumption of ST [142].

Beginning in 2002, an American-Swedish research group used a World Health Organization database to describe in detail the impact of snus use on smoking among the population in northern Sweden during the period 1986–2004 [46, 143, 144].

Among men, the prevalence of all tobacco use was stable during the study period, at about 40 percent. However, there were striking, and opposite, changes in prevalence of smoking and snus use. Smoking prevalence was 19 percent in 1986, and it was lower in all subsequent surveys, reaching 9 percent in 2004. The prevalence of exclusive snus use increased from 18 percent in 1986 to 27 percent by 2004. Snus use was the dominant factor in the higher prevalence of ex-smoking among men compared to women (prevalence ratio 6.18, 95 percent CI 4.96–7.70).

Among women, the prevalence of all tobacco use also was steady at 27 to 28 percent, and women smoked at higher rates than men in all surveys. But these studies showed that snus use was associated with lower smoking rates among women in 1999 and 2004. Smoking prevalence was about 25 to 27 percent in 1986, 1990 and 1994, but declined to 21 percent in 1999, and 16 percent in 2004. The prevalence of snus use was 0.5 percent in 1986 and increased to 1.9 percent in 1990, 2.0 percent in 1994, 5.1 percent in 1999 and 8.9 percent in 2004.

In these reports snus use was not associated with smoking initiation, as the prevalence of smoking among former snus users was low in all survey years (3–4 percent). The evidence showed that among adult men in northern Sweden the dominant transition is from smoking to snus, not vice versa.

In 2003 Foulds et al. reviewed the evidence relating to the effects of snus use on smoking and concluded, "Snus availability in Sweden appears to have contributed to the unusually low rates of smoking among Swedish men by helping them transfer to a notably less harmful form of nicotine dependence." The investigators noted that "in Sweden we have a concrete example in which availability of a less harmful tobacco product has probably worked to produce a net improvement in health in that country" [145].

In 2005 Furberg, et al. examined tobacco use data from the Swedish Twin Registry, finding that regular snus use was associated with smoking cessation, not initiation, among almost 15,000 male participants. Both regular and occasional snus use were protective against having ever smoked [146].

In 2006 Ramstrom and Foulds examined data from a 2001–02 nationally representative Swedish social survey. They found that snus use among men was significantly protective against smoking initiation (OR = 0.3, CI 0.2–0.4). They also found that snus was the most commonly used cessation aid among men (used by 24 percent of men on their most recent quit attempt). Men who used snus as a quit-smoking aid were more likely to quit successfully than those using nicotine gum (OR = 2.2, CI = 1.3–3.7) or the patch (OR = 4.2, CI = 2.1–8.6), which was also true for women [147].

V. POLICY ISSUES

A. ST use: gateway to smoking cessation, not smoking initiation

Data from research studies in Sweden and the United States do not support the allegation that widespread use of ST serves as a gateway to smoking, especially among youth. A 2003 policy statement published in Tobacco Control, coauthored by Clive Bates, former director of Action on Smoking and Health (U.K.) and five other eminent tobacco research and policy experts, dismissed the notion that ST use led to smoking in Sweden: "To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe" [148]. Foulds reached a similar conclusion: "This review suggests . . . that in Sweden snus has served as a pathway from smoking, rather than a gateway to smoking among Swedish men" [145].

A 2005 study examined tobacco use among 15- to 16-year-old schoolchildren over a 15-year period, from 1989 to 2003 [149]. The investigators found that the prevalence of regular snus use among Swedish boys increased from about 10 percent to 13 percent from 1989 to 2003, but the prevalence of regular smoking was very low and declined, from about 10 percent to under 4 percent. The prevalence of snus use among girls was very low, and the prevalence of smoking was about double that of boys over the entire period. The authors concluded that snus use did not appear to be a gateway to smoking among Swedish youth but instead was associated with low-smoking prevalence among boys.

In the United States investigators have not found credible evidence that ST use is a gateway to smoking among American youth. In 2003 Kozlowski et al. analyzed data from the 1987 INHIS survey and concluded that there was little evidence that ST use was a gateway to smoking, because the majority of ST users had never smoked or had smoked cigarettes prior to using ST [133]. The investigators noted that their results coincided with earlier work from Sweden and with a tobacco industry-sponsored survey from 1984 [150].

In 2003 O'Connor et al. examined data from the 2000 National Household Survey on Drug Abuse [151]. They described the impact of ST use on subsequent cigarette smoking initiation as "minimal at best." O'Connor et al. also examined data from the CDC's Teenage Attitudes and Practices Survey for evidence that ST use served as a gateway to smoking among youth [152]. They concluded that ST use was not associated with smoking initiation after appropriate control for confounding by well-recognized psychosocial predictors of smoking. This is in contrast to an earlier report that did not control for confounding and found a positive association [153].

Claims of a gateway effect persist, even with lack of credible evidence, prompting O'Connor et al. to note in 2005, "Continued evasion of the [harm reduction] issue based on claims that ST can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information" [154]. That quote introduces the next topic, information and misinformation about ST and tobacco-harm reduction.

B. Information and misinformation about ST and tobacco-harm reduction

Kozlowski et al. have argued persuasively that smokers have a fundamental right to accurate information about safer forms of tobacco use [155–157]. The research group established the underlying rationale for the provision of this information, citing principles of the Universal Declaration of Human Rights, the doctrine of informed consent, and business ethics contract theory, under which companies have a moral obligation to inform customers about important information regarding their products.

In 2001 the U.S. Supreme Court may have provided a legal basis for holding tobacco manufacturers responsible for providing truthful information about the differential risks of ST use and smoking. Writing the majority opinion in *Lorillard* v. *Reilly*, in which a 5–4 majority of the Court ruled that broad advertising restrictions by the Commonwealth of Massachusetts violated the commercial free-speech rights of tobacco manufacturers, Justice Sandra Day O'Connor wrote that,

> "The State's interest in preventing underage tobacco use is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products" [158].

1. Fundamental right to information

Over the past 20 years, many public health and tobacco policy experts have argued that smokers have a fundamental right to accurate information about less hazardous products so that they can make informed choices if they are unable or unwilling to quit tobacco altogether. In 1984 Kozlowski commented on both the challenges and the potential of tobacco-harm reduction, writing that "the use of less-hazardous tobacco, if prohibitionist impulses can be put aside, may have an important role in the treatment of the smoking and health problem . . ." [9].

In 1994 Rodu proposed that a "public health policy that recognizes ST as an alternative to smoking would benefit individuals confronted with the unsatisfactory options of abstinence or continuing to smoke" [10]. In a 1995 book, Rodu told smokers that "ST products allow you, the hard-core and long-term smoker, to take back a measure of control over your health by indulging in a far safer form of tobacco use" [13].

One concern about tobacco-harm reduction is that dissemination of information about less hazardous tobacco products might adversely affect public health if it creates new users. However, the risk/use equilibrium addresses this issue [159]. If ST use is 50 to 100 times less hazardous than smoking, it would require 50 to 100 more ST users to reach the level of public harm produced by smoking. In other words, it would take 2.3 to 4.5 billion ST users to have the same death toll as 45 million American smokers do today, an impossible scenario in the U.S. population of 290 million people.

Kozlowski's message in 2002 was clear:

> "Cigarettes kill about half of those who smoke them . . . It is urgent to inform smokers about options they have to reduce risk . . . public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such relevant information [on tobacco risks]" [155].

That same year, the prestigious Royal College of Physicians of London made its hopeful statement that "some manufacturers may want to market ST as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community" [128].

Since then a growing number of experts have weighed in on the case for providing smokers relevant risk information and safer tobacco options. In 2002 Cummings argued for a market approach involving risk information:

> "Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain. Capitalism, and not government regulation, has the greatest potential to alter the worldwide epidemic of tobacco-related disease" [160].

In 2003 Kozlowski et al. expanded on the rationale that smokers are entitled to information about safer products, addressing concerns that provision of risk information might adversely affect public health: "Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail" [161].

2. Misinformation from governmental and other organizations

Americans are badly misinformed about the risks of ST use, especially in comparison with smoking. In 2005 a survey of 2,028 adult U.S. smokers found that only 10.7 percent correctly believed that ST products are less hazardous than cigarettes [154]. In another survey, 82 percent of U.S. smokers incorrectly believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes [162].

A 1999–2000 survey of 36,012 young adults entering the U.S. Air Force found that 75 percent of males and 81 percent of females incorrectly believed that switching from cigarettes to ST would not result in any risk reduction, while another 16 percent of males and 13 percent of females incorrectly believed that only a small risk reduction would occur. Only 2 percent of males and 1 percent of females correctly understood that a large risk reduction would occur by switching from cigarettes to ST [163]. That survey also found that the overwhelming majority of subjects believed that switching from regular to low-tar cigarettes conferred greater reduction in risks than switching from cigarettes to ST.

It is not clear how Americans have become so confused about tobacco risks. But it is clear that misinformation about ST products is available in copious quantities from ostensibly reputable sources, including governmental health agencies and health-oriented organizations. Phillips et al. have made some of the most pointed comments about this phenomenon:

> "Certain health advocates believe it is acceptable to mislead people into making choices they would not otherwise make . . . Through the use of various tactics, advocates who oppose the use of ST as a harm reduction tool have managed to convince most people that the health risk from ST is several orders of magnitude greater than it really is. The primary tactic they use is making false or misleading scientific claims that suggest that all tobacco use is the same. . . . Apparently motivated by their hatred of all things tobacco, they are trying to convince people to not switch from an extremely unhealthy behavior to an alternative behavior that eliminates almost all of their risk" [164].

The tactic has worked in the United States, as Americans, almost without exception and regardless of general and health education levels, believe that the risks from ST are similar to those from smoking. In particular, Americans incorrectly believe that switching from smoking to ST use will create a large increased risk for oral cancer. Phillips has characterized this popular misinformation as the "you might as well smoke" message, since it tells people that if they are using ST, they could switch to smoking with no increase in risk, while smokers considering switching to ST should not bother [165].

Phillips et al. systematically reviewed content about ST use on the Web in 2003 and found that the risks of ST use are almost always conflated with those of smoking [165]. Roughly one-third of the time, there are explicit claims that ST is as bad as or worse than smoking. Most of the rest of the time the information is arranged to imply similar risks, though there is no such explicit statement. There are also a variety of specific claims that are not supported by the literature.

Government agencies, other organizations and members of the public health community have a moral obligation **not** to misinform smokers about products that have fewer risks than cigarettes. Nevertheless, researchers have exposed numerous cases of misinformation from governmental sources. For example, in 2003 Kozlowski and O'Connor criticized Web sites of the CDC and the Substance Abuse and Mental Health Services Administration for erroneously reporting that ST products were not safer than cigarettes, pointing out that "the misleading health information on ST fails to meet the government criteria against deception in research" [156].

At a 2003 U.S. House subcommittee hearing, U.S. Surgeon General Richard Carmona testified:

> "I cannot conclude that the use of any tobacco product is a safer alternative to smoking . . . There is no significant evidence that suggests ST is a safer alternative to cigarettes" [166]. Scott Leischow, Chief of the Tobacco Control Research Branch at the NCI, presented similar testimony at a concurrent hearing [167]. Carmona's statement prompted Rodu, who also presented testimony at that hearing [168], to comment that the Surgeon General was "sadly ill-informed about the Nation's No. 1 health problem, cigarette smoking." Rodu strongly criticized Carmona, writing that he should be compelled to "tell American smokers the truth about all available options for quitting. After all, the 10 million smokers who will die over the next two decades are, in a very tangible way, his responsibility and his legacy" [169].

In March 2004, Ken Boehm of the National Legal & Policy Center (NLPC), a nonprofit organization committed to promoting open, accountable and ethical practices in government, filed a request under the Data Quality Act (DQA) for correction of a document from the National Institute of Aging (NIA) that contained misinformation regarding the relative risks of ST versus cigarettes. (The other DQA requests on ST can be seen at the U.S. Department of Health and Human Services Web site [170]) The request resulted in a change of wording from the original text: "Some people think ST (chewing tobacco and snuff), pipes, and cigars are safer than cigarettes. They are not."

The revised wording from NIA was: "Some people think ST (chewing tobacco and snuff), pipes, and cigars are safe. They are not."

The claim that ST products are not "**safe**" is a tactic that can be traced back to the 1986 Comprehensive Smokeless Tobacco Education Act, which required as one of three warnings on all ST products: "This product is not a safe alternative to cigarettes."

In 1995 Rodu criticized this warning as ludicrous and suggested that other consumer products like automobiles, lawnmowers, aspirin and red meat don't meet absolute criteria for safety [13]. A decade later, Kozlowski and Edwards criticized this type of uninformative warning in a study entitled, "'Not safe' is not enough: smokers have a right to know more than there is no safe tobacco product" [157]. These authors believe that smokers deserve more information:

> "The 'not safe' or 'not harmless' messages don't address the reality that some tobacco products are substantially safer than others . . . Saying tobacco 'isn't

safe' isn't incorrect, but it isn't saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information."

Ken Boehm from NLPC summarized the arguments against misinformation:

"This is the kind of evidence Americans should be able to review and make their own decisions. Despite the best efforts of the largest government bureaucracy in the history of the Republic, Americans still prefer to do their own thinking. And as we do our own thinking on the merits of reduced-risk products such as ST, none of us needs misinformation supplied by our own government" [171].

With regard to a policy as "credible, logical and eminently do-able" as tobacco-harm reduction [172], it is unfortunate that arguments against deception are actually necessary.

VI. CONCLUSION AND RECOMMENDATIONS

The past 40 years have brought ever more assertive public health campaigns against cigarette smoking. A coalition of well-funded public and private agencies has as its goal a reduction in the prevalence of cigarette smoking. The coalition's influence has resulted in pervasive health warnings, ever more intensive quit-smoking programs, and recently the social ostracism of smokers and the industry that supplies them. Yet 45 million Americans continue to smoke, and far too many die from smoking-related diseases.

The American Council on Science and Health has been part of this anti-smoking coalition for several decades. Throughout its history ACSH has published many articles about the health risks of smoking. And it has held the tobacco industry accountable for its part of the devastating toll from tobacco. ACSH founder Elizabeth Whelan published a landmark anti-smoking book, *A Smoking Gun?: How the Tobacco Industry Gets Away with Murder* [173].

ACSH was founded in 1978 by a group of scientists who had become concerned that many important public policies related to health and the environment did not have a sound scientific basis. These scientists created the organization to add reason and balance to debates about public health issues and bring commonsense views to the public.

The mission of the ACSH is to promote sound science in regulation, in public policy, and in the courtroom and to assist consumers, via the media, in distinguishing real health threats from purely hypothetical ones. ACSH believes that strong support of tobacco-harm reduction is fully consistent with this mission; as this report documents, there is a strong scientific and medical foundation for tobacco-harm reduction, and it shows great potential as a public health strategy to help millions of smokers.

Tobacco-harm reduction empowers smokers to gain control over the consequences of their nicotine addiction. At its simplest it is nonintrusive and solely educational, and therefore has a strong moral rationale. The strategy is cost-effective and accessible today to almost all smokers. But its implementation will require rethinking of conventional tobacco control policies and their premises.

The ACSH believes that the following actions will benefit smokers:

1. **Agencies of the Federal Government (most notably the Office of the Surgeon General) and health promotion organizations (such as the American Cancer Society and the Mayo Clinic) should discontinue the campaign of misinformation that irresponsibly misrepresents the scientific information about and use of ST products.** They endanger their reputations as sources of trusted health information by providing messages about ST products that are neither accurate nor credible. The campaign of misinformation should be replaced with an educational program that emphasizes the differential risks of all forms of tobacco use.

2. **Regulatory restrictions on the manufacture and sale of nicotine replacement medications should be revised.** Nicotine is addictive, but it plays little or no role in the development of most smoking-related diseases. Manufacturers of nicotine replacement medications should be permitted to sell higher doses of the drug within flavor/delivery systems that are satisfying and enjoyable for smokers at costs that are competitive with cigarettes. In addition, smokers should be informed that permanent use of NRT is vastly safer than continuing to smoke. This could be accomplished by new labels on NRT packaging and additional labels on cigarette packs: "Notice: Nicotine does not cause cancer, heart diseases or emphysema."

3. **Manufacturers of tobacco products should follow the lead of British American Tobacco (BAT) and acknowledge that ST use is vastly safer than smoking.** BAT has openly admitted that oral ST products are safer than cigarettes,

and this company is actively engaged in test-marketing Swedish snus in Sweden, Norway and South Africa [174]. At the press date of this report, cigarette manufacturers in the United States have introduced ST products in limited test markets, but they have made no statements regarding differential health risks. This is unacceptable, given the state of the science documented in this report.

4. **Any Federal legislation that addresses the regulation of tobacco should include provisions that adequately reflect the differences in risks between combustible tobacco products and ST products or NRT.** This includes careful review of current proposals before Congress to ensure that the legislation is written to regulate the labeling and marketing of products based on their risks. The goal should be to give users of tobacco the necessary information they need to understand the differences between various tobacco and nicotine products so they can make the appropriate health choices and decisions.

5. **Pending enactment of more comprehensive regulation, the U.S. Congress should repeal the federally-mandated warning that now appears on ST products:** "This product is not a safe alternative to cigarettes." This warning not only misleads smokers; it may send a message to ST users that they might as well smoke. The warning should be replaced with the following, which would appear as an onsert with *cigarette packages*—"Warning: Smokeless tobacco use has risks, but cigarette smoking is far more dangerous. Quitting tobacco entirely is ideal, but switching from cigarettes to ST can reduce greatly the health risks to smokers and those around them." Placement of this warning with cigarettes ensures that it reaches the target audience, continuing smokers.

6. **State legislatures should follow the lead of Kentucky and establish rational risk-based tax policies for tobacco products.** In 2005 the Commonwealth of Kentucky enacted an excise tax structure for cigarettes and ST products that was based on differential risks. The final bill stated:

> "The General Assembly recognizes that increasing taxes on tobacco products should reduce consumption, and therefore result in healthier lifestyles for Kentuckians. The relative taxes on tobacco products proposed in this section reflect the growing data from scientific studies suggesting that although smokeless tobacco poses some risks, those health risks are significantly less than the risks posed by other forms of tobacco products. Moreover, the General Assembly acknowledges that some in the public health community recognize that tobacco-harm reduction should be a complementary public health strategy regarding tobacco products. Taxing tobacco products according to relative risk is a rational tax policy and may well serve the public health goal of reducing smoking-related mortality and morbidity and lowering healthcare costs associated with tobacco-related disease."

ABBREVIATIONS: **ACS**—American Cancer Society; **ACSH**—American Council on Science and Health; **BAT**—British American Tobacco; **CDC**—Centers for Disease Control and Prevention; **DQA**—Data Quality Act; **EU**—European Union; **FDA**—Food and Drug Administration **NCI**—National Cancer Institute; **NHIS**—National Health Interview Survey **NIA**—National Institute on Aging **NIH**—National Institutes of Health **NLPC**—National Legal Policy Center **NRT**—Nicotine replacement therapy **RR**—Relative risk; **ST**—Smokeless tobacco; **TSNA**—Tobacco specific nitrosamine **U.K.**—United Kingdom; **U.S.**—United States.

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PREPARED STATEMENT OF ANNE LANDMAN, TOBACCO DOCUMENT RESEARCH AND CONSULTING, GLADE PARK, CO

I have been a tobacco document researcher since 1998. After almost a decade of reading tobacco industry documents, I have become acutely aware of the industry's strategies and tactics for undermining public health. Documents show that Philip Morris is at least 10 years ahead of the rest of society in anticipating future scenarios to regulate cigarettes, advertising, etc. For example, they had the basic tenets of the 1998 Master Settlement Agreement (MSA) drawn up in 1991, in anticipation that Congress would try to pass a total ban on cigarette advertising.

It is my belief that legislation to regulate tobacco products should be thoroughly vetted by highly experienced tobacco control advocates and public health-sided tobacco industry strategists and that all loopholes in the existing proposed legislation bill be completely eliminated. Regulation of tobacco products, should, in fact ideally be drafted with, or by, experienced *public health authorities* with the sole purpose of protecting public health. Tobacco companies should be permitted input, but they should not be permitted to be the driving force behind such legislation. Documents show that Philip Morris has maintained an internal program since 1999 specifically to drive the enactment of FDA regulations in its favor. Reading the existing legislation, and knowing of PM's internally devised 5 core principles (the company's requirements of what it requires in FDA regulations) I fear Philip Morris has had a hand in drafting, and is currently driving, the passage of the existing proposed measure.

Realizing that the eventual regulation of cigarettes was inevitable, in 1999 PM started an internal project to enact Food and Drug Administration (FDA) regulations on its own terms. The plan was called the *Regulatory Strategy Project*. The goal was to enact FDA regulations according to 5 core principles that would assure the company retained a measure of control over advertising and marketing, and assure a future market for cigarettes. The core principles, if achieved, would have the effect of safeguarding the company's ability to market cigarettes with a minimum of restrictions, transfer responsibility for fully informing the public about the dan-

gers of tobacco use onto the FDA and take it off the manufacturers, and transfer legal liability for the safety of tobacco products onto the FDA, while allowing cigarette companies the ability to continue to design and market cigarettes as they see fit.

A 2001 PM strategy memo shows that pursuit of FDA regulations would help complicate tobacco issues for the public. This constitutes a positive for PM, since it would blur the "black and white" divisions between public health and tobacco companies). Pursuit of FDA regulations would provide a positive public relations benefit for PM. The memo states,

> "Unfortunately for the industry, the tobacco debate in recent years suffered from oversimplification, perpetuated by media coverage that depicts tobacco-related issues as 'black and white,' with tobacco companies playing the predictable role as evil corporate giant . . ."

It continues,

> "The debate over FDA reform has the potential to complicate this portrayal in a manner that will specifically benefit Philip Morris. The simple fact that other tobacco companies will likely come out on the opposite side of the issue—against FDA regulation—provides Philip Morris a chance to distinguish itself from its competitors as a good corporate citizen. Positioned appropriately, the campaign can actually serve two purposes: achieving Philip Morris's goal of instituting regulation of the tobacco industry while also realizing significant public affairs benefits."

(*Campaign to Achieve FDA Regulation of Tobacco*, Philip Morris memo from 22 March 2001, Bates No. 2085235845/5847.)

SPECIFIC COMMENTS ON THE PROPOSED LEGISLATION

The proposed legislation spends more time listing what FDA *cannot* do to regulate tobacco than what it *can* do. It effectively ties FDA's hands in responding to current research, science and health threats posed by tobacco. For example, section 906 of the current legislation "cements" the age of sale of tobacco at 18 years. This is despite the understanding that raising the age of purchase of tobacco products to 19 would make significant inroads in getting cigarettes out of high schools. However, under the current bill, such a change would be prohibited nationwide. A measure like this, that limits peoples' ability to enact stricter legislation, is called Preemption. Philip Morris has long had an internal program (called its "*Accomodation/Preemption Program*") to pass preemptive laws benefiting the company in all 50 States. PM's preemptive programs in my opinion have set back the progress of public health smoking laws by at least a decade. Preemption of local ordinances by state-level legislation has long been considered a "deal breaker" by health advocates when clean indoor air legislation have been introduced. To explicitly avoid preemption, Congress should pass a bill that sets *minimum* standards for the FDA, but that does *not* preempt the FDA's ability to do more.

The proposed legislation also takes a strong product/ingredient-focused approach to regulating tobacco. In fact, the tobacco control community has moved beyond this approach. The tobacco companies themselves have spent 40–50 years on research and development of their products without releasing information about their research or activities for public scrutiny. Current tobacco control theory focuses less on the product and much more on eliminating the harm done to nonsmokers from secondhand smoke and denormalizing use of the product. This approach is not mentioned anywhere in the bill, and should be a central focus of *any* FDA effort to regulate tobacco.

The proposed legislation also fails to address or preclude the likely occurrence that tobacco companies will start including language on their labels and in advertisements to the effect of **"This product manufactured in accordance with FDA standards."** Such messages would have the effect of seriously misleading the public into believing that cigarettes have been somehow made safer or less harmful, or that the Government sanctions their use.

Since the beginning of its existence, the FDA has been charged with assuring that products under its scrutiny are safe. This bill would represent the first time the agency would be charged with managing a product that is inherently unsafe. The appropriateness of this should be seriously questioned, to the extent that Congress should consider whether some different and separate agency should be established to manage the Government's efforts to regulate cigarettes. FDA's management of a deadly product could seriously erode and undermine the public's remaining confidence in the agency.

I am also concerned that the current bill will have the effect of transferring liability for the manufacture of a deadly product onto the Government, and take liability off the tobacco companies. There is no provision in the bill that specifically protects the Government from charges of complicity in the manufacture and distribution of a known harmful product.

The proposed legislation in many places conflates the pursuit of public health with avoiding disruption of the tobacco trade, as in an excerpt from p. 60 that says,

> **"Such date . . . [of establishing a tobacco product standard] shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade."**

You simply cannot have it both ways. The fact is that a healthy tobacco trade is antithetical to public health, within and outside the United States. This clause is another indication that the bill was drafted with the tobacco industry's needs in mind, rather than the public's best interests.

The bill assumes that tobacco use is primarily a problem of youth, and thus relies heavily on a youth-focused approach to advancing the public health. The youth-focused view has largely lost favor with serious tobacco control advocates, since tobacco document research revealed that a youth-focused approach to tobacco control plays directly into the hands of tobacco companies. The companies have used the over-emphasis on youth smoking to deflect the attention of legislators and rule-makers away from the fact that smoking is a society-wide problem, not simply a youth problem. Congress should not lose focus on the fact that the issue is not one simply of youth smoking (the preferred focus of the tobacco industry); it is the *ongoing promotion and sale of a deadly product*.

Congress need also be aware of some very problematic loopholes in the bill as it is written. In one clause from sec. 908, the bill states:

> (c) RECALL AUTHORITY.—(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product.

My interpretation is that this clause has the effect of sanctioning the already-existing defects in tobacco products that cause illness and death. If a tobacco product is determined to have a WORSE manufacturing defect that makes it even MORE deadly, THEN the onus would be on FDA to issue a cease and desist order for sales of the product. But if the product is just at its normally deadly level, FDA's hands are tied—no cease and desist order, no recalls. This simply is bad policy.

There are no provisions in the current bill that address ongoing problems of contamination that are inherent in the manufacture of cigarettes, specifically the contamination of cigarettes with bugs and bug larvae, bits of rubber and lubricating oils from conveyor belts in manufacturing facilities, pieces of foam from tobacco drying barns, blood, bits of metal, and other contaminants like ink from printing on cigarette paper and the off-gassing of plastics used in packaging that are revealed as ongoing problems in tobacco industry quality control documents.

FDA should be given full and unfettered authority to act on any and all current science and research regarding tobacco, and to take whatever actions are necessary to reduce the problem of society smoking. FDA should have complete authority to regulate all areas of nicotine administration, as well as other constituents and ingredients, and that authority should be made *completely explicit*.

Taken as a whole, Philip Morris internal documents indicate that PM's goals in pushing for FDA regulation are:

(1) To assure a future market for cigarettes,

(2) To preserve the company's ability to make cigarettes that appeal to their market,

(3) To safeguard the company's ability to market cigarettes without restrictions,

(4) To prevent FDA from obtaining any real authority to restrict the marketing and promotion of cigarettes,

(5) To give FDA the responsibility of fully informing the public about the dangers of tobacco use, and take this responsibility off of the manufacturers,

(6) To transfer legal liability for the safety of tobacco products onto the FDA, while allowing cigarette companies to continue to design and market cigarettes as they see fit.

It seems to me that the current bill allows the tobacco industry to achieve all this.

I urge Congress to carefully go through the bill and re-craft so that it allows public health authorities to make real progress against tobacco use in this country. Do not lose this chance to do what is best for society for a change, instead of what is best for Philip Morris.

PREPARED STATEMENT OF JOHN R. POLITO, ESQ., EDITOR, WHYQUIT, MOUNT PLEASANT, SC

Dear Chairman Kennedy, WhyQuit is the Internet's oldest and largest quit smoking forum devoted exclusively to abrupt nicotine cessation, the quitting method employed by 80 percent to 90 percent of all long-term successful ex-smokers. As an all volunteer forum we dream of the day when the need for our free education, counseling and support services is at end and the team can turn their energies and passions to new causes. But, sadly, the bill before you would better be titled "The Nicotine Addiction Industry Protection Act."

It seeks to grant the Food and Drug Administration (FDA) limited authority to regulate cigarettes and tobacco. At first blush the idea sounds great. In fact, an initial reading of the full bill will likely reinforce that opinion. But don't we want America's 9,000 FDA food and medicine watchdogs ringing alarms when any product is found responsible for even a single death? How can we not pollute their mission and minds by commanding them to accept regulatory oversight and thus some degree of responsibility for hundreds of thousands of smoking-related deaths annually?

The FDA's full mission statement reads as follows:

> "The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."

Key Congressional "findings" from the bill assert that "tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects," "nicotine is an addictive drug," "virtually all new users of tobacco products are under the minimum legal age to purchase such products," and "tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year and approximately 8,600,000 Americans have chronic illnesses related to smoking."

Clearly, America's leading cause of preventable death isn't a medicine or food but by the bill's own findings an inherently dangerous and highly addictive killer. Isn't it obvious that the Federal Trade Commission (FTC), pursuant to the Federal Cigarette Labeling and Advertising Act of 1966 (15 U.S.C. §§ 1331–1340, as amended) is the proper Federal agency for addressing what are primarily tobacco advertising, marketing and sales oversight responsibilities.

But instead, the bills language, which clearly had strong input from Philip Morris USA, is loaded with provisions that tie the FDA's hands. It prohibits the FDA from removing all nicotine from cigarettes, from banning their sale, from requiring that tobacco be removed from neighborhood convenience stores (what to youth is the neighborhood candy, chip, ice cream and soda store), and from raising the age of purchase above age 18.

Philip Morris USA's Web site notes the February 15, 2007 introduction of the bill and states, "PM USA strongly supports this bipartisan legislation and urges Congress to take quick action" on the bills. Philip Morris asserts that the bill will bring "predictability" to the tobacco industry in the United States. Predictability?

This bill is a tobacco industry dream come true—an official government birth certificate that guarantees the right to sell a chemical that the Surgeon General claims is at least as addictive as heroin to 18-year-old high school students across the Nation, 18-year-olds who want to be liked. Try to find any convenience store without a buy 1 get 1 free or buy 1 get 2 free deal. They make captivating gifts that all but guarantee that underage recipients will become new friends who'll soon return begging for more.

Although the bill is well intended, it plays smack dab into the tobacco industry's hand. The industry always seems two moves ahead of health policymakers but considering that its economic survival is at stake it must stay ahead. When the 1998 Master Settlement Agreement with the States ended tobacco product advertising in high youth readership magazines they simply shifted those dollars into neighborhood convenience stores—into what is now "nicotine addiction central."

We beg committee members to think like a tobacco company. Imagine watching horror as smoke-free workplace laws sweep the Nation and nearly all States raise cigarette taxes in an attempt to price nicotine products beyond the disposable income of most youth. But what's now just starting to sweep the tobacco control community is a realization that cigarettes, by far the dirtiest drug delivery device ever devised, are no longer needed.

In November 2003 GlaxoSmithKline consultants reported that nearly 37 percent of all nicotine gum users were engaged in chronic long-term use of at least 6 months. We have no reason to believe that nicotine lozenges, releasing 25 percent more nicotine than gum, won't be just as high. Although nicotine replacement therapy products have shown 1.5- to 2-fold efficacy over placebo in randomized clinical trials, once outside the door and going head-to-head against cold turkey they fall flat on their face. But replacement nicotine's true value to society isn't in cessation but as an ongoing daily dependency alternative to cigarettes.

Which city in America would have been the first to ban the sale of all cigarettes and have a city-wide transfer campaign to help smokers adapt to cleaner forms of nicotine delivery? What would have happened to youth and adult smoking rates in that community? Like smoke-free workplace air, could such a movement quickly sweep the entire Nation? Under this bill we'll never know.

Section 907(b)(3) of the bill, entitled "POWER RESERVED TO CONGRESS," "expressly reserves" to Congress the power to ban all cigarettes. If we were thinking ahead, instead of another aspect of Federal preemption why couldn't this reservation have expressly shared such power with the States or their political subdivisions?

As for tasking the FDA with determining which of 4,000 cigarette smoke constituents are the most deadly and then battling the industry to have one or more removed, picture for a moment the marketing representations that would be made in association with selling this reduced risk product that's still extremely deadly. In fact, as soon as this bill is passed all cigarette advertisements will instantly be able to honestly proclaim that they are in full accord with all Food and Drug Administration safety requirements. Imagine how that message will play inside a 15-year-old's mind.

We encourage the committee to amend the bill to task all sales, marketing and advertising provisions to the FTC while including a strong preemption disclaimer that makes it clear that the States are free to regulate all aspects of advertising, marketing and sales, including the power to ban any or all forms of nicotine delivery, with the exception of altering required tobacco product health warnings if tobacco products are sold.

If the committee insists on going forward with this ill-advised bill it should be amended to:

- Make it clear that, as with alcohol, the States and their political subdivisions have full authority to ban the sale of any or all classes of nicotine delivery devices, including all forms of nicotine replacement therapy.
- Authorize the FDA to raise the smoking age to 21.
- Authorize the FDA authority to limit the sale of any class of nicotine delivery device to stores to which those who are underage are denied access. Responsible stores need to make a choice. They either want to market and sell what many consider earth's most captivating chemical or cater to children but they cannot do both.
- Authorize the FDA to both remove all nicotine from tobacco products and ban the sale of any class of nicotine delivery device.
- Include an express provision that any reference to FDA regulation of tobacco during any products liability jury trial will result in a mistrial and a statutory penalty of $100,000.
- Amend the warnings to require that alternating nicotine addiction warnings appear on one side of each cigarette pack sold, with a health warning appearing on the other side. For example, Canada's addiction warning reads, "Warning Cigarettes are Highly Addictive—Studies have shown that tobacco can be harder to quit than heroin or cocaine." Canadian youth smoking rates have fallen dramatically since the warning first appeared in 2000. Relative risk information is critical if youth are to make informed decisions. Youth also need to know how quickly dependency can occur, the warning signs, and the truth about how ineffective over-the-counter quitting aids such as the nicotine patch and gum actually are with a 93 percent 6-month smoking relapse rate as determined by GlaxoSmithKline consultants. Otherwise we provide them a false belief that quitting is easy when in fact 50 percent of adult U.S. smokers are losing 13 to 14 years of life. As for giving dependency warnings equal weight with health warning, it is nearly impossible to experience most health risks unless the user first becomes dependent, the greatest risk of all.

Provide clearer language that the Secretary is not only free to amend existing warnings but to create new warnings.

If this were any other consumer product the FDA would instantly battle to have it removed from the market. The bill attempts to pound a square peg into roundness. It cannot be done. Although all sponsoring this bill are well intended they should put themselves in the shoes of the average FDA employee and reflect upon how this bill will fundamentally alter their mission and thinking in regard to product risk analysis. Is that really what's best for America? We're making great strides. Give the States full authority to regulate sales and then, like smoke-free workplace laws, watch the magic unfold.

PREPARED STATEMENT OF VICKI VOLDAL ROSENAU, BARNES COUNTY TOBACCO-FREE NETWORK, VALLEY CITY, ND

For many years, I have been reading and re-reading expert analyses and conclusions (both pro and con) regarding the provisions that are now included in this year's version of so-called "FDA Regulation of Tobacco": *the Kennedy-Cornyn bill.*

I've probably studied this issue more thoroughly than any other person in the state of North Dakota. This careful consideration has brought me to the inescapable conclusion that, if enacted, this legislation would do significant, serious harm to the public's health. **Because the 155 pages are so fraught with pitfalls and loopholes and blatant sellouts, it is not feasible to "amend" it to a state of wholesomeness. Therefore, the bill should be abandoned.**

As if the compelling negative evidence that has been piling up for years were not enough, the recent arrival-on-scene of R.J. Reynolds' cunning "Camel No. 9" promotion offers just one final ounce of proof that the Kennedy-Cornyn bill is a sham. Why? Because, even though this brand-new, slick, hot-pink fuchsia campaign makes a blatant appeal *to young girls*, **the proposed "FDA bill" would do absolutely nothing to prohibit this powerful exploitation of youthful vulnerability.**

PREPARED STATEMENT OF MICHAEL SIEGEL, M.D., M.P.H., PROFESSOR, SOCIAL AND BEHAVIORAL SCIENCES DEPARTMENT, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH, BOSTON, MA

I am a Professor in the Social and Behavioral Sciences Department at the Boston University School of Public Health and as a physician trained in preventive medicine and public health, I have been a tobacco control researcher, practitioner, and teacher for the past 21 years. I spent 2 years at the Office on Smoking and Health at the Centers for Disease Control and Prevention (CDC), and I am quite familiar with the issues involved in Federal tobacco control regulation and policy. I was at CDC during Dr. David Kessler's original investigation into the possibility of FDA claiming jurisdiction over tobacco products, and helped advise FDA at that time. I have published more than 60 peer-reviewed articles in the medical and public health literature, most concerning tobacco policy. I have testified as a witness for the plaintiffs in seven tobacco-related lawsuits, including the *Engle* case which resulted in an unprecedented $145 billion verdict in favor of the plaintiffs. I have testified in more than 50 local and State hearings in support of smoke-free bar and restaurant laws. In summary, I am about as anti-smoking as one can be.

Proponents of the proposed FDA tobacco legislation have argued that this bill would end special protections for the tobacco industry, protect the public's health, reduce tobacco use, make cigarettes safer, and save lives. However, a detailed analysis of the actual provisions of the legislation makes it clear that quite the opposite is true. The bill would provide unprecedented special protections for Big Tobacco—protections not enjoyed by any other industry whose products are regulated by the FDA. The bill would harm the public's health at the expense of protecting the financial interests of the largest tobacco companies. The bill would likely increase tobacco use, create a false impression that cigarettes are safer, end the prospects for a truly safer cigarette, and in the long run, result in an increased number of deaths from tobacco use. Supporters of the bill are full of rhetoric, but when you take the time to actually examine the bill and the regulatory framework it establishes, you see that this legislation is in the best interests of the Nation's leading tobacco company—Philip Morris; it is not in the best interests of protecting the public's health.

1. THE REGULATORY SCHEME ESTABLISHED BY THE LEGISLATION IS PURE LUNACY

The Bill Would Create the Illusion of Safer Cigarettes Without Any Evidence That the Product Is, or Can be Made Safer

The system of tobacco product safety standards set up by the bill is pure lunacy. Although the rhetoric by groups like the Campaign for Tobacco-Free Kids sounds

great, the truth is that there is no evidence that these standards would actually result in a safer product.

The problem is that we simply do not know which of the constituents in tobacco smoke, and at what quantities, are responsible for what diseases. So the Campaign for Tobacco-Free Kids can talk all they want about how FDA will be able to reduce levels of certain toxins and produce a safer cigarette, but that's a pipe dream. It would be difficult to conduct, long-term epidemiologic studies, where you'd have to follow smokers of conventional vs. new products for 10–20 years, before you could have an answer to this question. But in the mean time, we wouldn't know what the risks are—or even if the risk could be decreased.

Essentially, the bill gives the FDA a mandate which it cannot carry out. The only way to know whether any particular reductions in specific smoke constituents would result in a safer product would be to carry out long-term epidemiologic studies, using smokers as guinea pigs. Perhaps some would view that as acceptable because the product is dangerous anyway. However, the problem is that smokers are going to naturally assume that these products are safer—and we won't know that is true. This legislation would greatly deceive smokers into thinking that the product is safer, when it may well not be any safer at all, and could potentially be more hazardous.

Unfortunately, we simply do not have any idea whether it is even possible to reduce the toxicity of cigarettes by reducing the levels of specified components.

The entire approach is flawed, because if you want safer cigarettes, you need to use the free-market approach to set up competition between the companies for a safer product. This legislation does the opposite. It takes away the free market completely and puts all decisions into the hands of FDA. But it gives the FDA a mandate which sets up impossible standards that could never be met for new products. What it really does is ensure that existing products will be institutionalized and protected from competition. This, indeed, is the reason why Philip Morris supports the bill, and all the smaller companies oppose the bill. What the smaller companies despise is the removal of any serious chance to compete in the market—and largely, the market we are talking about is potentially safer products.

Philip Morris wants to freeze the market as is, so that Marlboro—one of the highest risk products imaginable—will be able to dominate the market, without any serious competition from potentially safer products which could advertise themselves as being safer than Marlboro and thus gain market share among the "health-conscious" segment of smokers who are looking to reduce their risks while still satisfying their demand for cigarettes.

If you really think about it, you'll see that the approach of trying to reduce the levels of specific smoke constituents is complete lunacy. When you have no idea which constituents, in what combination, and at what concentrations, cause which diseases that are associated with smoking, then it is impossible to produce a cigarette that you know will be safer simply by mandating a reduction in the levels of various smoke constituents.

The one thing you will never hear the supporters of this legislation do is estimate the number of lives they think this legislation will save. All they can do is talk about "countless" lives being saved. And they are **quite correct**. The lives are countless. You cannot count them because they do not exist.

It is estimated, for example, that there are over 60 compounds in tobacco smoke which cause cancer. So what sense does it make to require the companies to take out two or three of them? What if they take out the wrong ones? What if the actual compound which causes most of the cancer is not one of those chosen to be removed? What if smokers believe that this is a safer product and start smoking more? This approach could actually kill people, rather than save lives.

And it could also kill people by reducing youths' perceptions of the hazards of cigarette smoking. If youths are led to believe—correctly—that the FDA now regulates every ingredient of the cigarette and that—incorrectly—because of this, countless lives will be saved, does it not make sense for these kids to infer that cigarettes are not as bad as they used to be? We know for a fact that any decline in the perceived harm of cigarettes results in an increase in youth smoking. So the proposed FDA legislation could well kill more people than it saves.

The bottom line is that there is no point in giving the FDA regulatory authority over cigarettes unless there is evidence that there is something that the FDA could do to regulate cigarettes to unequivocally make the products safer. To start the FDA on a crapshoot where they would choose random smoke constituents to reduce or eliminate in cigarettes makes no public health sense. It will give an FDA stamp of approval to tobacco products, but without actually making them any safer.

2. THE LEGISLATION WOULD BE A DEATH KNELL FOR THE DEVELOPMENT OF TRULY SAFER TOBACCO PRODUCTS

The Bill Would Make it Impossible for Tobacco Companies to Market Truly Reduced Risk Cigarettes and Would Eliminate Any Incentive to Develop Such Products

The bill puts a death knell to harm reduction as a strategy. It prohibits the marketing of any newer, safer cigarette, unless it meets FDA approval. But here's the catch—in order to meet FDA approval, you would have to prove that the product improves health, both on an individual and a population level. To do that, you'd have to conduct epidemiologic studies in which smokers were followed for 10–20 years. And you'd have to hope that they stuck with their products (conventional vs. new), without switching, for the entire period. In short, this is impossible. Thus, this legislation would make it impossible to produce and market safer cigarettes. It essentially takes all the incentive away. No cigarette company is going to want to spend millions of dollars on testing and producing a safer cigarette when they know it is going to be virtually impossible for them to ever market it.

And this is precisely why Philip Morris favors this legislation. Philip Morris realizes that the bill sets up an impossible standard for new products. Thus, it ensures that the existing market is basically frozen—obviously, this is a dream come true for the company with the largest current market share, because it stifles competition.

The only way to get safer cigarettes would be to allow the free market to produce them—not by creating this elaborate regulatory scheme.

In fact, if you actually read the legislation [see section 901(g)(1)], you'll see that it is not just **virtually** impossible to meet the standards required to market a reduced risk product, it is **actually** impossible. In order to prove that a product reduces health risks as it is actually used, both on an individual and population basis, you'd have to demonstrate the results of a study in which the product is marketed the way it would be marketed in real life—that is, as a reduced risk product. But you can't market it as a reduced risk product until you've proven that it reduced risks.

This is truly a catch–22. You cannot market a product as reduced risk until you've proven it reduces risk, but you cannot possibly prove that it reduces risk until you've marketed it as such.

Thus, the proposed legislation not only represents a *de facto* end to the prospect of truly safer products—it represents an actual death knell for any meaningful harm reduction strategy.

The critical flaw in the proposed legislation is section 911(g)(1). This is the Modified Risk Product section of the bill.

The Modified Risk Product section of the proposed FDA legislation would make it virtually impossible for modified risk products to enter the market, while at the same time, allowing reduced exposure products to essentially be falsely marketed as reduced risk products (thus institutionalizing the very problem that the health organizations have expressed so much concern about).

Here are the specific problems:

1. The legislation lists several criteria for achieving approval of a modified risk product. The most important are the following: "the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will: (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(1)(A), the (A) clause above places an insurmountable obstacle in the path of approval of modified risk products. In order to demonstrate that the product, as actually used by consumers, will significantly reduce the risk of tobacco-related disease to individual users, large-scale, long-term epidemiologic studies are necessary. Even ignoring the requirement under 911(g)(1)(B), the (B) clause above (which itself appears to introduce an insurmountable obstacle), the bill as currently written precludes any harm reduction approach to tobacco control both by making it impossible for such products to meet the conditions for approval and by eliminating any incentive (especially economic) to develop such products. Thus, the bill may have the exact opposite effect that many believe it should have. It protects the existing high-risk products on the market.

It is critical for the public and policymakers to understand the ramifications of section 911(g)(1). In order to market a reduced risk product, a cigarette company would have to demonstrate that the product, as **actually used** by smokers, would

substantially reduce the **actual risk of disease** among **individual** tobacco users.

There is only one way to do this. And that is to conduct a long-term epidemiologic study in which one compares the disease risk of the modified product with that of a comparison product over a long time period and among a large population of smokers.

There are all kinds of complications with conducting such a study. First, it would be tremendously expensive. Second, it would take, at a minimum, 10–20 years to follow the smokers long enough to monitor changes in disease. For cancer risks in particular, you would have to follow smokers for about 20 years before you would be able to draw definitive conclusions regarding any reductions in risk.

Third, there are all kinds of research complications that would make it difficult to draw accurate conclusions. The only way to credibly demonstrate a reduction in risk would be to conduct a randomized clinical trial, where smokers were randomized to either smoke conventional cigarettes or the putative reduced risk cigarettes. But conducting a randomized trial of smoking would be unethical; such a study is impossible.

The best that could be hoped for is a natural experiment type of study in which a product is "test-marketed" and that population of smokers (i.e., guinea pigs) are monitored for 10–20 years. But this is a catch–22. How can you test-market the product if you need to obtain FDA approval before you can test-market it? The only way you could do this would be to market the product as a conventional cigarette (not let anyone know that it is a potentially reduced risk product). But to do that, you would destroy the study, because it is your obligation to demonstrate that as **actually used** by consumers, the product would reduce risk. Smokers might use the product very differently if they believe it is a reduced risk product than if they don't.

In other words, the legislation does not merely make it **difficult** to market a reduced risk product. It makes it **literally impossible**.

2. The bill contains a special rule that would allow FDA to approve certain modified risk products that cannot meet the criteria listed under (A) and (B) above. Such products must only claim to be reducing exposure to, or reducing levels of, or being free of a particular constituent. Specifically, such products can be approved if "scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1)." In such cases, the major criterion that must be met is as follows: "the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is anticipated in subsequent studies."

Thus, section 901(g)(2)(A) essentially allows products that do not claim to reduce risk but merely claim to reduce exposure to or levels of a particular constituent to be approved by simply showing that a reduction in risk is **anticipated** in subsequent studies. This is a very weak standard. As long as there is any promising preliminary evidence, one could argue that reduced risk is expected if it were to be studied (this is a far cry from demonstrating reduced risk, especially given the many uncertainties including the actual use of the product by consumers and unintended side effects or consequences).

The effect of 901(g)(2)(A), then, is essentially to allow the approval of reduced exposure products and to allow these products to be marketed as such, even though there is shoddy scientific evidence of any health benefit. This institutionalizes the very problem (unsubstantiated health claims) that health groups supporting this legislation have expressed so much concern about. The fact that the bill does not allow these products to represent themselves as reducing health risk is largely irrelevant, because consumers are going to perceive them as reducing risk. How else would someone interpret a claim of reduced exposure?

Of note, the bill does require that there be testing of consumer perception which shows that as the product is proposed to be labeled and advertised, it will not mislead consumers into thinking that the product reduces health risk. However, there are no restrictions on who must do the consumer testing and what the conditions or protocols must be. It would be relatively easy for a company to do consumer testing in such a way that they obtain the result they want to show. Anyone familiar with survey research, focus group studies, or other types of formative research knows that the way questions are asked and the specific protocols used can shape consumer responses substantially. Similarly, post-market surveillance protocols are left to the companies.

The proposed FDA legislation is thus the worst of both worlds. On the one hand, it allows companies to gain a government sanction to market products under the guise of reduced risk by merely calling their product reduced exposure. On the other

hand, it prevents companies from marketing products that may truly be reduced risk products by putting an impossible regulatory burden in the path of such products.

Despite all the rhetoric, the proposed FDA legislation would do nothing to save lives, but would instead ensure that the highest risk products remain firmly entrenched in the marketplace, without any competition from what could be life-saving alternatives. Of course, this lack of effective competition is why Philip Morris adores this legislation.

What it comes down to is protecting the profits of the Nation's largest tobacco company at the expense of the public's health. That Philip Morris is lobbying for this legislation makes perfect sense, and it is the company's fiduciary responsibility to do nothing less. That the Campaign for Tobacco-Free Kids and other major anti-smoking groups are joining alongside Philip Morris in promoting this legislation is nothing less than a travesty.

3. THE LEGISLATION MAKES A PUBLIC HEALTH BLUNDER—ASKING THE FDA TO PREVENT THE ADDICTION OF KIDS BY LOWERING NICOTINE LEVELS, BUT PREVENTING THE AGENCY FROM ELIMINATING THE NICOTINE

Due to a Mechanism Known as Compensation, Reducing Nicotine Levels Would be a Public Health Disaster; Smokers Would Smoke More, Increasing Tar Delivery and Deaths from Cancer and Chronic Lung Disease

According to a recent report released by the Harvard School of Public Health,[1] cigarette companies steadily increased the nicotine yield of their cigarettes during the period 1997–2005. The report describes the increase as being a total of 11 percent over the 7-year period 1998–2005, or an average increase of 1.6 percent each year during that period.

Major anti-smoking groups also hailed the study and told the public that it shows the need for FDA regulation of tobacco products. The Campaign for Tobacco-Free Kids used the study results to call for passage of legislation that would grant the Food and Drug Administration (FDA) authority to regulate tobacco products[2]:

> "A new study released today by the Harvard School of Public Health shows the critical need for Congress to enact legislation granting the U.S. Food and Drug Administration (FDA) authority over tobacco products. The Harvard study expands on and confirms an August 2006 study released by the Massachusetts Department of Public Health that found that tobacco companies have deliberately increased the levels of nicotine in cigarette smoke since 1998. The FDA legislation would require tobacco companies to disclose to the FDA changes in their products and provide FDA the authority to require them to reduce levels of constituents, like nicotine that make them more harmful or more addictive. . . . The fact that the tobacco companies have been able to secretly increase nicotine levels in tobacco smoke occurred only because no Federal or State agency currently has regulatory authority over cigarettes or what tobacco companies put in cigarettes. . . . The proposed legislation would grant the FDA the authority and resources to stop harmful tobacco company practices that continue to addict children . . . ."

The steady and significant increase in nicotine yields cigarettes over the past 8 years or so sounds like a concerning finding. It sounds like cigarette companies are increasing the addictive potential of their cigarettes and harming the public's health in a way that demands passage of the proposed FDA tobacco legislation. At least this is what the major anti-smoking groups want the public to think.

There are, however, two major problems with this.

First, an increase in nicotine yields does not necessarily mean that the public's health has been harmed. It is well documented that smokers compensate in response to changes in nicotine yields to maintain exposure to a relatively constant nicotine dose. This is why "light" cigarettes are not safer products. While the nicotine levels are lower, smokers compensate by simply smoking more; this negates the potential benefits of reduced nicotine and tar levels.

In a similar way, smokers might be expected to compensate by smoking slightly less if nicotine yields increase. This could actually have a marginally positive health benefit if it reduces overall cigarette consumption.

In fact, the report[1] acknowledges this important point:

> "The increase in smoke nicotine yield does not necessarily signify any change in exposure within the population of smokers, particularly as human smoking behavior is compensatory and will adjust for differences in smoke yield."

If anything, the proposed legislation would actually harm efforts to protect the public's health. By focusing on increases in nicotine yields as if they are necessarily

harmful to public health, the legislation implies that decreases in nicotine yields would be a good thing. But the truth is that reduced nicotine yields could be harmful to public health because they would likely increase cigarette consumption (due to compensation), leading to increased tar delivery and higher rates of lung and other cancers as well as chronic lung disease.

If lawmakers are disturbed by the addictiveness of cigarettes, then there's only one thing that can be done—and that's to require the elimination of the nicotine. Short of that, there's nothing that can be done. At least not anything beneficial. Requiring reductions in nicotine levels would be the worst thing we could do, because cigarette consumption would rise due to compensation, causing increased tar delivery and increased disease and death.

Regulating the levels of nicotine to make sure that they don't increase would be absolutely useless. Forcing the levels to come down would be absolutely disastrous for the public's health. There is no point in using the addictiveness of cigarettes to argue for the need for FDA regulation unless what you are calling for is granting the FDA the power to eventually eliminate the nicotine from cigarettes.

If the Campaign for Tobacco-Free Kids and other anti-smoking and public health groups were truly sincere in their public statements that we need to do something to protect kids from cigarette company attempts to addict them through the manipulation of nicotine in cigarettes, then the only viable option is to remove the nicotine. Nothing else would work—and in fact, merely lowering the levels of nicotine would actually harm the public's health.

Let's face it. This legislation represents a purely political compromise to protect the financial interests of the tobacco companies. Maybe that is the right thing to do, but let's cut out the rhetoric and simply admit that this is all about politics and not about protecting our children from the addictive nicotine in cigarettes.

On January 17, Senator Edward Kennedy released a statement[3] in response to the Harvard University School of Public Health report which concluded that nicotine yields of cigarettes have increased steadily over the past 8 years. In the statement, Senator Kennedy condemned Big Tobacco for addicting millions of young smokers due to these rising nicotine levels and called it a travesty for Congress to be an accomplice to this addiction by failing to enact legislation that would allow the Food and Drug Administration (FDA) to prevent this from happening.

Senator Kennedy said[3]:

> "This study is an extraordinary public service by Harvard's School of Public Health. It's dramatic new proof that Big Tobacco is addicted to addicting millions of young smokers into lifetimes of illness and early death. Congress has been an accomplice in the travesty because of the success of the tobacco lobby in blocking real reform. Hopefully, the study will be a wake-up call to persuade Republicans and Democrats alike to enact long overdue legislation allowing the FDA to regulate cigarettes and deal with their enormous risks."

Unfortunately, Senator Kennedy's statement deceives the American public into believing that the legislation which Senator Kennedy has introduced would actually do something to protect our Nation's youths from the addictive nature of nicotine in cigarettes.

It turns out that the legislation that is proposed would not do anything to address the problem of the nicotine addiction of our Nation's children.

In contrast, the proposed legislation would actually institutionalize the addiction of our Nation's children into law, ensuring that the Food and Drug Administration could never address the problem of nicotine addiction of our children by requiring the elimination of nicotine from cigarettes. The legislation would ensure that cigarettes always contain nicotine, and thus always maintain the potential to addict our children, regardless of whether we ever reach a point where social norms change in a way that would otherwise make feasible the FDA's gradual phasing out of nicotine from cigarettes.

Ironically, if you want to give the FDA the power to possibly reduce the harms of cigarettes, the one thing that might actually work would be to **mandate very high levels of nicotine in cigarettes**.

This would have two beneficial effects: first, it would substantially reduce the intensity of smoking and levels of consumption, reducing tar delivery and lowering cancer and chronic lung disease risks.

Second, it would make cigarettes all but "unpalatable" for kids, ensuring that fewer young people would take up the habit and have it turn into an addiction. But established smokers would still be able to obtain their nicotine.

This proposed legislation would not allow the FDA to mandate increases in nicotine levels in cigarettes. According to section 907(a)(4)(a)(i) of the legislation, the FDA could only require **reductions** of certain constituents in cigarettes.

4. THE LEGISLATION WOULD PRECLUDE THE SINGLE MOST EFFECTIVE REGULATORY ACTION TO PROTECT HEALTH THAT IS POLITICALLY AND TECHNOLOGICALLY FEASIBLE

By Precluding the FDA from Requiring an Increase in the Nicotine Yields of Cigarettes, the Bill Eliminates a Regulatory Option Recommended by the Institute of Medicine that Could Produce a Safer Cigarette

It honestly seems disingenuous to me to condemn the cigarette companies for addicting our Nation's youths with the nicotine in their cigarettes and then to support legislation that would institutionalize the addiction of our Nation's youths by precluding the FDA from removing the nicotine. It seems disingenuous to me to suggest to the public that we need FDA legislation to address the problem of the nicotine in cigarettes, but then support legislation that precludes FDA from doing anything other than reducing the nicotine levels.

The reason? Reducing nicotine levels will not make cigarettes non-addictive. Reducing nicotine levels will not stop kids from smoking. Reducing nicotine levels will not end the problem of the addiction of our Nation's youths.

What will reducing nicotine levels do? It will create a public health disaster by deceiving the public into thinking cigarettes are safer. It will lead to compensation by smokers, who will smoke more to maintain their dosage of nicotine. These smokers will therefore be exposed to higher levels of tar, which will lead to more cancer and emphysema. In short, reducing nicotine levels, without eliminating the nicotine, will kill people.

I think it is most reasonable to argue that removing the nicotine from cigarettes is not a feasible solution to the problem of addiction. I would never criticize someone for suggesting that the FDA should not be given the authority to require the elimination of nicotine from cigarettes. However, I find it inappropriate to mislead people by suggesting that the increased nicotine yields in cigarettes demands enactment of the FDA legislation that has been introduced in Congress. If the fact that cigarette companies are using nicotine to addict youths is a travesty and it needs to be stopped, then the only way to do that is to get rid of the nicotine. You can't bemoan the presence of nicotine in cigarettes, suggest that we need legislation to take care of the problem, and then deceive the American people by supporting legislation whose fine print actually precludes the FDA from taking care of the problem.

I can't over-emphasize this fact: reducing the nicotine yields of cigarettes will not take care of the problem.

What is so disturbing about this story is that we, as tobacco control advocates, have condemned the tobacco industry for doing precisely this: reducing the nicotine yields of their cigarettes.

In fact, we have taken the tobacco companies to court and helped to convict them of racketeering and fraud by virtue of the fact that they chose to decrease the nicotine yields of their cigarettes and market the cigarettes as having lower nicotine yields and therefore being "lighter." We have argued, apparently successfully, that marketing low-nicotine-yield cigarettes is fraudulent, because it deceives the American people into thinking that the product is somehow safer when the truth is that it is not any safer.

So why in the world would we propose a regulatory scheme in which we will do to the public exactly what the tobacco companies have done and been convicted of a crime for doing?

Tobacco control groups and advocates who are supporting this FDA legislation are essentially calling on the Government to do exactly what the tobacco companies tried to do, but for which they were accused and convicted of racketeering and fraud: to reduce nicotine yields of cigarettes.

Such an action by the FDA would certainly mislead smokers into thinking that the product is safer. The truth, however, is that the product would not be any safer. And it might actually be more dangerous.

The truth is that, short of removing the nicotine, the only effective regulatory action that could actually protect the public's health would be to require increases in the nicotine yields of cigarettes. Greatly increasing the nicotine/tar ratio of cigarettes would allow smokers to obtain the same amount of nicotine dosage while inhaling substantially lower amounts of tar. This could potentially reduce cancer and chronic lung disease rates.

However, the proposed legislation precludes the FDA not only from eliminating the nicotine, but also from requiring such increases in nicotine.

According to section 907(a)(4)(A)(i) of the proposed legislation: "A tobacco product standard established under this section for a tobacco product—(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—(i) for the **reduction** of nicotine yields of the product."

So the FDA cannot do the one thing that might actually produce some health benefits from regulation of the nicotine content of cigarettes.

5. THE LEGISLATION WOULD ESSENTIALLY TRANSFER THE MISREPRESENTATION OF THE SAFETY OF CIGARETTES FROM THE TOBACCO COMPANIES TO THE GOVERNMENT

By Establishing Product Safety Standards for Which There is Not Adequate Evidence of a Health Benefit, the Government Would Be Making Precisely the Same Type of Fraudulent Health Claims for Which Judge Kessler Found the Tobacco Companies Guilty

In her final opinion in the Department of Justice tobacco lawsuit against the tobacco companies, Judge Gladys Kessler ruled that the defendants had engaged in fraud by marketing cigarettes that rated lower yields via machine testing in a way that falsely led consumers to believe that these products offered a health benefit over higher machine-yield products.

A major part of the basis for this decision was a body of literature demonstrating that machine-yields of nicotine and other tobacco constituents have no direct relationship with actual human exposure, and thus with actual health risk, either on an individual or a population level. Machine yields, for example, do not adequately account for changes in human smoking behavior (e.g., compensation) which accompany any change in the yields of cigarettes.

A report published recently in the journal Tobacco Control and written by a group of tobacco control experts confirmed not only that machine-measured toxin yield information is virtually meaningless, but that newer advances in the way in which these yields are measured—which attempt to more closely simulate actual smoking behavior—are inadequate, and even these new methods do not yield information that is of any consumer value.[4]

> "Although each of the testing regimes will help to "characterise" how a product performs under a given set of smoking conditions, none of the smoking regimes "represent" human behaviour in terms of compensatory smoking and none is likely to produce emissions that will be markedly associated with human exposure or risk, either for individual smokers or for population-level differences between brands." . . .
>
> "After nearly 40 years—and after great cost to public health—the public health community is now coming around to the realisation that lower ISO emission cigarettes are not lower-risk products. Unfortunately, many regulators fail to understand the distinction between "product characterisation" and predicting human exposure. At the same time as they insist that cigarette emissions are not measures of risk, various regulators continue to use cigarette emissions in ways that assume a link between the machine emissions and human exposure. Many jurisdictions continue to require that quantitative levels of tar, nicotine and carbon monoxide appear on packages. These numbers continue to be misunderstood and misused by smokers, including smokers in the most affluent and highly educated countries in the world. To date, there is no evidence that quantitative emissions constitute effective consumer information, and several scientific bodies have rightly called for the removal of these emissions from packages. . . . the tobacco industry should be prohibited from using machine emissions in any of its labelling, advertising or marketing directed at consumers, even if accompanied by "warnings" or disclaimers, such as those that currently appear in the United States and Europe." . . .
>
> "Patterns of use must be examined to understand the interaction between product design and smoking behaviour in humans, and to identify systematic differences across products. Products that deliver fewer toxins for a fixed volume of smoke and also promote greater smoke intake when used by consumers are not lower-risk products. Likewise, products that deliver higher amounts of toxins, but discourage repeated use might potentially be seen as harm reducing compared with conventional cigarettes."

This is the flawed logic that underlies the proposed FDA legislation: We know that measurements of the amounts of various constituents in cigarettes have no demonstrable relationship with actual human exposure or with actual human health risk, so we propose a system to regulate the safety of cigarettes that relies upon reducing the measured levels of various smoke constituents. What an absurd idea.

We attack the tobacco companies for relying upon cigarette constituent measurements in making implied health claims, take them to court, get them convicted for fraud, and then proceed to go ahead and propose to set our own cigarette constituent level regulations, thereby making our own unsubstantiated implied health claims.

Unfortunately, the idea isn't just absurd. It's also damaging. The reason? Because like the machine-measured nicotine yields that we blasted the tobacco companies for relying upon in their communications, these FDA-sanctioned tobacco constituent levels will have no demonstrable relationship to the public's health, yet they will most certainly be interpreted by consumers as conveying an improved degree of safety.

There is no question that by virtue of cigarettes being placed under the regulatory jurisdiction of the FDA and by virtue of FDA promulgating "product safety standards," the public is going to assume that cigarettes have been made to be a safer product. However, those product safety standards are none other than specified reductions in a number of specifically chosen tobacco constituents, **whose levels have not been shown to correlate directly with human health risk.**

Essentially, what the proposed FDA legislation would do is simply change who is committing the fraud. Right now, it's the cigarette companies doing the dirty work, marketing reduced tar and reduced nicotine cigarettes in a way that deceives consumers into believing that these products are known to be safer. If the FDA legislation is enacted, then it will be the Government who is doing the dirty work, implying to the public that reduced X and Y cigarettes are known to be safer, when there is absolutely no evidence that such a product would, in fact, be safer.

No wonder why Philip Morris loves this legislation so much. It completely takes away the risk of litigation for fraud, yet allows the tobacco companies to tell consumers that they are complying with stringent product safety standards, assuring a safer product that is produced under the strict scrutiny of the Food and Drug Administration.

This whole thing has the potential to institutionalize the fraud that the tobacco companies have committed, but to put it into the hands of our own Government.

The *Tobacco Control* review article[4] points out many reasons why regulation of tobacco smoke constituent levels would not necessarily produce a safer product:

> "Not all constituents change to the same extent or even in the same direction under different testing regimes—for example, the NNK and benzo[a]pyrene: nicotine ratios decrease under more intense puffing conditions, whereas the nicotine ratio for carbon monoxide increases, as does the overall tar:nicotine ratio. It is unclear to what extent certain emissions can be reduced independently of others. Manufacturers have also shown their skill in substantially reducing machine emission levels through subtle design changes. Recent evidence from the United Kingdom suggests that tobacco manufacturers have adhered to the '10–1–10' limits on ISO emissions simply by increasing the level of filter ventilation so that brands provide deceptively low readings under machine conditions. Filter ventilation is the most prominent, but by no means the only design change available to manipulate yields. . . . Emission limits will require considerable resources to implement and monitor, resources that may exceed the current capacity of regulators. There are also concerns that emission limits would exempt tobacco manufacturers from liability. Most important, it is uncertain how consumers will respond to emission regulation. Despite clear scientific statements to the contrary, consumers may interpret emission limits as an indication that cigarettes are less harmful—much in the same way that they have interpreted emission reductions in the past. In fact, future emission limits may be even more likely to undermine perceptions of risk than in the past: "new" emission reductions would be based on a "superior" machine method, would be more comprehensive in scope, and may have the formal endorsement of the [FDA]. . . . one can also envision how manufacturers might shape consumer response through packaging and marketing. Overall, regulations that achieve modest reductions in smoke toxicity but result in fewer quitters or more initiators are not effective policy measures."

But the most important reason why the product safety standard approach taken in the proposed FDA legislation is a potential disaster is that there is simply no evidence that cigarettes can be made to be a safer product, in actual human practice, simply by mandating a reduction in levels of specified smoke constituents.

We simply do not know which constituents, at what levels, and in what combination, result in what degree of risk of what diseases that are caused by smoking.

Anyone who promises you that they are going to "*save countless lives*" via these product safety standards (precisely what the Campaign for Tobacco-Free Kids is telling its constituents) would probably also be effective in selling you a bridge in Brooklyn.

In one respect, the Campaign for Tobacco-Free Kids is precisely correct in stating that this legislation is going to save countless lives. It is so unclear that product safety standards will do **anything** to reduce overall health risks and that it is im-

possible to count **any** lives that will be saved. Perhaps that's why the Campaign is having trouble counting them.

Ultimately, there's only one way that I think even has the potential to be successful in developing safer cigarettes or other tobacco products. And that's to allow the free-market system to work. Free-market competition could, possibly, result in a race to see which company could come up with safer products. The proposed FDA legislation, however, destroys the possibility of this free-market competition by making it impossible for any tobacco company to market a truly reduced risk product.

What the bill does, on the other hand, is set up a competition to see who can market a reduced exposure product, which, just like reduced-nicotine or reduced-tar cigarettes, is likely to be just as effective in killing people, but which would most certainly be interpreted by the public as implying a reduced health risk.

Essentially, what the proposed legislation does is set up a system of government-administered public fraud in order to benefit the tobacco companies.

6. RATHER THAN SET UP A MEANINGFUL SCHEME FOR REGULATION OF TOBACCO PRODUCTS, THE LEGISLATION MERELY PROVIDES WINDOW DRESSING

The legislation that some health groups have been claiming creates an effective public health policy that actually does the following:

• It bans the presence of strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee in cigarettes, but does not inherently disallow the presence of hydrogen cyanide, carbon monoxide, N-nitrosodimethylamine, benzene, radioactive polonium 210, or nitrogen dioxide.

• It requires FDA to ban any tobacco product that contains a severely harmful chemical defect, but explicitly prevents FDA from doing the same with tobacco products that contain thousands of severely harmful chemicals, so long as those chemicals are ordinarily contained in tobacco products.

• It provides for stringent regulation to prevent adulterated or misbranded products, but leaves the "pure" and "properly branded" deadly products largely unregulated.

• It requires that manufacturers report any adverse health effects of its products that are **unexpected**, but the **expected** 450,000 or so deaths per year due to these products require no special attention.

• It expresses grave concern for the tremendous harm to the public health caused by tobacco products that falsely purport to reduce disease risk, but does not seem to find the harm caused by the high-dose products to be of much alarm.

• It strictly regulates new tobacco products introduced to the market for safety and health, but allows existing products to continue killing hundreds of thousands of Americans each year.

• It expresses grave concern over youth access to tobacco products and calls for **comprehensive** restrictions on the sale of tobacco products to minors, but it explicitly prevents FDA from regulating the sale of cigarettes in any specific retail establishments (including malls, grocery stores, restaurants, gas stations, convenience stores, bowling alleys, and even pharmacies).

• It provides for extremely rigorous and comprehensive (and probably impossible) tobacco company reporting of brand-specific levels of tobacco smoke constituents, but does not require any particular action concerning the more than 4,000 constituents that are already known to be harmful.

• It requires the FDA to establish a series of health standards regarding the nicotine and harmful constituents of tobacco smoke (and no health standard other than finding the cigarette itself to be inherently and unacceptably toxic is rational or defensible), but then prevents FDA from requiring even the gradual elimination of nicotine from cigarettes, or from requiring the gradual shift to a system of prescription-only cigarette access, or from ever requiring even a gradual elimination of cigarette products from the market.

• It requires the FDA to prescribe labeling requirements for the **proper use of the tobacco product**. How does one **properly** inhale thousands of dangerous chemicals and scores of deadly carcinogens?

• It requires FDA to consider periodically **new** medical data on cigarette risks, but the **existing** evidence on the established risks of cigarettes can be largely ignored.

• It requires notification to all tobacco product users of the substantial health risks of any new tobacco products, but no special notification procedures for the existing deadly products.

• It requires FDA to recall and ban any tobacco product that contains a manufacturing defect that is not **ordinarily** present in tobacco products, but a serious defect—such as producing death in one out of every two long-term users—is fine, so

long as the deaths are caused by an **ordinary** constituent of the product rather than a **new** manufacturing defect.

• It allows the FDA to prescribe strict regulations to protect the public's health from sub-standard packing and storage, but the fact that what is being packed and stored is inherently dangerous is of little concern. The FDA may prescribe stringent regulations to eliminate any pesticide residues on the tobacco, but the rest of the toxins **inside** the tobacco are not necessarily regulated.

The fatal flaw of the legislation is the unacceptable degree of restriction of FDA's potential actions which makes it impossible for FDA to act appropriately within the legislative mandate it is given.

Although this legislation eliminates the chocolate in cigarettes and prevents cigarette companies from misrepresenting their new products as being safe, the latter has been happening for more than half a decade, and the dangers of existing "normal risk" products are far more important than anything else. We should be focusing our efforts on addressing the Nation's current tobacco-use epidemic, which is killing more than 400,000 Americans each year.

7. THE PROPOSED LEGISLATION WILL BE DETRIMENTAL TO THE PUBLIC'S HEALTH

By Giving Tobacco Products an FDA Stamp of Approval, the Legislation Will Undermine the Public's Appreciation of the Dangers of Cigarettes, but Without Actually Ensuring that These Products are Significantly Safer

This legislation is **severely detrimental** to the best interests of the public's health. While the health groups supporting the bill are arguing that although it's not perfect, it's better than the status quo, a careful analysis reveals that it is **not** better than the status quo, but instead, would represent a substantial loss for public health.

The three major reasons why this is the case are:

(1) The overall regulatory framework of the bill is counter-intuitive to basic public health principles. The bill would protect existing cigarette products by making it nearly impossible for potentially reduced risk products to enter the market. At the same time, it would allow tobacco companies to market products as having reduced levels of certain toxins without having to provide any substantial evidence of a health benefit. Thus, the basic regulatory framework established by the bill as relates to reduced risk products would do two disastrous things. First, it would make it virtually impossible for reduced risk products to enter the market. It would take away any economic incentive for companies to do meaningful research and development of potentially significantly safer products. Second, it would actually institutionalize the problem of misleading health claims regarding reduced exposure products—the very problem that the health organizations keep emphasizing is so unacceptable. But the bill itself creates a regulatory framework by which companies can market their products as being reduced exposure products without any solid scientific substantiation of a health benefit. The public does not consist of scientists. The public is going to interpret a reduced exposure claim as being a reduced risk claim. Thus, the problem of unsubstantiated (implied) health claims about tobacco products will not only remain, it will now be sanctioned and operated through FDA.

(2) The bill would essentially put an end to the prospect of any meaningful punishment of the industry, receipt of punitive damages for victims of classes of victims of tobacco-caused death, disease, and personal suffering, or achievement of real industry changes through litigation. In previous litigation, the tobacco companies have successfully used the argument that they are already regulated so there is no need for further steps to deter future bad behavior. They gained tremendous mileage from the tobacco settlement in this regard. But they would gain even greater mileage from FDA regulation. They would then be able to claim that the Federal Government has assumed jurisdiction over all aspects of tobacco operations, including manufacture, new product introductions, health claims, health standards, ingredients, additives, and smoke constituents, nicotine, advertising, access, and marketing (which would be true), and that there is therefore no need for any further injunctive relief or punitive damages to deter future bad activity—it is all under FDA's control now. And from a public perception standpoint they would be right.

It is important to understand that the important point is **not** whether the legislation **actually** gives the companies any immunity or protection from litigation. The important point is simply whether or not the companies can **use** the fact of being regulated by FDA to achieve *de facto* immunity by taking advantage of the **public perception** that the problem is basically taken care of.

(3) This legislation is likely to result in increased, not decreased deaths from tobacco products, for the following reasons:

(a) It will make it virtually impossible to research, develop, introduce, and market new potentially less hazardous tobacco products. It essentially freezes the market as it is and entrenches existing high-risk products into the market. It puts an end to any meaningful possibility of harm reduction as a tobacco control approach.

(b) It will undermine current and future litigation: the companies will be able to successfully use the argument that they are already regulated to stave off injunctive relief and substantial punitive damages in litigation by appealing to jurors' perceptions that the problem is "taken care of." The highly exaggerated claims of the positive public health impacts of this legislation that the health organizations are making are only contributing to this perception.

(c) It will reduce the public's perception of the inherent harms of cigarettes. By promulgating health standards, FDA will be giving the public the perception that cigarettes are now safer to smoke. The public is not necessarily aware of the 4,000 toxins and 50+ carcinogens in the smoke, nor are they epidemiologists—if they are told that the nitrosamines have been removed, they are naturally going to perceive that the problem is being taken care of, or at least largely taken care of. Since we know that smoking prevalence is directly proportional to the degree of perceived harm from smoking, this will lead to an increase in smoking prevalence (at least compared to what would have occurred in the absence of the legislation).

(d) Most importantly, there are no documented mechanisms by which the legislation will save lives. Health groups supporting this legislation have not produced a single solid, evidence-based argument of how this bill will save lives.

There are really only three ways in which this could occur:

First, the bill could save lives if the performance standards reduced the relative risk of smoking-related diseases. There is absolutely no evidence that this is the case—we simply do not know the specific constituents that are responsible for the diseases as well as the relative contribution of each, alone and in combination, nor do we have any evidence for there being a decreased relative risk associated with product changes that eliminate or reduce a single or a few components.

Second, the bill could save lives if it encouraged the research, development and marketing of actual reduced risk products. But in fact, the bill does the opposite. It puts an almost impossible barrier in front of the development and marketing of these potential products. It also puts a virtually insurmountable barrier over other potential harm reduction efforts—such as promoting the use of snus or other less hazardous nicotine-delivery devices.

Third, the bill could save lives if it reduced youth smoking. It has been well documented that youth access restrictions, implemented in actual widespread practice, do nothing to reduce youth smoking. So the access regulations are essentially meaningless. And the three access restrictions that **could** potentially reduce youth smoking have been precluded (raising the legal age of purchase, restricting the types of establishments that sell tobacco, and phasing in some sort of prescription-access system).

Research has also documented that the kinds of marketing restrictions imposed by the bill are not effective in reducing youth smoking, or even in reducing youth exposure to cigarette advertising. There are simply too many avenues for the tobacco companies to market their products, and anything short of a near total ban on advertising and promotion of tobacco products (which clearly would violate the First Amendment based on the Supreme Court's interpretation) is unlikely to have a substantial effect on youth smoking. A number of articles document that even major changes in policy, such as removing ads completely from youth-oriented publications, does not reduce youth exposure to this advertising to any meaningful (from a public health perspective) degree.

In fact, *Central Hudson* provides a perhaps insurmountable obstacle to the advertising restriction approach to tobacco control, because of two basically conflicting prongs. First, the restrictions would need to be comprehensive enough so that they have a substantial impact on smoking behavior. Second, the restrictions would have to be crafted as narrowly as is possible to address the relevant government interest. It remains to be seen whether this can be done and if it can result in regulations that have a substantial public health effect. We simply don't have evidence yet that it can be done, and there is no justification for highly touting this bill as being the ultimate answer to curtailing cigarette advertising.

Finally, the bill could save lives if it reduced adult smoking (or youth smoking) by reducing cigarette demand. It won't do that by increasing the competition in the marketplace and it won't do that by increasing the public's perceptions of the inherent risks of smoking.

In summary, there simply is no documented evidence to suggest that (or how) the proposed legislation will save lives. In contrast, there is well-documented evidence (including substantial literature in the fields of tobacco product chemistry, tobacco

epidemiology, psychology and public opinion research, framing theory, and mass communications [including marketing and advertising] research) to suggest that the legislation is unlikely to provide any public health benefits in terms of reducing the relative risk of smoking or increasing the use of lower-risk tobacco products, but that it is likely to produce public health harm through its institutionalization of high-risk products, its barriers to the introduction of reduced risk products, its probable effects on litigation, its probable effects on public opinion and attitudes towards tobacco products and towards the tobacco industry, and its probable effects on slowing down the pace of other tobacco control legislative efforts (including what will be a chilling effect on State and local tobacco control legislation).

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PREPARED STATEMENT OF ELIZABETH WHELAN, M.P.H., SC.D., GILBERT L. ROSS, M.D., AND JEFF STIER, ESQ., THE AMERICAN COUNCIL ON SCIENCE HEALTH (ACSH), NEW YORK, NY

Mr. Chairman, the mission of the American Council on Science and Health (ACSH) is to promote sound science and to inform policy debates about public health, providing independent scientific evidence and analysis to clarify the scientific record in order to educate the public and assist policymaking. As such, we are writing on behalf of ACSH to lend our voice to others who have criticized S. 625, a bill recently introduced in the Senate and referred to your committee. We believe, as experts in the field of tobacco-related health effects and public health policy, that this bill would unnecessarily disregard a large and growing body of scientific evidence pertaining to the relative dangers posed by smoking and smokeless tobacco.

As you know, there has been a 50-year public health campaign against smoking cigarettes in the United States. Evidence has mounted, and indeed continues to mount, about the health risks associated with smoking cigarettes. And yet, despite widespread awareness of the general risks, cigarette smoking remains by far the greatest preventable cause of death in the United States, claiming more than 400,000 lives every year. While we can hardly say the public health campaign has failed—indeed, the ubiquitous acknowledgement of smoking's risks can be considered a major accomplishment of public health consumer education—the campaign has long offered what should now be considered a false dichotomy to smokers: quit or die, instead of fostering awareness of harm-reducing alternatives to cigarettes for those who cannot quit nicotine altogether.

Indeed, after all these years, there is no reason to doubt that smokers know that cigarettes are unhealthful, yet they continue to smoke, in large part because of the difficulty of quitting. Unfortunately, quit rates with traditional methods are abysmal. This is where research published by ACSH might prove useful in this particular debate, and in the crafting of an improved, more beneficial version of S. 625.

The conventional wisdom, perpetuated not only by cigarette companies but by otherwise reliable sources, including the U.S. Surgeon General, includes the fallacy that all tobacco products are equally harmful to public health. That is, smokeless tobacco, cigars, cigarettes, and pipe tobacco are, from a public health perspective, the same thing. Scientific studies have proven that they are not, and a rapidly-growing body of evidence confirms that they are not. Any effort to regulate tobacco

products must explicitly acknowledge the differences in health risks between types of tobacco.

The fact is that modern smokeless tobacco products are considerably less harmful than cigarettes. No one should start using any form of tobacco if they can avoid it, of course, but for those who are already inveterate smokers and unable to quit nicotine altogether, smokeless tobacco at least provides a far, far safer (albeit not completely risk-free) way of receiving nicotine. Public policies that ignore this fact undermine public health, especially the health of those specifically designated to be in the protected, vulnerable group. Unfounded, unscientific pronouncements that lump all tobacco products and their risks together ultimately undermine the basic purpose of tobacco-regulatory policies. S. 625 does not distinguish between harmful smoked tobacco and the demonstrably less harmful smokeless tobacco, to the detriment of millions of nicotine addicts. ACSH supports the announced goals of S. 625—the reduction of smoking and smoking-related illnesses, clearer and streamlined regulation of tobacco, and the protection of children—but we strongly disagree with the bill's failure to appreciate the opportunity presented by the scientific evidence distinguishing smoking and smokeless tobacco.

Consider a limited but informative case in Sweden. ACSH recently reported on a study to gauge the efficacy of a program that encourages smokers to switch to smokeless tobacco products as an alternative both to smoking (which they know is harmful to them) and complete tobacco abstinence (which they have found extremely difficult). The results of the study are extremely positive. The program works. It works so well, in fact, that Sweden now has the lowest smoking-related mortality rates in the world. A similar program in the United States, where smoking is a bona fide public health disaster, could save thousands of lives and vast amounts of health-related expenditures. Harm reduction programs using smokeless tobacco as an option, even small programs, would seem to be a welcome opportunity to build on the successes and learn from the failures of our decades-old public health campaign against smoking. Smokeless tobacco is demonstrably less harmful than cigarettes, while making it much easier for some smokers to quit cigarettes. A transition from smoking to smokeless tobacco—and for many, from smokeless to abstinence—could produce great benefits for public health. It seems clear that it ought to at least be allowed a chance to work.

With even the U.S. Surgeon General failing in some public statements to rank the profoundly different health risks from different forms of tobacco—differences that, if known to the general public, might save lives by means of harm reduction—we must take care not to perpetuate the myth of smoking and smokeless tobacco equality. Part of what S. 625 ought to do is to correct the public record regarding that myth, and until it does so, ACSH urges that the bill be modified or amended to allow lower-exposure products, such as smokeless tobacco, easy or at least equal access to the tobacco marketplace.

AMERICAN ASSOCIATION OF PUBLIC
HEALTH PHYSICIANS (AAPHP),
ROLLING MEADOWS, IL 60008–1842,
February 26, 2007.

MEMORANDUM

TO: Senator MIKE ENZI, c/o Amy Muhlberg

FROM: JOEL L. NITZKIN, M.D., M.P.H., DPA, Chairman, AAPHP Tobacco Control Task Force

SUBJECT: Statement for the Record re. S. 625—FDA Regulation of Tobacco Products; ref 2/27/07 Committee Hearing

HON. SENATOR ENZI: I am writing this note in my capacity as a public health physician with over 30 years of experience dealing with tobacco-related legislation, and on behalf of the American Association of Public Health Physicians (AAPHP), as Chair of the AAPHP Tobacco-Control Task Force.

On behalf of AAPHP, I am urging that the "fast track" for this legislation be temporarily derailed to allow in-depth consideration of the full text of S. 625/H.R. 1180 by Senators, Representatives, and national organizations who have endorsed this legislation on the basis of one or more widely circulated summary descriptions of this bill.

AAPHP endorses FDA regulation of tobacco products in accordance with Koop-Kessler guidelines (the Report of the Koop-Kessler Advisory Committee on Tobacco Policy and Public Health (December 18, 2003) *http://repositories.cdlib.org/tc/re-*

ports/koop). Unfortunately, this bill, with its current text, has the potential to do significant harm in terms of increasing illness, death and other costs to society from tobacco products. **Our reading of this bill, in its current form, leads us to believe that it offers no possibility of any public health or other community benefit.**

This bill has the enthusiastic endorsement of many prominent health-related national organizations, apparently on the basis of a brief description of its contents developed and distributed by the Center for Tobacco Free Kids (CTFK). Their summary hypes this bill as enabling FDA to eliminate advertising of tobacco products to children, disclose the ingredients of their products and require them to remove or reduce harmful ingredients.

The bill has wording which, if taken out of context, leads to these impressions. Unfortunately, in the opinion of AAPHP, other wording included within this 155 page bill totally eliminates any possibility of public health benefit—and reasonably assures the opposite result.

The text begins with an accurate description of the illness, death and cost-related burdens now imposed on our society by tobacco products. It then proceeds to enshrine in law the concept that this burden is fully acceptable to Congress and the FDA—with the major purpose of the FDA regulation to prevent misbranding and adulteration of tobacco products that might threaten even higher risk of illness and death.

Our huge toll of illness and death from current tobacco products is not due to adulteration and misbranding. It is due to the inherent toxicity of the tobacco itself. Framing the problem in terms of misbranding and adulteration will invite current tobacco manufacturers to advertise and prominently label their products as "FDA Approved." If this bill, in its current form, is passed into law.

The provisions in the bill to allow FDA to reduce harmful components of tobacco smoke are more than totally neutralized by a series of provisions that require FDA to carry a technically impossible burden of proof (that reduction of that single component will reduce the health impact), by provisions that give the politically appointed secretary of the agency veto power over any proposed regulation, by requiring (rather than passively allowing) congressional action before any regulation is implemented, and by requiring FDA to "consider" whether any proposed regulation would increase the demand for contraband tobacco products. This last provision stands as an open invitation to tobacco companies to assert in court that any proposed change in the composition of its tobacco products that change the taste, reduce the attraction to nicotine addicts or significantly increase the cost of manufacture could increase the demand for contraband.

In addition, the bill prohibits FDA action to ban any tobacco products, to require reduction of nicotine levels to zero or to raise the allowable age to purchase tobacco products above 18.

The bill does prohibit marketing directly to children. It does nothing, however, to inhibit advertising "directed" at young adults to suggest initiation of tobacco use as a rite of passage to adulthood. The provision of the bill, referencing the tobacco industry's "first amendment rights" imposes on FDA the burden to demonstrate that such advertising, is, in fact, intended for underage potential smokers.

Both Altria and the public health community have written guidelines defining what each would consider appropriate FDA regulatory authority. The tobacco industry guidelines specify the ability to manufacture and market its products to adults without governmental interference. S. 625 fully meets all of the tobacco industry specifications. The public health specifications, known as the "Koop/Kessler Guidelines" were originally developed in the mid-1990's, then republished in 2003. They specify authority by FDA to take whatever action is needed relative to manufacture, advertising and distribution of tobacco products to protect the health of the public. S. 625 violates Koop-Kessler guidelines by virtue of major limitations imposed on FDA authority.

The current regulatory and reporting requirements strongly favor the current market leader and impose substantial costs and time delays relative to the introduction of new tobacco products into the marketplace, while allowing "minor" alterations of currently marketed products with little FDA interference. They specify studies and reports easily provided by Altria, but prohibitively costly to smaller firms—thus the strong endorsement by Altria, but opposition from other tobacco companies.

AAPHP is recommending that S. 625 be temporarily derailed from it's current fast-track to allow due consideration of the issues noted above, based on a careful reading of the entire bill rather than brief and possibly biased summary descriptions.

For easy reference—the full bill, our analysis with page and line-number specifications of key provisions, and the Koop-Kessler guidelines have been posted on *www.aaphp.org*.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY, SENATOR ENZI, SENATOR BURR, SENATOR HATCH, AND SENATOR COBURN BY MATTHEW L. MYERS

QUESTIONS OF SENATOR KENNEDY

Question 1. Does the Federal Trade Commission have the expertise to effectively regulate tobacco industry marketing? How does the expertise of the FDA to regulate tobacco industry marketing, as well as tobacco products, compare with that of the FTC?

Answer 1. The Federal Trade Commission (FTC) does not have the requisite expertise to effectively regulate tobacco industry marketing or tobacco products upon which marketing and claims are based. The FTC, by its own admission, is "an agency of lawyers and economists" and is not a science-based agency and does not have the necessary scientific, medical and public health expertise to evaluate scientific claims and data regarding tobacco products.[1] The FDA is the only science-based, public health agency with the expertise required to evaluate cigarette design and content and scientific claims of reduced harm that will ultimately protect consumers.

Furthermore, the FTC is a law enforcement agency whose primary task is to enforce the law—such as the Federal Trade Commission Act's Section 5 prohibition against false and deceptive advertising—not protect the public's health. In most instances, the FTC acts retrospectively against one bad actor once a violation has occurred. In contrast, FDA is charged with protecting the public's health and as a public health agency routinely acts prospectively to address problems. Through the rulemaking process, FDA sets regulation standards for an entire industry and addresses problems comprehensively. The FTC's rulemaking authority is extremely limited and rarely used. (maybe elaborate)

The FTC's track record provides ample evidence of its inability to carry out the functions that are assigned to FDA in this legislation. The type of "light" and "low tar" marketing that has resulted in millions of Americans switching to these products falsely thinking they are safer has been allowed to continue by the FTC for decades without challenge.[2] The only time the FTC has gone after a manufacturer in the last 20 years with regard to "light" and "low tar" marketing are in the few cases where there is evidence that a company's reports do not even accurately report tar and nicotine levels according to the FTC testing system.

Furthermore, the only case the FTC has brought with regard to tobacco marketing is a case challenging the use of a cartoon character to sell Camels and the FTC did not act for more than 4 years after the Camel cartoon character was introduced. Despite the overwhelming evidence linking tobacco marketing to youth tobacco use, a virtual flood of ads that others have identified as impacting youth tobacco use, findings by the National Academy of Sciences in 1994,[3] the exhaustive findings by the FDA as part of the documentation issued in support of its Proposed Rule[4] and other studies linking tobacco marketing to youth tobacco use, the FTC has taken no action to curtail or stop any of these campaigns.

The capability of talented and skilled scientists and researchers currently employed by FDA, who are able to conduct sophisticated analyses and evaluate complex scientific data, including an analysis of the impact of different products on the human body, is the best example of why FDA is the right agency to regulate tobacco products. The FDA's scientists regularly evaluate the impact of foods, drugs, cosmetics and medical devices, the same expertise and skills that are needed to carry out the functions given to the FDA in the pending legislation. For example, analysis of toxicity data for tobacco products and/or various constituents (including smoke constituents) could be conducted by the FDA's National Center for Toxicological Re-

[1] Testimony by Timothy Muris, FTC Chairman, June 3, 2003, before the Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection, U.S. House of Representatives.

[2] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Chapter One: Public Health Implications of Changes in Cigarette Design and Marketing Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001; Tobacco Control Legal Consortium, The Verdict Is In: Findings from *United States* v. *Philip Morris*, Light Cigarettes (2006).

[3] Institute of Medicine, National Academy of Sciences, *Growing Up Tobacco Free* (1994).

[4] August 1995.

search, whose mission "involves fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA."[5]

FDA's various centers that oversee foods, drugs, medical devices, and biologics are home to career chemists, toxicologists, statisticians, epidemiologists, and surveillance and consumer marketing experts with the relevant skills needed to assume regulatory oversight of tobacco products. These are the types of functions and skills that will be critical to building an effective, science-based regulatory regime for tobacco products. In addition to evaluating complex scientific data, the FDA applies this knowledge toward the marketing and advertising associated with any approved product to ensure that it is consistent with the evidence for that product and delivered to consumers in an understandable and truthful manner that does not exaggerate the benefits or misrepresent the risks associated with the use of that product—key skills and expertise that will be critical in FDA's oversight of tobacco product marketing and claims.

Question 2. Concern was expressed at the hearing that FDA regulation of tobacco products would create the public perception that cigarettes had the FDA "seal of approval," misleading consumers into believing that the products were less harmful. What provisions are contained in S. 625 to make clear to the public that the FDA has not approved the use of cigarettes or other tobacco products? Are there additional safeguards that could be included in the legislation to make this even more clear?

Answer 2. The real problem is that today consumers mistakenly believe that tobacco products are regulated by the Government for health and safety purposes, not that consumers will be misled about the relative safety of tobacco products and the Government's role if this legislation is enacted. This legislation will ensure that consumers are not misled by the tobacco industry about the relative safety of their products, and it provides FDA the authority to make sure the tobacco industry does not misuse the legislation to give the public the false impression that FDA has concluded that tobacco products are safe.

Many consumers already believe that cigarettes and other tobacco products—and the claims being made in their advertising—are already regulated and approved by the Federal Government.[6] When consumer misperceptions about government approval are combined with the current marketing practices of the tobacco companies which are not regulated in terms of their scientific accuracy, merit, or truthfulness, we have a recipe for a public health disaster—a disaster we have already seen take place in the form of light and low tar cigarettes—and a disaster that this legislation will prevent in the future.

The history of light and low tar is a poignant and tragic example that it is the status quo that is misleading consumers about the relative safety of tobacco products. In its historic report on light and low tar cigarettes, the National Cancer Institute[7] concluded that:

1. Many consumers use the terms "Light" and "Ultra-Light" as a guide to the riskiness of particular brands of cigarettes.
2. Many smokers choose Light and Ultra-Light brands because they believe that such cigarettes are less likely to cause health problems.
3. Individuals who are most concerned about smoking risks and most interested in quitting adopt low-yield brands.

These types of misleading actions would be corrected by the current legislation. In addition to consumer misperceptions about light and low tar, the NCI found, regarding the marketing of these products by the tobacco companies, that:

1. Advertisements of filtered and low-tar cigarettes were intended to reassure smokers (who were worried about the health risks of smoking) and were meant to prevent smokers from quitting based on those same concerns.
2. Advertising and promotional efforts were successful in getting smokers to use filtered and low-yield cigarette brands.

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[5] National Center for Toxicological Research, *http://www.fda.gov/oc/oms/ofm/accounting/cfo/2002/NCTR.htm* (Web site accessed March 15, 2007).

[6] "Smokers' responses to advertisements for regular and light cigarettes and potential reduced-exposure tobacco products," Nicotine & Tobacco Research, Volume 6, Supplement 3 (December 2004) S353–S362.

[7] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001, *http://cancercontrol.cancer.gov/tcrb/monographs/13/*.

3. Internal tobacco company documents demonstrate that the cigarette manufacturers recognized the inherent deception of advertising that offered cigarettes as "Light" or "Ultra-Light," or as having the lowest tar and nicotine yields.

Furthermore, as found by Judge Kessler in her August 2006 ruling against the tobacco company defendants in the Department of Justice tobacco lawsuit (for more details on Judge Kessler's findings for the entire case, see Tobacco Control Legal Consortium, *The Verdict Is In: Findings From United States* v. *Philip Morris* (2006), *http://www.tobaccolawcenter.org/dojlitigation.html)*,

> "Contrary to their internal documents, Defendants also continue to deny that low tar cigarettes are just as hazardous to smokers as full-flavor cigarettes, in part because of smoker compensation. In 1998, Philip Morris, RJR, B&W, and Lorillard jointly stated to the FTC that compensation was so "weakly documented" that the FTC should not require disclosure warnings to alert consumers, and that they were "unaware of evidence," other than that presented in Monograph 7, 520842199–2295 at 2243, 2289 (US 88618), that consumers viewed low-tar cigarettes as safer. Defendants are well aware from their own research that a majority of smokers believe that low-tar cigarettes are healthier, are willing to buy them for precisely that reason, and are willing to sacrifice taste for what they believe to be less harmful cigarettes. Nonetheless, to this day, Defendants still deny that, as Monograph 13 found, low-tar cigarettes are just as dangerous as full-flavor cigarettes. These RICO violations are likely to continue." [*Judge Kessler's Final Opinion, page* 1609].

Several sections in this legislation give the FDA authority to prohibit a tobacco company from advertising or asserting that its product has received "FDA Approval" or from making some other similar affirmative statement in its labeling or advertising from being made. Sections 903, 906(d), 907 and 910 give FDA specific authority over the content of labels, labeling and advertising. These sections provide FDA clear authority to prohibit these types of claims on the basis that they will mislead consumers about the harmfulness of tobacco products. Specifically, if the FDA determines that such a statement would result in increased individual risk and/or population level harm, the authority FDA is granted over the labeling of the product is sufficient to allow FDA to prevent such "seal of approval" statements from ever taking place.

Question 3. S. 625 creates an entirely new section of FDA law for the regulation of tobacco products, with standards that were specifically designed to deal with the unique issues raised by the use of tobacco. Contrary to what some have claimed, under the legislation the FDA would not be regulating tobacco products the same way it regulates drugs and medical devices. Would you explain the key differences in the tobacco regulatory process?

Answer 3. S. 625 recognizes that tobacco products are uniquely lethal[8] and cannot be "safe and effective," the standard that FDA applies to many products under its jurisdiction and, therefore, the bill adopts a different standard that is appropriate for tobacco products and consistent with the agency's overall mission of protecting the health of the American public. Instead of maintaining the status quo under which we do nothing to reduce the harm of tobacco products, the standard in the bill is based on what actions are "appropriate to protect the public health," taking into account the impact of any proposal on the health of the "population as a whole, including users and non-users" of tobacco products. Thus, the bill gives the FDA the authority to take actions it believes will reduce the number of people who die from tobacco.

It gives the FDA the authority to use its skills and expertise to evaluate the health impact of different products on consumers to reduce, to the extent possible, the harm caused by tobacco products, using a standard that recognizes that tobacco products are currently used by approximately 50 million consumers, are not safe and are addictive. It recognizes that a different standard is needed in this situation and includes a standard that will allow FDA to save lives.

The bill puts in place measures to prevent kids from starting to smoke and to ensure that smokers are not dissuaded from quitting by misleading claims, and it establishes a process to reduce the harm from tobacco products to those who are unable to quit. The goal of this legislation is to reduce the number of people who needlessly die prematurely from tobacco use.

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[8] U.S. Department of Health and Human Services. The Health Consequences of Smoking: A Report of the Surgeon General. Executive Summary. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

Although the legislation uses a different standard for the regulation of tobacco products, the agency will apply the same basic set of skills that it has used for decades. The core competencies of the FDA can and should be applied to the regulation of tobacco products. FDA's various centers that oversee foods, drugs, medical devices, and biologics are home to career chemists, toxicologists, statisticians, epidemiologists, and surveillance and consumer marketing experts with the skills required to assume regulatory oversight of tobacco products. In fact, FDA is the only agency with the scientific and health expertise, as well as regulatory experience required, to adequately evaluate tobacco products.

Question 4. Under S. 625, the entire cost of FDA regulating tobacco products would be paid for by a user fee imposed on the tobacco companies based on their market share. Therefore, there would be no impact on the existing resources that FDA receives to discharge its current regulatory responsibilities. Would you describe how this funding for tobacco regulation would work?

Answer 4. This legislation creates a new, separate funding mechanism for FDA's new tobacco product-related responsibilities. The legislation allows FDA to determine the best way to structure its staff to carry out the functions assigned to FDA, but funds are provided to allow FDA to hire the additional staff it will need to carry out the activities required by this legislation. The new responsibilities would be funded through a user fee on the tobacco industry, so it would have no impact on the funding provided to FDA to carry out its other important activities. The user fees are allocated among the manufacturers of tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S. tobacco product market. It should be noted that many of the groups that support this legislation care deeply about the many current important tasks conducted by the FDA.

Furthermore, the estimated funding levels provided for in the legislation, which ramp up to $300 million annually in year three, are based on FDA's prior experience regulating tobacco from 1996–2000, along with previous budget estimates provided by FDA to Members of Congress drafting legislation to provide the agency with authority over tobacco products.

Question 5. What impact would the user fee paid to the FDA by the tobacco companies have on the price of a pack of cigarettes?

Answer 5. The user fee would have minimal impact on the price of a pack of cigarettes. In 2006, 18.1 billion packs of cigarettes were sold.[9] If pack sales continue to decline by about 1.5 percent per year, 17.56 billion packs of cigarettes would be sold in 2008. In 2008, the cost of the program is estimated to be $85 million. Therefore, it would take less than half a cent per pack to raise this amount. In 2009, pack sales would be about 17.29 billion and the cost of the program is estimated to be $175 million. It would take about 1 cent per pack to raise this amount. When the program is fully funded at $300 million a year, the cost would still be less than 2 cents per pack.

Question 6. Some have claimed that FDA regulation of tobacco products would provide a liability shield for tobacco companies. Does FDA regulation as set forth in S. 625 provide any liability protection for tobacco companies that are sued by the victims of tobacco-induced disease?

Answer 6. The bill will not change the rules applicable to product liability litigation brought by citizens against the tobacco industry. The bill states explicitly that it does not provide any liability protection for tobacco companies. There are two specific provisions of the legislation that address this issue:

- Sec. 4(a) of the legislation (p. 15 of S. 625) states,

  "Nothing in this Act (or an amendment made by this Act) should be construed to . . . affect any action pending in Federal, State or Tribal court, or any agreement, consent decree, or contract of any kind."

- Sec. 917(b) of the legislation (p. 109 of S. 625) states,

  "No provision of this chapter relating to a tobacco product should be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

In addition to these provisions, it is important to note that just because an industry is regulated does not mean it is shielded from legal action for violating State tort laws.

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[9] Orzechowski & Walker, *Tax Burden on Tobacco*, 2006.

Question 7. In his testimony, Dr. Blum claims that the bill will "inhibit tougher State and local tobacco control efforts." This is inaccurate. In fact, S. 625 removes certain existing preemptions so that States and localities will have much greater authority to regulate, particularly in the area of tobacco advertising and marketing, than they do under current law. Would you explain what authority States and local governments will have under this bill to regulate tobacco products?

Answer 7. The bill allows the States to continue to do all that they are currently doing or have done to prevent tobacco use, limit youth access to tobacco, assist and encourage tobacco users to quit and to protect individuals from secondhand smoke. The legislation also expands State authority to regulate tobacco product marketing. Under the legislation, State and local governments would continue to be free to adopt measures regulating the sale, distribution, and possession of tobacco products (regardless of age); to limit exposure to secondhand smoke; to restrict youth access to tobacco products; and to enact fire safety standards for tobacco products. In short, the bill does not restrict States from pursuing policies such as smoke-free workplace laws, tobacco taxes, fire-safety standards, age requirements, identification checks, retailer licensing and fines, and other restrictions on the sale and distribution of tobacco products that have been instrumental in reducing tobacco use. States would also be able to impose additional reporting requirements on tobacco manufacturers (as Massachusetts, Texas and Minnesota have done) if there was any meaningful information FDA was not getting or not sharing that a State thought would be useful.

Today, States have no authority to regulate cigarette marketing. The legislation alters the existing preemption of State authority over cigarette marketing in the Federal Cigarette Labeling and Advertising Act (FCLAA), so that States will for the first time since 1969 have the ability to regulate cigarette marketing. As a result, States and localities could impose bans or restrictions on the time, place and manner, but not content, of the advertising or promotion of cigarettes, to the full extent permitted under the first amendment. (States already have this authority for smokeless tobacco products.) For example, if permitted under the first amendment, a State could ban or restrict in-store advertising or limit in-store advertising to locations away from the checkout counter or near products kids buy or limit the number of in-store ads.

FDA would have exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified risk products. This is consistent with the way the FDA regulates other products under its jurisdiction. This is an area of regulation that the States have not undertaken in the past and one that would require significant resources and technical/scientific capability given the complexity of the issues to be addressed. The FDA is unique in possessing the combination of scientific expertise and regulatory experience that is necessary.

In addition to preserving and in some ways expanding State and local authority, this legislation will also significantly enhance the impact of State tobacco prevention and cessation initiatives by curtailing tobacco marketing that encourages children to start using tobacco and discourages current tobacco users from quitting. The more than $15 billion a year the tobacco companies spend on marketing[10] dwarfs the $597.5 million a year the States currently spend on prevention and cessation.[11] The bill will enhance State prevention efforts by giving the FDA authority to restrict marketing that appeals to children.[12] It will enhance cessation efforts by banning deceptive terms like "light" and "low-tar" and giving the FDA authority to strictly regulate reduced risk claims that are intended to encourage smokers to switch rath-

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[10] U.S. Federal Trade Commission (FTC), Cigarette Report for 2003 (2005), data for top six manufacturers only.

[11] Campaign for Tobacco Free Kids, "A Broken Promise to Our Children: The 1998 State Tobacco Settlement Eight Years Later," *http://www.tobaccofreekids.org/reports/settlements/2007/execsum.pdf.*

[12] National Cancer Institute. Changing Adolescent Smoking Prevalence " Where it is and Why. Smoking and Tobacco Control Monograph No. 14. Chapter 13 "The Role of Tobacco Advertising and Promotion in Smoking Initiation"; Tobacco Control Legal Consortium, The Verdict Is In: Findings From *United States* v. *Philip Morris*, Marketing to Youth (2006); Giovino, G. et al. "Use of Flavored Cigarettes Among Older Adolescent and Adult Smokers: United States 2004." PowerPoint Presentation; Carpenter, C., et al. "New Cigarette Brands with Flavors That Appeal to Youth: Tobacco Marketing Strategies; Health Affairs, November/December 2005, Volume 24, number 6.

er than quit.[13] In addition, there is considerable evidence that the stronger health warnings mandated by the bill will enhance prevention and cessation campaigns.[14]

Question 8. In his testimony, Dr. Blum claims the legislation is "grandfathering in high risk products." That is inaccurate. Under S. 625, FDA will have the authority to set standards for existing products, ordering the removal or reduction of toxins and ingredients that make cigarettes more addictive. Would you explain the process by which FDA could require changes to be made in the composition of cigarettes that are already on the market?

Answer 8. The bill gives the FDA broad authority to regulate the manufacturing, marketing and sale of both *existing* and *new* tobacco products.

More specifically, under section 907 of the legislation, cigarettes (new or existing products) may not have candy or fruit flavorings—such as vanilla, chocolate, strawberry, cinnamon, or many other flavors—as a characterizing flavor.[15] Section 907 also empowers FDA to require changes in new and existing products. Section 907 for the first time gives the FDA the authority to require tobacco companies to make changes to existing products such as Marlboro, Camel and Newport, the brands most popular with young people. S. 625 provides FDA the authority to require changes to tobacco products to protect the public health through the issuance of product standards. Such changes could include the reduction or elimination of ingredients, additives, constituents, including smoke constituents, or reduction in nicotine yields, or changes to the construction and components of products.[16]

In addition, under section 904 of the bill, each tobacco manufacturer is required to submit to the Secretary a listing of all ingredients in each tobacco product; a description of the content, delivery, and form of nicotine in each tobacco product; a listing of all constituents, including smoke constituents, in each tobacco product; and all documents that relate to the health effects of their products, their constituents (including smoke constituents), ingredients, components, and additives. Further, if at any time a tobacco product manufacturer changes its products—by adding a new tobacco additive, increasing the quantity of an existing tobacco additive, eliminating or decreasing an existing additive, or adding or increasing an additive—it must notify the HHS Secretary of the changes. The Secretary will publish a list of the harmful and potentially harmful constituents by brand and quantity annually.

Question 9. S. 625 authorizes the FDA to "impose restrictions on the advertising and promotion of a tobacco product consistent with and to the full extent permitted by the first amendment to the Constitution." The legislation does not set particular restrictions, but authorizes the FDA to determine the most effective restrictions by regulation. This will allow the FDA to respond by regulation to changes in the marketplace so that the restrictions remain effective over time in deterring youth smoking and in preventing misleading advertising. The bill procedurally reinstates the regulation that the FDA adopted in 1996 after an exhaustive fact finding process. However, FDA retains full authority to modify those regulations going forward. Would you comment on how this process is structured in the legislation and how it will operate?

Answer 9. This legislation both adopts specific marketing restrictions that FDA has found have a significant impact on young people and gives FDA the authority to restrict tobacco marketing further "to protect the public health" to the extent permitted by the first amendment. The legislation is carefully crafted to comply with the requirements of the first amendment.

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[13] U.S. Department of Health and Human Services. Reducing Tobacco Use: A Report of the Surgeon General—Chapter 5: Regulatory Efforts. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2000.

[14] Campaign For Tobacco-Free Kids Factsheet, "U.S. Cigarette Warning Labels Don't Work Well—FDA Legislation Would Fix That."

[15] Giovino, G. et al., "Use of Flavored Cigarettes Among Older Adolescent and Adult Smokers: United States 2004." PowerPoint Presentation; Carpenter, C., et al., "New Cigarette Brands with Flavors That Appeal to Youth: Tobacco Marketing Strategies; Health Affairs," November/December 2005, Volume 24, number 6.

[16] Ashley D. et al., "Tobacco-specific nitrosamines in tobacco from U.S. brand and non-U.S. brand cigarettes," Nicotine & Tobacco Research, (2003) 5, 323–331; U.S. Department of Health and Human Services. Reducing Tobacco Use: A Report of the Surgeon General—Chapter 5: Regulatory Efforts. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2000; National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services (HHS), Report on Carcinogens, Eleventh Edition, January 2005 *http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s176toba.pdf*.

The bill requires the FDA to reinstate the specific marketing restrictions previously adopted by the FDA. This allows the FDA to adjust those regulations without further congressional action if the situation warrants.

If ever there is a justification for restricting commercial speech, this is such a case. Tobacco is this Nation's No. 1 preventable cause of death and disease.[17] It is illegal to sell tobacco products to minors, and it has been the legitimate goal of the Government to do what it can to curtail marketing that encourages young people to start using tobacco, that misleads adults about the hazards of tobacco and different tobacco products, and to reduce the number of people who die from tobacco use.

Time and time again the evidence has shown that tobacco marketing plays a role in contributing to youth tobacco use, that tobacco marketing has mislead millions of consumers, that the marketing of light and low tar products has misled consumers to switch to these products rather than quit smoking, and that the marketing of these products has undermined efforts to educate the public effectively about the heath hazards of these products.[18]

For over 40 years, attempts have been made to address these problems through restrictions—both mandatory and voluntary—that are less restrictive than those imposed by this legislation, but none of these prior efforts have been successful because of the tobacco industry's behavior. In the 1960s Congress added a small health warning to tobacco products and banned cigarette advertising on TV and radio and the tobacco industry dissuaded Congress from going further by promising not to market to young people and not to mislead the public through its own so-called Voluntary Advertising Code. These actions were not enough to stop the tobacco companies from continuing the same behavior.

After Congress enacted the TV ad ban, the tobacco companies promised not to undermine its effectiveness by sponsoring sporting events on TV, a promise they almost immediately violated by sponsoring the Virginia Slims tennis tour and later violated again and again by their sponsorship of motor racing (e.g., NASCAR's Winston Cup). After the staff of the FTC found in 1981 that tobacco industry marketing continued to focus on themes that appealed to children and undermined the existing health warnings, the tobacco industry once again went before Congress to argue that further regulation was not needed because they were serious about enforcing their own advertising code. Thus, while Congress imposed new health warnings on tobacco products, it did not adopt further marketing regulations.

But in the 1990s, investigations of tobacco marketing revealed once again that tobacco marketing continued to appeal to and impact children, deceive adults and minimize the health effects of tobacco products. In the mid-1990s the FDA conducted an exhaustive study of tobacco industry marketing, as did the Institute of Medicine of the National Academy of Sciences and the Surgeon General.[19] All reached the same conclusions.

In 1998 the State Attorneys General attempted to curtail deceptive tobacco industry marketing and tobacco industry marketing that impacted children. Yet, Judge Gladys Kessler of the U.S. District Court for the District of Columbia found last August, despite all of these prior efforts, the tobacco industry continues to engage in marketing practices that put our children at risk, that mislead consumers and that wrongfully minimize the health effects of tobacco and tobacco use.

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[17] U.S. Department of Health and Human Services. The Health Consequences of Smoking: A Report of the Surgeon General. Executive Summary. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

[18] Hamilton, W.L., Norton, G. Ouellette, K., Rhodes, W.M., Kling, R., Connolly, G.N., Smokers' responses to advertisements for regular and light cigarettes and potential reduced-exposure tobacco products. *Nicotine & Tobacco Research* 2004; 6: (Suppl 3) S353–362; Slade, J., Connolly G. and Lymperis, D. Eclipse: does it live up to its health claims? Tobacco Control 2002; 11 (64–70); Harvard School of Public Health, Tobacco Research Program, Division of Public Health Practice, Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands 1997–2005, December 2006.

[19] National Academy of Sciences, Institute of Medicine, "Taking Action to Reduce Tobacco Use" (1998), *http://books.nap.edu/catalog.php?record_id=6060#toc*; National Academy of Sciences, Institute of Medicine, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths, (1994), *http://books.nap.edu/catalog.php?record_id=4757/*; 1994 Report of the Surgeon General: Preventing Tobacco Use Among Young People, *http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_1994/index.htm*; 2000 Report of the Surgeon General: Reducing Tobacco Use, *http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/index.htm*; Federal Register: August 28, 1996 (Volume 61, Number 168)], Page 44395–44618, Department of Health and Human Services, Food and Drug Administration, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule August 11, 1995 FDA Proposed Rule.

Last August's (2006) ruling by Judge Kessler in the Department of Justice tobacco lawsuit (*USA* v. *Philip Morris*, USA), represents the most comprehensive and detailed accounting of the tobacco industries historical and ongoing predatory marketing practices and gives additional, compelling and strong evidence in support of the rules set forth in the legislation. Amongst her many findings against the tobacco company defendants, Judge Kessler found that:

• "There is a reasonable likelihood that Defendants' RICO violations will continue in most of the areas in which they have committed violations in the past. Defendants' practices have not materially changed in most of the Enterprise's activities, including: denial that ETS causes disease, denial that Defendants market to youth, denial of the addictiveness of nicotine, denial of manipulation of the design and content of cigarettes, suppression of information and research, and claims that light and low tar cigarettes are less hazardous than full-flavor cigarettes." [*Judge Kessler's Final Opinion, pages 1606–1607]*

• "Defendants continue to engage in many practices which target youth, and deny that they do so. Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents. Defendants are well aware that over 80 percent of adult smokers began smoking before the age of 18, and therefore know that securing the youth market is critical to their survival. There is therefore no reason, especially given their long history of denial and deceit, to trust their assurances that they will not continue committing RICO violations denying their marketing to youth." [*Judge Kessler's Final Opinion, pages 1607–1608*]

• "Although Defendants recently began to finally admit that smoking is addictive, no Defendant publicly informs consumers that nicotine is addictive, much less that smoking is a nicotine-driven addiction. See Findings of Fact Section V(B)(4). Defendants minimize the issue as a "quibble over the precise wording of the addictiveness of smoking." JD Br. at 39. To the contrary, the issue is Defendants' refusal to admit publicly that nicotine is physiologically addictive, that smoking is a nicotine-driven addiction, and that, therefore, quitting is not a simple act of willpower. At trial, the General Counsel for Philip Morris, Denise Keane, admitted that the "Smoking is Addictive" statement that Philip Morris removed from cigarette packs after buying three Liggett cigarette brands in 1999 was both correct and material. She also agreed that it is material for people to know that Philip Morris agrees that the nicotine delivered in cigarette smoking is addictive, but it does not say so publicly. Keane TT, 1/18/05, 10458:6–17. The deliberate mission of admittedly material information about nicotine addiction is not a mere "quibble." It is fraudulent, with consequences for those who smoke and those, especially young people, who are considering whether to start smoking. Defendants have thus made clear that, despite their internal research to the contrary, they remain unwilling to admit publicly that nicotine is addictive and that smoking is an addiction driven by nicotine. Such RICO violations are reasonably likely to continue." [*Judge Kessler's Final Opinion, page 1608*]

The FDA Rule and the marketing restrictions in this legislation on tobacco advertising and marketing were carefully tailored to reduce underage exposure only to the types of tobacco marketing that has the greatest impact on children, while still leaving numerous ways for tobacco advertising to reach adult customers. Judge Kessler's decision demonstrates that there remains a strong factual basis for these restrictions today even though FDA's investigation was conducted 10 years ago. For example, the FDA Rule's restrictions on outdoor and point-of-sale tobacco-product advertising to black print on white background do not restrict what can be said about tobacco products or otherwise block the communication of truthful information about tobacco products to adult consumers but only make the ads less attractive or alluring to kids (and these restrictions do not even apply to tobacco ads in adult-only locations). In fact, the advertising of financial investments has long been limited to black and white text-only ads without any constitutional objections.

After 40 years of attempting to address the Government's legitimate interests with all of these less restrictive efforts, the specific marketing restrictions in the pending legislation are amply justified as a reasonable next step.

Prior to Judge Kessler's ruling in the DOJ trial, there was already strong and ample legal precedent to support the advertising restrictions proposed in the legislation. These restrictions are consistent with the standards set forth by the Supreme Court in *Lorillard Tobacco Co.* v. *Reilly*. The bill's restrictions address a legitimate government interest; there is significant evidence that they will advance these interests; and given the prior history and current tobacco industry marketing practices, there is overwhelming evidence that these restrictions are necessary to protect the Government's legitimate interests.

The Court has firmly established that reducing underage use of tobacco products is a substantial and legitimate government interest that can justify time, place and manner restrictions on commercial speech, and that restrictions on tobacco-product advertising practices that have been documented to impact youth, mislead adults and wrongfully distort the health effects of tobacco properly advance those interests.

Question 10. Some have claimed that it will be difficult for convenience stores and other retailers to comply with the responsibilities that the legislation places on them to prevent the sale of tobacco products to minors. Would you explain what the responsibilities of retail sellers of tobacco products will be, and what safeguards have been included in the bill to protect retailers who are attempting to comply in good faith with the regulations?

Answer 10. S. 625 addresses the problem of illegal sales of tobacco products to children in the manner that has been proven most effective. When FDA implemented the youth-access provisions of the FDA Tobacco Rule[20] between 1996 and 2000, there were no significant problems with its administration or with retailer compliance, and that should hold true when the pending legislation passes and the Rule's youth access provisions are re-implemented. Put simply, the FDA Rule youth-access provisions require retailers to check the ID of any young person seeking to purchase tobacco products to prevent and reduce illegal sales to children. When in place previously, FDA enforced these youth access restrictions, not by employing Federal agents, but by contracting with State and local officials, such as health departments and police departments. By 2000 FDA had contracts with every State to conduct compliance checks and had an extensive outreach program that provided resources and information to retailers. FDA tried to ensure that retailers fully understood their responsibilities under the youth-access provisions, as well as the penalties associated with noncompliance. In addition, FDA provided retailers with a mediation procedure to resolve complaints and avoid litigation.

The National Association of Convenience Stores (NACS) has been the most active entity complaining about the re-implementation of the FDA Rule regarding youth access to tobacco products. It should be noted, however, that NACS did not oppose similar legislation introduced by Senator John McCain in 1998. The 1998 McCain legislation fully adopted the 1996 FDA rule that applied to retailers, but did not contain the provisions that have been added to the pending legislation to address concerns that have subsequently been raised by NACS.

The current legislation directly addresses previously voiced retailer concerns.

- The pending FDA legislation says that retailers shall *not* be held liable for an employee making a sale to a minor who presents a false government issued ID if the retailer has adopted and enforced a written policy against sales to youth, and informed its employees of applicable laws. [Sec. 103(l)(1)(F)].
- Section 103(e) provides that "to the extent feasible, the Secretary shall contract with the States . . . to carry out inspections of retailers within that State in connection with the enforcement of this Act." At the same time, it is clear that Federal involvement is necessary. The so-called "Synar Amendment," currently requires States to enact and enforce youth tobacco access laws but studies by the State attorneys general, FDA and others have found that Synar has failed to curtail illegal tobacco sales to kids effectively. Similarly, a 2001 GAO study found that "State implementation of Synar and [HHS] oversight raise concern about the quality of State estimates of the percentage of retailers that sell tobacco products to minors."[21] The data is clear: current law helps, but has not solved, the youth sales problem. On the other hand, the implementation of the FDA Tobacco Rule's youth access provisions from 1996 to 2000 dramatically improved the situation, and can do so again.
- The FDA legislation actually states that no retailer shall be required "to maintain records relating to individual purchasers of tobacco products for personal consumption." [Title III, Sec. 921(b)(5)]
- Some complained that between 1996 and 2000 FDA played "a 'gotcha' game" with retailers collecting violations against a retailer and then dumping them on a retailer all at once, without prior notice, to get massive fines. According to FDA, that did not happen. In any case, additional protections to address these complaints have already been added to the FDA legislation, requiring "timely and effective no-

[20] Federal Register: August 28, 1996 (Volume 61, Number 168)], Page 44395–44618, Department of Health and Human Services, Food and Drug Administration, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule August 11, 1995 FDA Proposed Rule.

[21] U.S. General Accounting Office, Report to the Ranking Minority Member, Committee on Government Reform, House of Representatives, "Synar Amendment Implementation: Quality of State Data on Reducing Youth Access to Tobacco Could Be Improved" (November 2001).

tice to the retailer of each alleged violation at a particular retail outlet," "an expedited procedure for the administrative appeal of an alleged violation," and numerous other specified procedural rights and protections for retailers. [Title I. Sec. 103(l)(1)] The bill also requires clear guidance from FDA as to what constitutes a "repeated violation" and how long a period free of violations would produce a clean slate. [Sec.103(l)(1)(A&E)]

• A provision has been added to the legislation "providing for an expedited procedure for the administration of alleged violations." [Section 103(l)(1)(C).]

• The FDA legislation has a graduated series of penalties and does not subject any retailer to higher-level fines or forbid their sale of tobacco products unless the retailer has repeatedly sold tobacco products to kids at a specific outlet, repeatedly been caught, and repeatedly failed to remedy the situation. [Title I. Sec. 103(f)] The legislation also specifically provides that violators that do not engage in a new violation for a period of time after their initial violation get a clean record and cannot be subjected to the penalties that apply to repeat violators. [Title I. Sec. 103(l)(1)(E)].

• The FDA legislation appropriately focuses on the retailers because they not only directly profit from illegal sales to kids but also have the most power to stop such illegal sales from occurring. Moreover, FDA's authority extends to manufacturers, importers, distributors, and retailers, but not to clerks and end users. The States already have the authority to pass the kinds of laws NACS proposes and the FDA legislation does nothing to preempt or weaken any such State laws. In fact, the vast majority of the States already have laws on the books that penalize youth who try to purchase tobacco products.

State attorneys general and other experts have recommended that any effort to reduce youth access to tobacco products include an agency designated with clear responsibility for enforcement, frequent and realistic compliance checks, and meaningful penalties including graduated fines and ultimately, prohibiting sales of tobacco products to minors. The provisions of this legislation are based on these solid research findings and are designed to curtail illegal tobacco sales to minors.

Other issues that have been raised by retailers that either are addressed or were corrected previously:

1. The FDA legislation does not establish Federal licensing of all tobacco product retailers. There is no language in the FDA legislation or the FDA Tobacco Rule implemented by the legislation that establishes Federal retailer licensing.

2. This legislation is still needed despite the declines in youth tobacco use. In fact, recent declines in youth smoking rates have stagnated and youth smoking remains at unacceptably high levels. Close to one out of every four high school youth is a current smoker. While progress has been made, every single day 4,000 additional new kids try their first cigarette, and another additional 1,000 kids become new daily smokers.

3. The legislation goes out of its way to treat all retailers fairly. Many of the restrictions on retailers in the FDA Tobacco Rule apply to "any person, who sells cigarettes or smokeless tobacco to individuals for personal consumption," which includes Internet and other mail-order sellers. [Rule Sec. 897.3(h); 897.14]. Internet and other mail-order sellers of tobacco products are also specifically prohibited from redeeming coupons or sending free samples through the mail. [Rule Sec. 897.16(c)(2)(i)]. Also, FDA has full authority to establish additional rules that would also apply specifically to Internet sellers, such as onsite age and identity verification and the like, as needed. [See, e.g., Title I, Sec. 906(d)(1)] NACS also fails to acknowledge that separate Federal legislation to place requirements on Internet and other mail-order tobacco product sellers has been introduced in a past session of Congress and will be introduced again soon. In addition, the State attorneys general have already taken steps toward reducing the Internet tobacco product sales problem.

4. The bill does not give tobacco product retailers in adult-only facilities an unfair advantage. The vast majority of the provisions relating to retailers in the FDA legislation and the FDA Rule apply to *all* retailers. While certain ad restrictions in the Rule do not currently apply to some ads in adult-only facilities, Sec. 913 of the FDA bill orders FDA to apply all advertising restrictions that apply to retailers in youth-accessible facilities to retailers primarily engaged in tobacco product sales that are located in adult-only facilities, as well.

5. Nothing in the FDA tobacco legislation restricts the sales of such cessation products in convenience stores.

6. Some oppose the FDA bill's provision prohibiting any outdoor advertising within 1,000 feet of a school or playground because they say it will prohibit convenience stores located within any such 1,000 feet perimeter from having any indoor tobacco product advertising, In fact, the provision that establishes the 1,000 feet restriction

specifically prohibits only "outdoor advertising" described as "including billboards, posters, or placards," and does not make any mention of either retail outlets or ads located inside retail outlets. [Rule Sec. 897.30(b)].

7. The requirement holding retailers liable for selling tobacco products that do not have the warning labels on them is meant to curtail the sale of counterfeit tobacco products, parallels provisions currently in Federal and State law that hold retailers liable for selling cigarettes without required tax stamps on them (and retailers could check for proper warning labels at the same time that they are checking for valid tax stamps). The only tobacco products that would not have the required labeling (or tax stamps) would be contraband and counterfeit tobacco products, and retailers should not be allowed to sell such illegal products. At the same time, to reduce the label-checking requirements on retailers, the FDA legislation was already revised to clarify that retailers are not responsible for checking to see whether warning labels comply with the requirements governing when warnings need to be rotated.

Question 11. Have there been significant differences in enforcement of youth sales restrictions under the FDA rule between 1996 and 2000 and under subsequent State efforts pursuant to the Synar Amendment? Which system has been more effective?

Answer 11. In 1992, Congress passed the Synar Amendment, which requires States and territories to enact laws prohibiting the sale of tobacco to minors and to enforce these laws effectively. Study after study has found that the Synar requirements alone are inadequate and that it has failed to curtail illegal sales of tobacco to kids. The State Attorneys General produced such a study in the 1990s,[22] as did the FDA in 1995. A 2001 GAO study found weaknesses in State implementation of Synar provisions and the U.S. Department of Health and Human Services (or SAMHSA, the agency responsible for overseeing Synar implementation) oversight of State activity.[23] Specifically, GAO found that some States used inaccurate and incomplete lists of tobacco retailers from which to select samples for inspection. Second, States did not use a standardized protocol to conduct inspections; as a result, most States used minors younger than 16 to conduct inspections and told minors not to carry identification on inspections. Research suggests that these protocols artificially lower violation rates. Third, HHS approved some States' reported violation rates even though the rates were calculated incorrectly. Finally, HHS relied on States to verify their own inspection results and did little to verify the accuracy of the State data. This is a particular problem since a State's substance abuse block grant could be reduced for failing to meet annual violation rate goals, giving States an incentive to report artificially low violation rates. Also, there was great variability in how States enforced the law. Some States did an excellent job enforcing the law, while many were non-compliant.[24] More recent data that suggest that over time, more States have begun to effectively enforce the Synar requirements, don't take into account the fact that States measure enforcement differently and the impact of FDA's enforcement program.

Another weakness of the Synar Amendment is that it does not require States to use penalties to enforce the law; States are only required to report evidence of actions taken to enforce State laws. Research shows that enforcing existing laws against cigarette sales to kids through regular retailer compliance checks and issuing civil penalties to retailers can significantly reduce youth smoking.[25] The data are clear: the Synar Amendment helps but does not solve the problem.

In contrast, as a regulatory agency, FDA took a different approach to limit youth access to tobacco products. FDA's program focused on enforcement and assessed penalties against retailers who repeatedly sold tobacco products to youth. The youth access provisions of the original FDA regulations in place from 1996 to 2000 were effective in reducing illegal sales to youth. Congress appropriated funding for this program, and FDA enforced the youth access restrictions, not by employing Federal agents, but by contracting with State and local officials, such as health departments and police departments. By 2000, the FDA had contracts with every State to conduct the compliance checks and had an extensive outreach program that provided resources and information to retailers.

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[22] No Sale: Youth, Tobacco and Responsible Retailing. Findings and Recommendations of a Working Group of State Attorneys General. December 1994.

[23] U.S. General Accounting Office, Report to the Ranking Minority Member, Committee on Government Reform, House of Representatives, "Synar Amendment Implementation: Quality of State Data on Reducing Youth Access to Tobacco Could Be Improved" (November 2001).

[24] DiFranza JR. "Are the Federal and State Governments complying with the Synar Amendment?" Archives of Pediatric and Adolescent Medicine 153(10): 1089–97, October 1999.

[25] DiFranza JR and Dussalt GF. "The Federal Initiative to Halt the Sale of Tobacco to Children—the Synar Amendment, 1992–2000: Lessons Learned." Tobacco Control 14:93–98, 2005.

Question 12. Several witnesses alluded to the inadequacy of the Master Settlement Agreement between the States and the tobacco companies as a means of regulating industry advertising and marketing practices. Please describe the types of advertising and marketing that are not covered by the MSA, and explain the limitations on enforcement of the restrictions that are contained in the Agreement when a company violates them.

Answer 12. Although a constructive step in the right direction, the multistate settlement agreement with the cigarette companies (MSA) does not adequately address the problem of tobacco use in the United States. According to the cigarette companies, the MSA dramatically changed the way they market their cigarettes. The cigarette companies also say that they are no longer trying to increase the number of smokers and no longer market their deadly products to kids. In fact, studies show that tobacco-industry marketing has reached record levels since the settlement, with much of the increase in strategies that reach and influence kids. From 1998 to 2003, cigarette company marketing increased by 125 percent nationwide, with cigarette company marketing in 2003 totaling at least $15.1 billion (or more than $40 million per day), a record high.[26] These tobacco industry marketing increases have overwhelmed any public health benefits from the marketing restrictions that were put into place in late 1998 by the Master Settlement Agreement (MSA) between the States and the tobacco companies. Other examples of cigarette company marketing after the settlement include:

• This month, R.J. Reynolds launched Camel No. 9, a cigarette clearly aimed at girls and young women. Camel No. 9 has sleek packaging, flowery ads and the slogan "light and luscious." News reports have estimated that RJR is spending between $25 and $50 million to launch its new product. Full-page ads are running in women's magazines that have high youth readership such as Glamour, Cosmopolitan, Marie Claire, InStyle and Vogue. Point-of-sale marketing is expected to be heavy and is already saturating stores and bodegas in New York City.

• In 2005, R.J. Reynolds launched a music-themed Kool marketing campaign, aimed at both African-American and Latino youth. This Kool Be True advertising campaign featured young, hip, multi-ethnic models, often with musical instruments, and appeared in magazines popular with young African-Americans and Latinos, including *Jet, Essence, Latina and Cosmopolitan En Espanol*.

• In 2004, R.J. Reynolds introduced a pineapple and coconut-flavored cigarette called "Kauai Kolada" and a citrus-flavored cigarette called "Twista Lime." RJR also introduced Camel "Winter Blends" with flavors including "Warm Winter Toffee" and "Winter MochaMint." Ads for these cigarettes appeared in magazines with significant youth readership such as Rolling Stone, Glamour, Cosmopolitan and Elle. The U.S. Smokeless Tobacco Company is marketing spit tobacco with flavors including berry blend, mint, wintergreen, apple blend, vanilla and cherry. The marketing of candy-flavored cigarettes has been condemned by public health experts as being aimed at trying to get kids to experiment with smoking. A study by the Roswell Park Cancer Institute found that 17-year-old smokers (23 percent) were more than twice as likely to use flavored cigarettes as 24–26-year-old smokers (9 percent).[27]

• Also in 2004, Brown & Williamson implemented the Kool Mixx cigarette marketing campaign clearly aimed at youth, and African-American youth, in particular. The Kool Mixx campaign featured images of young rappers, disc jockeys and dancers on cigarette packs and in advertising. The campaign also included radio giveaways with cigarette purchases and a Hip-Hop disc jockey competition in major cities around the country.

• In 1999, the first year after the multistate settlement agreement (MSA), the cigarette companies spent a record $8.2 billion on advertising and promotions, an increase of $1.5 billion, or 22.3 percent—and the largest 1-year increase since the U.S. Federal Trade Commission (FTC) began tracking tobacco-industry marketing expenditures in 1970.[28]

• A July 2000 study found that after a settlement-mandated ban on tobacco billboard advertising went into effect, tobacco-company advertising and promotions in-

[26] U.S. Federal Trade Commission (FTC), Cigarette Report for 2003, 2005 [data for top six manufacturers only].

[27] Giovino, G. et al., "Use of Flavored Cigarettes Among Older Adolescent and Adult Smokers: United States 2004." PowerPoint Presentation.

[28] U.S. Federal Trade Commission (FTC), Cigarette Report for 2003, 2005 [data for top six manufacturers only].

creased significantly at retail outlets—and 75 percent of teens visit a convenience store at least once a week.[29]

• In May 2000, The *Wall Street Journal* and a new study by the Massachusetts Department of Public Health separately reported that cigarette company advertising in magazines with large youth readerships had increased by 33 percent since the MSA was signed.[30]

It is critical that we address tobacco product marketing because there is compelling evidence that much of this advertising and promotion is directed at kids and successfully recruits new tobacco users. A 2002 monograph by the National Cancer Institute, which reviewed the research on tobacco advertising and promotion and its impact on youth smoking, found that tobacco advertising and promotional activities are important catalysts in the smoking initiation process. The NCI report also found, based on a review of the extant research, that "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable." [31] The MSA's restrictions on cigarette marketing do not meaningfully restrict cigarette company marketing practices, including many that reach and influence kids.

The MSA Allows the Following Cigarette Company Marketing Practices to Continue:

• Permits *outdoor* advertising for cigarettes and other tobacco products with signs of 14 square feet or smaller on the buildings or property of any business where tobacco products are sold (including at stores next to schools and playgrounds) and at any events sponsored by the tobacco industry.

• Places no limits or restrictions on any cigarette or tobacco product advertising *inside* the more than half a million businesses where tobacco products are sold.

• Places no limits or restrictions on cigarette or other tobacco advertisements in newspapers and magazines, even if they have large numbers of underage readers.

• Places no limits or restrictions on advertising or selling cigarettes or other tobacco products on the Internet. See specific provisions of FDA Rule.

• Places no limits or restrictions on direct-mail advertising of tobacco products;

• Permits each tobacco company to continue a single tobacco-product brand-name sponsorship of an event not specifically prohibited (see above), such as auto racing or rodeo events, with the limit of a "single" sponsorship defined to allow the companies to sponsor an entire single series of auto races, rodeos, or other events (such as all NASCAR races);

• Places no restrictions on the televising of tobacco brand-name sponsored events.

S. 625 addresses each of these areas. It also recognizes that the tobacco industry has often circumvented rules designed to curtail both marketing to children and misleading of the public and provides FDA the needed authority to adopt new rules to address new conditions as they arise.

The need for this legislation, despite the Master Settlement Agreement, is further demonstrated by the findings of Judge Kessler last August. Judge Kessler's Opinion included 238 pages that recite both the tobacco industry's long time marketing to children and continued marketing that reaches and impacts young people. It is a devastating indictment of both the efforts and the ability of the tobacco companies to continue to use marketing to reach and appeal to our youth despite the MSA and all prior efforts to retrain their behavior. As Judge Kessler concluded,

> ". . . Defendants continue to engage in many practices which target youth, and deny that they do so. Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents. Defendants are well aware that over 80 percent of adult smokers began smoking before the age of 18, and therefore know that securing the youth market is critical to their survival. There is therefore no reason, especially given their long history of denial and deceit, to trust their assurances that they will not continue committing RICO violations denying their marketing to youth." [*Judge Kessler's Final Opinion, pgs. 1607–1608*]

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[29] Wakefield, M, et al., "Changes at the point of purchase for tobacco following the 1999 tobacco billboard advertising ban." University of Illinois at Chicago. Research Paper Series, No. 4, July 2000.

[30] Turner-Barker, D. & W. Hamilton, Cigarette Advertising Expenditures Before and After Master Settlement Agreement: Preliminary Findings, Massachusetts Department of Public Health (May 15, 2000), *http://www.state.ma.us/dph/mtcp/report/mag.htm*; Fairclough, G., "Are Cigarette Ads in Magazines Angling for Teens?," The Wall Street Journal (May 15, 2000).

[31] National Cancer Institute, *Changing Adolescent Smoking Prevalence*, Smoking and Tobacco Control Monograph No. 14, NH Pub. No. 02–5086, November 2001.

S. 625 is much needed legislation that would grant FDA the authority necessary to crack down on marketing and sales to children.

QUESTIONS OF SENATOR ENZI

Question 1. The real question here is not whether the Federal Government should regulate tobacco—it should, and it does already. Given that numerous Federal and State agencies, including the Federal Trade Commission, the Federal Communications Commission, the Department of Justice and many others, already regulate tobacco, why do you believe involving FDA will have a greater impact?

Answer 1. Despite the fact that there are several Federal agencies with extremely limited authority over very narrow aspects of the tobacco issue, tobacco and tobacco marketing remain unregulated for health purposes. There is no agency with a mandate to regulate tobacco for the purpose of protecting the public health and/or reducing the number of people who die from tobacco use. There is no agency with any regulatory authority that also possesses essential scientific expertise to protect public health. Overall, there exists a gaping hole in the Federal safety net as it relates to tobacco.

The FCC's role is limited to monitoring compliance with the decades old ban on television and radio prohibitions on tobacco advertising. The DOJ's role is limited to enforcing potential violations of the congressionally mandated labeling requirements on cigarettes. The FTC's role is equally limited. It enforces the specific congressionally mandated labeling requirements for smokeless tobacco products, is supposed to collect data on total tobacco industry marketing expenditures and issue a report containing that information. In addition, section 5 of the FTCA gives the FTC the law enforcement responsibility over false and deceptive marketing, as that term has been traditionally defined that includes but is not limited to tobacco. As the former Chairman and the former Director of the FTC's advertising division have testified before Congress, the FTC lacks the scientific expertise and public health mandate to carry out these tasks, even the tasks related to marketing, that are assigned to the FDA in this legislation. By its own admission the FTC is "an agency of lawyers and economists" and is not a science-based agency and does not have the necessary scientific, medical and public health expertise to evaluate scientific claims and data regarding tobacco products.[32] Furthermore, FTC is a law enforcement agency whose primary task is to enforce the law against false and deceptive advertisements without regard for whether technically accurate statements have a major adverse impact on public health and result in consumers making health decisions based on incomplete information. The FTC's ability to craft industrywide solutions is extremely narrow. As a result, in almost every instance the FTC acts retrospectively against one bad actor once a violation has occurred.

In contrast, FDA is charged with protecting the public's health and as a public health agency acts prospectively to address problems. The FDA possesses talented and skilled scientists and researchers who are able to conduct sophisticated analyses and evaluate complex scientific data of the impact of different products on the health of consumers. For example, the FDA's National Center for Toxicological Research mission "involves fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA." FDA's various centers that oversee foods, drugs, medical devices, and biologics are home to career chemists, toxicologists, statisticians, epidemiologists, and surveillance and consumer marketing experts with very relevant skills to begin the process of assuming regulatory oversight of tobacco products. These are the types of functions and skills that will be critical to building an effective, science-based regulatory regime for tobacco products. These are the skills we need to employ in the pursuit of ensuring that all scientific avenues are explored to lower the toxicity and reduce the morbidity and mortality associated with tobacco products and their marketing and claims.

FDA is unique in that it is the one agency that combines scientific expertise with experience in exercising regulatory authority.

Question 2. Dr. Blum included a number of old cigarette ads with his testimony. In ad after ad, the tobacco companies have co-opted existing science and regulation as an advantage to their products over others. For example, in the Carlton ad, it says "U.S. Government testing confirms—Carlton is lowest!" Is there anything in this bill that precludes a tobacco company from including on its cigarette package

[32] Testimony by Timothy Muris, FTC Chairman, June 3, 2003, before the Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection, U.S. House of Representatives.

label or in its advertisements a statement that says "This product was made in accordance with FDA standards?"

Answer 2. Every ad that Dr. Blum showed would be prohibited by the current legislation. Dr. Blum correctly used these ads to show how the tobacco industry has deceived millions of consumers. What he did not note was that the current bill prohibits these tactics by eliminating the terms "light," "low tar" and claims like "Carlton is lowest" because the public incorrectly perceives these types of claims as indicating that Carlton exposes consumers to lower levels of toxic substances.

It is also important to note that while Dr. Blum correctly cited a number of ads as being deceptive and harmful to public health, these ads were permitted to continue by the Federal Trade Commission. It is a good example of the limitations of the FTC. FTC does not have the expertise or the authority to protect the public against this type of advertising. Dr. Blum's testimony illustrates that currently, no Federal agency has the authority to review health claims or stop tobacco companies from misrepresenting the facts and misleading consumers. The legislation would address this problem in a manner consistent with sound scientific standards.

In addition, S. 625 gives FDA the authority to preclude a tobacco company from including on its cigarette package or in its advertisements a statement that says this product is "FDA Approved" or is "made in accordance with FDA standards." Five separate sections of the bill give the FDA full authority to control what a manufacturer says in its label, labeling and advertising, authority sufficient to permit the FDA to ban the kind of statements that are the subject of this question.

In addition, the bill explicitly prohibits any person from labeling, advertising or taking any other action directed to consumers that states or implies that the product is less hazardous than other tobacco products or reduces exposure to substances in tobacco products without first having sought and obtained FDA approval according to the standards set forth in the legislation.

Finally, if the committee believes that the legislation should contain an express prohibition of the type of statements that are the subject of this question, the public health supporters of this legislation would not object.

Question 3. The drug industry user fees pay for more than half of the FDA drug review program. This has caused a lot of consternation among some patient and consumer groups who are concerned about potential industry influence on the agency. Do you have concerns about the tobacco industry paying for 100 percent of the tobacco review program?

Answer 3. We would be concerned if this legislation or the fee structure gave the tobacco industry influence over how the FDA would implement this legislation. It does not. Under this legislation, the tobacco industry does not have any authority over how the money is spent, how FDA sets its priorities, or how much FDA receives. The user fee system in this bill provides FDA with adequate resources to effectively regulate tobacco products. Another strength of the user fee system is that, unlike the MSA, funding for FDA is not dependent upon the amount of tobacco used, but rather on manufacturers' share of the entire U.S. market.

Question 4. The bill says a tobacco product cannot be labeled with the term "light" or "low tar" unless it has been shown to actually reduce the risk of harm or disease. However, the legislation does not demand that existing light or low tar products be removed from the market or even modified, unless a complicated and lengthy process for determining a product standard is set. Just the labeling has to be changed. If we already know that these products are not in fact better for consumers, why wouldn't we directly try and get them off the market?

Answer 4. This provision will have an immediate and substantial benefit to the public health. It is the marketing of these products in ways that have misled consumers into believing that they are less hazardous that has caused millions of smokers to switch rather than quit. Preventing the tobacco companies from continuing to mislead the American public about the relative harm of these products will represent a major step forward. However, unless this legislation is enacted, consumers will continue to be misled by the tobacco industry on the issue of light and low tar cigarettes—a point highlighted by Judge Kessler in her August 2006 ruling against the tobacco company defendants in the Department of Justice tobacco lawsuit,

> "Contrary to their internal documents, Defendants also continue to deny that low tar cigarettes are just as hazardous to smokers as full-flavor cigarettes, in part because of smoker compensation. In 1998, Philip Morris, RJR, B&W, and Lorillard jointly stated to the FTC that compensation was so "weakly documented" that the FTC should not require disclosure warnings to alert consumers, and that they were "unaware of evidence," other than that presented in Monograph 7, 520842199–2295 at 2243, 2289 (US 88618), that consumers

viewed low-tar cigarettes as safer. Defendants are well aware from their own research that a majority of smokers believe that low-tar cigarettes are healthier, are willing to buy them for precisely that reason, and are willing to sacrifice taste for what they believe to be less harmful cigarettes. Nonetheless, to this day, Defendants still deny that, as Monograph 13 found, low-tar cigarettes are just as dangerous as full-flavor cigarettes. These RICO violations are likely to continue." [*Judge Kessler's Final Opinion, page 1609*]

Today, in the absence of this legislation, we are left with a situation described by the National Cancer Institute[33] in which:

1. Many consumers use the terms "Light" and "Ultra-Light" as a guide to the riskiness of particular brands of cigarettes.
2. Many smokers choose Light and Ultra-Light brands because they believe that such cigarettes are less likely to cause health problems.
3. Individuals who are most concerned about smoking risks and most interested in quitting adopt low-yield brands.

Once enacted this legislation will give the FDA the authority—for the first time—to also look at whether the establishment of product standards related to these products can further add to the public health benefit, but that decision is properly left to the FDA and is to be based on the best available science. Decisions about the content of tobacco products and what changes should be ordered in the content of tobacco products should be made by scientists based on an evaluation of what changes will best protect the public health and this bill gives precisely that authority to the FDA.

QUESTION OF SENATOR BURR

Question. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer. Without this legislation tobacco products not only remain on the market, they continue to be unregulated for health purposes. The status quo is a situation in which no Federal agency has the authority to require the tobacco companies to disclose what they know about their product or to require any tobacco company to make any change in any tobacco product to make it less harmful or less addictive.

Under this legislation, for the first time ever, a science-based agency will be able to evaluate tobacco products, review health claims, and assess the risks associated with these products, and require changes in tobacco products in order to reduce the number of toxins in them and/or to require changes in nicotine levels based on a scientific assessment of what will best protect the public health and reduce the number of people who die from tobacco use. It is long past due that tobacco products be placed under the jurisdiction of an experienced, credible, science-based public health agency with the skills and expertise necessary to evaluate tobacco products and require changes to protect the public health.

The important issue is whether the legislation provides the most effective tools to protect the public health and reduce the number of people who die prematurely from tobacco use. We believe it does. Using sound scientific techniques, FDA can work to lower the harms associated with the use of tobacco products and can do so in the most responsible and effective way possible.

This legislation recognizes that there are approximately 50 million Americans addicted to tobacco today. Given this situation, the soundest public policy is one that seeks to reduce the number of those people who die from tobacco use, positively impacts the efforts of those who want to quit and prevents the tobacco companies from addicting another generation of our children. This bill does precisely that.

QUESTIONS OF SENATOR HATCH

Question 1. In your testimony, you talk about the surveys that your organization conducted on tobacco advertising. One of the findings found that children are almost twice as likely as adults to remember tobacco advertising. Did your survey go into how many of these children actually take up smoking? Hasn't the youth smoking trend started to decline?

Answer 1. There is compelling evidence that much of tobacco industry advertising and promotion impacts kids and contributes to the number of children who become

[33] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001, *http://cancercontrol.cancer.gov/tcrb/monographs/13/*.

tobacco users. A 2002 monograph by the National Cancer Institute, which reviewed the research on tobacco advertising and promotion and its impact on youth smoking, found that tobacco advertising and promotional activities are important catalysts in the smoking initiation process and concluded ". . . that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable."[34] A study published in the December 2006 issue of the peer-reviewed journal *Archives of Pediatrics and Adolescent Medicine* found that exposure to tobacco marketing, which includes advertising, promotions and cigarette samples, and to pro-tobacco depictions in films, television, and videos more than doubles the odds that children under 18 will become tobacco users. The researchers also found that pro-tobacco marketing and media depictions lead children who already smoke to smoke more heavily, increasing the odds of progression to heavier use by 42 percent.[35] These data are disturbing because kids continue to be exposed to tobacco advertising at high rates.

Tobacco use among young people did decline between 1998 and 2003. The best available science indicates that these reductions were prompted by a number of actions, including increases in cigarette excise taxes, enactment of comprehensive smoke-free workplace laws, and State tobacco prevention and cessation programs. The national truth[sm] campaign, conducted by the American Legacy Foundation, which is targeted at youth and includes television and radio advertising, grassroots efforts, and an interactive Web site, has also contributed to declines in smoking prevalence among high school students.[36] While we have made much progress, results from recent national surveys indicate that the Nation's progress in reducing youth smoking has stalled or slowed to a crawl.

What is also important to note is that since the Master Settlement Agreement was adopted in 1998 there has been a dramatic increase in tobacco industry marketing, including in areas that have been proven to impact children. Thus, it is no surprise that not a single published study has attributed any of the decline in youth tobacco use to any change in the tobacco industry's marketing. In fact, the CDC has concluded that one possible reason for the fact that the decline in youth tobacco use has stalled is the dramatic increase in tobacco marketing. Data from the most recent FTC report show that tobacco industry spending on marketing and promotion increased by 125 percent from 1998 to 2005. It also shows that major tobacco companies have sharply increased their marketing expenditures in categories known to lead to increased use among youth.[37]

It is a fair question to ask: Where would tobacco use rates be, had the tobacco industry not doubled its marketing efforts and spent its marketing expenditures in ways known to reach youth? There is consensus in the public health community that rates would have been lower, and ultimately fewer youth would die prematurely from smoking-caused disease. The marketing restrictions in this legislation are based on the best available science that documents the impact of current tobacco marketing practices and takes into consideration the evidence of the tobacco industry's continued marketing practices.

Question 2. I also noted in your testimony that while you understand why there are concerns about the FDA's resources, you believe that a new user fee imposed on the tobacco industry will take care of the resource issue. Mr. Myers, how do you know that the user fee imposed on the tobacco companies is the appropriate amount of money? What if it is too little? I would be interested in your thoughts on this issue.

Answer 2. The goal of this legislation is to insure that FDA is given adequate resources to do its job well and without taking any resources from other FDA activities. Thus, this legislation provides for a new and independent funding mechanism for FDA's new tobacco product-related responsibilities. The new responsibilities would be funded through a user fee on the tobacco industry, so it would have no impact on the funding provided to FDA to carry out its other important activities. The user fees are allocated among the manufacturers of tobacco products sold in the United States, based on the manufacturers' respective shares of the entire U.S. to-

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[34] National Cancer Institute, *Changing Adolescent Smoking Prevalence*, Smoking and Tobacco Control Monograph No. 14, NH Pub. No. 02–5086, November 2001.

[35] Wellman RJ, et al., "The extent to Which Tobacco Marketing and Tobacco Use in Films Contribute to Children's Use of Tobacco: A Meta-Analysis." *Archives of Pediatrics and Adolescent Medicine* 2006 Dec;160(12):1285–96.

[36] American Legacy Foundation. "Getting to the Truth: Assessing Youths' Reactions to the Truth[sm] and 'Think. Don't Smoke' Tobacco Countermarketing Campaigns," First Look report 9, June 2002.

[37] U.S. Federal Trade Commission (FTC), *Cigarette Report for 2003,* 2005 [data for top six manufacturers only].

bacco-product market. The groups that support this legislation care deeply about the many important tasks of the FDA including drug and device approval and the work the agency does to protect our food supply.

The estimated funding levels provided for in the legislation, which ramp up to $300 million annually in year three, are based on FDA's prior experience regulating tobacco from 1996–2000 along with budget documents and estimates provided by FDA during previous congressional debates on legislation to provide FDA with authority over tobacco products.

Question 3. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes for a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 3. First, nothing in this legislation will lead to a ban on cigarettes tomorrow and no one who supports this legislation supports such an action.

Second, the concerns expressed by these questions don't take into account the fact that tobacco does not just generate revenue for government, it imposes enormous costs on society and government. Studies demonstrate that tobacco use is a significant net drain on State governments, the American government and the economy. In monetary terms alone, tobacco costs the American economy nearly $97 billion every year in excess health care expenditures and nearly $98 billion every year in additional productivity losses.[38] In human terms, tobacco results in the annual, preventable deaths of more than 400,000 Americans and more than 8 times that figure in people living with a tobacco-caused illness or disease.[39] Clearly, a decline in tobacco use and a decline in tobacco-related disease will have a positive impact on the American economy, Federal budget, State budgets and, most importantly, on American families. If this legislation results in fewer children smoking and fewer people dying from tobacco, then any modest impact on tax receipts will be more than offset by gains in productivity and lower health care costs.

If this bill is enacted and rigorously implemented, it will produce a benefit for the Government and the public—both in economic terms and in the health of American families.

Question 4. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 4. The FDA legislation has a specific section relating to contraband tobacco products, Title III—Prevention of Illicit Trade in Tobacco Products. That section requires all packaging of tobacco products meant for sale in the United States to be labeled with the statement "Sale Only Allowed in the United States," which will make illegal diversions of such products more difficult. [Sec. 921(a)] In addition, that section requires the Secretary, within 9 months of the enactment of the legislation, to issue regulations regarding the establishment and maintenance of records by any person who manufactures, distributes, exports or imports tobacco products in order to make it easier for the Secretary to track and trace the paths taken by tobacco products through legal distribution channels and block their diversion into contraband trafficking. To enhance the Secretary's abilities in this regard, this section also provides the Secretary with authority to inspect records and to establish special codes, labels, and designs on the labels of tobacco products that facilitate tracking and tracing. [Sec. 921(b)]

Title III also requires manufacturers, importers, and distributors of tobacco products to report to the Attorney General whenever they have knowledge indicating

[38] Toll of Tobacco in the United States of America, Campaign for Tobacco Free Kids, *http://www.tobaccofreekids.org/research/factsheets/pdf/0072.pdf* (Web site accessed March 9, 2007).

[39] Toll of Tobacco in the United States of America, Campaign for Tobacco Free Kids, *http://www.tobaccofreekids.org/research/factsheets/pdf/0072.pdf* (Web site accessed March 9, 2007).

that any tobacco product they have manufactured, imported, or distributed has been diverted from legal channels and become contraband. [Sec. 921(d)] Pursuant to title III, the Comptroller General must also conduct a study of cross-border trade in tobacco products, including illicit trade and trade of counterfeit products, and issue a related report to Congress no later than 18 months after the enactment of the legislation. [Sec. 302].

Each of these provisions in title III should help to strengthen existing efforts to prevent and reduce contraband trafficking in tobacco products both within the United States and across its borders.

At the same time, the FDA legislation does not allow FDA to ban any class of tobacco products or eliminate nicotine in any tobacco products, which could prompt contraband trafficking and black market sales of the prohibited tobacco products or of nicotine-full versions of the tobacco products with no nicotine. [Sec. 907(b)(3)] In addition, FDA is directed to take into consideration the possible impact on contraband trafficking when requiring any changes to existing products or issuing any new product standards. [Sec. 907(b)(1)(E)].

It is also worth noting that the FDA legislation will not significantly increase tobacco product prices in the United States; so it should not promote any price-based increase in contraband trafficking. On the other hand, to the extent that the FDA legislation changes the appearance of tobacco product packaging and labeling and requires new anti-trafficking product codes or markings it will make tobacco products that are legally made in the United States even more distinguishable to enforcement officials and even harder to counterfeit.

QUESTIONS OF SENATOR COBURN

Question 1. What constituents would you recommend that the FDA require to be eliminated or reduced in cigarettes, and by how much would that reduction or elimination reduce the relative risk of tobacco-related diseases?

Answer 1. One of the strengths of the pending legislation is that it properly recognizes that the answer to a question like this should ultimately be made by individuals with complete information based upon the best available science with the authority to monitor the impact of any such decision and the breadth of authority to make adjustments as new information emerges and the impact of different choices is better and better evaluated.

The danger of making such a determination based on incomplete information in the absence of a comprehensive regulatory mechanism, such as that proposed by S. 625, is seen by what happened with "light" and "low tar" and by the even more recent experience in the European Union. When the FTC permitted tobacco companies to include tar and nicotine figures in their marketing as a result of the very simple testing system that produced those numbers, it was believed that there would be a benefit to consumers if they smoked products that reduced their exposure to toxic substances and "tar" was selected as the measure. It failed for a number of reasons. No agency controlled how tobacco companies altered "tar" levels so the tobacco companies were able to design their cigarettes to produce a level of "tar" on the FTC machine method that bore no relationship to the actual level of "tar" that consumers received. Further, the overly simple system did not recognize that not all "tar" is equal. Later research showed that even as "tar" levels went down on the machine test, levels of certain toxic substances in the "tar" actually went up. In addition, the simple machine test did not look at other variables such as the impact of the particle size of the constituents that make up "tar," the ability of the tobacco companies through chemical manipulation to alter the impact of the different components of the constituents of "tar" and "nicotine" or even technology that altered where the different constituents found in tobacco smoke lodged in the lungs of consumers.[40]

Even more recently, the European Union sought to reduce the harm caused by tobacco products based on very incomplete information and without any kind of meaningful regulatory controls over the product. The EU set standards for "tar" and "nicotine" levels in cigarettes. Yet, already research has shown that the tobacco com-

[40] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Chapter One: Public Health Implications of Changes in Cigarette Design and Marketing Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001; Tobacco Control Legal Consortium, The Verdict Is In: Findings From *United States* v. *Philip Morris*, Light Cigarettes (2006).

panies were able to design their cigarettes in such a way that consumers of products that met these standards were actually not getting less "tar" or "nicotine."[41]

We must be careful not to misinterpret these experiences. As NCI Monograph 13 in 2001 concluded, our experience to date does not demonstrate that if cigarettes actually deliver fewer and lower levels of toxic substances, they are not likely to produce less disease. The experience to date is that in the absence of a comprehensive regulatory system able to base decisions on sound science and monitor cigarette design, the impact of prior efforts have not produced meaningful differences of actual exposure by consumers. There continues to be widespread belief among the best available independent scientists that if tobacco companies could be compelled to produce products with dramatically lower levels of toxic substances in ways that resulted in a major reduction of exposure to consumers, those products would still remain deadly but would be likely to produce less disease.

This should not be surprising. Tobacco smoke contains over 4,000 chemicals, more than 200 of which are toxic and nearly 70 of which are known or suspected human carcinogens.[42] However, today, there is no Federal agency that has authority to require tobacco companies to identify what toxic chemicals appear in what products or brands or in what quantity. Nor is there any requirement of the tobacco companies to detail the testing they have conducted to test the health impact of different toxic substances in different brands/products. This legislation will give the FDA the authority to get this information, marry it with the best available science, and then determine the most appropriate action to take regarding these harmful substances both in terms of recommending changes to the product (e.g., performance standards) and informing consumers of the contents of these products and the risks associated with their use.

Therefore, any decision about what constituents should be lowered or eliminated needs to be made by an agency: able to control how the tobacco companies redesign their cigarettes to adjust to the new standard; able to monitor the impact of any such decision on the other components of the tobacco product and should be made with more information about current cigarette technology. FDA will be able to do that if this legislation is enacted and rigorously enforced. The attempt to simply identify specific components to be eliminated in the absence of the kind of authority to be given to FDA is far less likely to produce a meaningful public health impact.

Question 2. How will smokers alter their behavior in response to the introduction of cigarettes with new tobacco product standards? That is, what will be the effect on cigarette consumption of smokers now knowing that the FDA is tightly regulating all the constituents and ingredients in cigarettes?

Answer 2. Tobacco products are among the most unregulated consumer products on the market today and are exempt from important consumer protections such as ingredient disclosure and product testing. In this unregulated environment, tobacco companies are free to manipulate their products in ways that can make them more addictive and/or more harmful. Consumers have absolutely no knowledge of these changes, although these changes have been shown to impact consumer behavior. As the recent study from the Harvard School of Public Health demonstrates, tobacco companies have secretly and significantly increased the levels of nicotine in cigarette smoke over time.[43] We have no idea how this change has impacted consumers. We also know too little about other changes the tobacco industry has made (and continues to make) to their products to make them more appealing to current users, easier to use, and harder to quit. Regulatory oversight is essential if we are ever going to fully understand tobacco products and how changes to these products effects initiation and use.

A few other examples of what happens in the absence of regulation of the type proposed by this legislation also helps put this legislation in context. After the 1964 Report of the Surgeon General, millions of people switched to light and low tar cigarettes believing that such cigarettes exposed them to lower levels of toxic substances and reduced their risk of disease. As the National Cancer Institute Monograph 13 in 2001 found, these perceptions turned out to be inaccurate, in part because in the absence of regulation the tobacco companies were able to make design changes to

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[41] O'Connor RJ and Cummings MK et al., "How did UK cigarette makers reduce tar to 10 mg or less? British Medical Journal, 2006;332:302 (4 February), doi:10.1136/bmj.332.7536.302.

[42] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001.

[43] Connolly, Gregory N., et al., "Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands 1997–2005." Tobacco Research Program, Harvard School of Public Health, January, 2007.

cigarettes so that they produced low test results on the FTC testing machine that bore no relationship to the actual exposure consumers received.[44]

Another good example is what happened with nitrosamine levels in cigarettes after the introduction of light and low tar products. Nitrosamines are one of the potent carcinogens that have been identified in the smoke of tobacco products. Much to the surprise of many scientists, research conducted many years after the introduction of light and low tar tobacco products demonstrated that even as tar ratings on the FTC testing machine dropped, nitrosamine levels in cigarettes rose dramatically. In the absence of regulation, consumers did not know this potentially important fact. Indeed, the Government did not know this fact and as a result, government was not in a position to prevent the tobacco companies from allowing nitrosamine levels to rise.

Later after at least one major tobacco company said publicly that it was reducing nitrosamine levels, research demonstrated that nitrosamine levels in the products of this manufacturer as well as others remained high. Once again consumers were misinformed because no governmental agency regulated these products or had this information and no one was in a position to require the tobacco companies to lower the level of this carcinogen as well as others.

Other studies have subsequently shown that design changes in tobacco products have increased the potency of the nicotine in these products without the knowledge of either consumers or the Government and other studies have shown that design changes have altered levels of nicotine in other ways that the Federal Government did not know about. With a product almost always first used by children, there is good scientific reason to be concerned that changes to these products that increase the potency or level of the prime addiction causing agent increase the speed with which children become addicted and make it harder for tobacco users to quit.

S. 625 gives the FDA the clear authority to prevent these types of abuses by requiring tobacco companies to disclose for the first time the type of information that would prevent the tobacco companies from hiding this kind of information from consumers and to prevent a tobacco company from making product changes in secret that could make the product more harmful and more addictive. By helping to create a market place where consumers and the Government are better informed, we give consumers new tools to take steps to protect their own health and give government new tools to prevent the tobacco industry from continuing its current harmful practices.

Your question is: How will consumers respond? The evidence from our experience after the Surgeon General's 1964 is clear. Faced with new information about the health hazards of tobacco products, consumers in very large numbers quit or switched to products that they believed reduced their risk of disease. The problem was that those products did not actually reduce their risk of disease, tobacco marketing misled those consumers and no Federal agency had the power to intervene to make sure that the market place was filled with truthful and complete information. Unfortunately, many consumers already believe that cigarettes and other tobacco products—and the claims being made in their advertising—are already regulated and approved by the Federal Government.[45] The evidence is strong that consumers will benefit and be better able to take steps to alter their behavior if this legislation passes, even before FDA is able to initiate the processes that could lead to the elimination and/or reduction of toxic substances in tobacco products or changes in nicotine delivery.

S. 625 also gives FDA, for the first time, authority to require companies to make changes in existing products, including the removal of harmful ingredients. Under this legislation, FDA would determine whether an action regarding a tobacco product will "protect the public health." This standard would require consideration of whether a product change would reduce the overall harm caused by tobacco use, including the harm caused to individual tobacco users and the impact on the population as a whole.

Importantly, the legislation enables FDA to require changes in nicotine based on the best available science for the purpose of reducing the number of people who die from tobacco. The key is that the science will dictate the best approach. In evalu-

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[44] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001, *http://cancercontrol.cancer.gov/tcrb/monographs/13/*.

[45] "Smokers' responses to advertisements for regular and light cigarettes and potential reduced-exposure tobacco products," Nicotine & Tobacco, Volume 6, Supplement 3 (December 2004) S353–S362.

ating the impact of different possible changes in the levels of nicotine, FDA will be able to assess the impact on current smokers, smokers trying to quit and non-tobacco users and make its decision about what steps will be most effective in reducing the number of people who die from tobacco. It will be a broad multi-focused analysis that only an agency with broad authority, adequate information, significant scientific expertise and a focus on public health can achieve.

Question 3. In what way will reducing the nicotine levels in cigarettes improve the public's health, since we know that when nicotine levels are reduced, smokers compensate by smoking more? Won't this approach in fact hurt the public's health?

Answer 3. This legislation does not prejudge the best way to control nicotine to reduce the death and disease caused by tobacco. Instead, it gives the FDA the authority to examine what to do about nicotine based upon the best available science taking into account the impact of any such change on both individual smokers and the population as a whole. Thus, this legislation recognizes the important role played by nicotine, but also recognizes that what changes should be made require the FDA to look broadly and to examine carefully the best and newest science on the impact of different proposed changes.

In the absence of effective legislation to regulate the tobacco industry and their products and marketing, nicotine levels in tobacco products have been intentionally changed by the tobacco companies (unbeknownst to consumers or the Government) to make them more addictive and to deliver more rapid doses of nicotine. As concluded by Judge Kessler in her August 2006 ruling in the Department of Justice lawsuit against the tobacco industry:

> "The Defendants have repeatedly made vigorous and impassioned public denials—before congressional committees, in advertisements in the national print media, and on television—that neither smoking nor nicotine is addictive, and that they do not manipulate, alter, or control the amount of nicotine contained in the cigarettes they manufacture. The Findings of Fact contained in this section and section V(B), supra, provide overwhelming evidence that those statements are false." [*Judge Kessler's Final Opinion, page 653*]
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> "In sum, the evidence as presented in these Findings of Fact is overwhelming that Defendants have, over the course of many years, time and again—and with great self-righteousness—denied that they manipulated the nicotine in cigarettes so as to increase the addiction and dependence of smokers. Those denials were false." [*Judge Kessler's Final Opinion, page 654*]

The legislation before the committee would provide FDA with the authority to evaluate the nicotine content of all tobacco products (along with other chemical and design features of tobacco products that may impact addiction). Through this grant of authority, FDA would be able to determine, based on the best available science, what decision is in the best interest of public health, weighing both the individual risks and the population-level impact, that changes in the nicotine yields of tobacco products, up or down (but not down to "zero"), would generate.

As crafted, this legislation's approach maximizes the likelihood that any change in nicotine levels prompted by the FDA will in fact improve the public health because it will be able to force the tobacco companies to control other changes in the tobacco product, monitor closely the impact of any proposed change after it takes effect, take into consideration the impact of any proposed change on non-smokers, as well as on smokers attempting to quit or interested in quitting.

Tobacco smoke contains over 4,000 chemicals, more than 200 of which are toxic and nearly 70 of which are known or suspected human carcinogens.[46] However, today, there is no Federal agency that has authority to require tobacco companies to identify what toxic chemicals appear in what products or brands or in what quantity. Nor is there any requirement of the tobacco companies to detail the testing they have conducted to test the health impact of different toxic substances in different brands/products. One of the central goals of this legislation is to give the FDA the authority to get this information, marry it with the best available science, and then determine the most appropriate action to take regarding these harmful substances both in terms of recommending changes to the product (e.g., performance standards) and informing consumers of the contents of these products and the risks associated with their use.

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[46] National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02–5074, October 2001.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR BURR, SENATOR HATCH, AND SENATOR COBURN BY ELMER HUERTA, M.D., M.P.H.

QUESTIONS OF SENATOR ENZI

Question 1. FDA is the gold standard amongst public health regulators. I worry that under this bill, the public would interpret FDA regulation as an endorsement that the product was safe for consumption, when we know that tobacco is unsafe. I think tobacco companies, not public health, would benefit from the FDA "stamp of approval." How can you ensure that FDA regulation of tobacco will not lead to greater consumer acceptance of tobacco?

Answer 1. Meaningful FDA regulation of tobacco is not an endorsement that a tobacco product is safe for consumption. It is important that no tobacco company be permitted to claim that a product is in any way approved or endorsed by the FDA. To the contrary, the FDA regulatory process will ensure that the public finally has access to information about the harmful ingredients in tobacco products, including cigarette smoke constituents, and the horrendous impact they have on public health. Under the proposed legislation, the FDA would be granted the authority to stop tobacco companies from lying to and misleading the public with its false advertising and unsubstantiated health claims. FDA regulation of tobacco would also include direct reminders to the public about the dangers of smoking with significantly larger health warnings that tobacco products cause death and disease. As you put it so well, FDA is the gold standard and with its scientific expertise, it is the best agency to inform the public about the harms of tobacco products.

Question 2. This bill sets a very high bar for the introduction of reduced-risk products. In fact, I read it as possibly requiring randomized, controlled clinical trials before a product can be approved. In addition, the use of the "public health" standard makes showing evidence of an improved product more difficult than the normal Food, Drug and Cosmetic Act standard of "safe and effective." I worry that this means we will ossify the makeup of tobacco products on the market where they are, and make it harder to market a safer product. I assume this is not what you intended. Why do you believe that this bill will favor the introduction of safer products?

Answer 2. First, tobacco products can never be "safe or effective," and that is why a new public health standard is established in the proposed legislation to regulate tobacco products. FDA regulation of tobacco would allow tobacco companies to continue to develop new products, but would require that any health claim attached to a product is based on sound science. The tobacco companies already market products as less hazardous or safer without having to verify these claims. We need only look at the experience of "light" and "low tar" to see how the tobacco industry developed a new product and then used false and deceptive labeling and advertising to mislead smokers into thinking they were consuming a safer product. Existing products and new products would both have to conform to the FDA performance standards. Tobacco companies that want to create products that are actually less hazardous should welcome this standard.

Question 3. Philip Morris supports the bill. Philip Morris management has an obligation to its shareholders to maximize profits. These two things together mean that the company believes it can sell more cigarettes for a longer time under this bill than if there were not a bill. How can you then be confident that the bill, as written, really will serve the public health in the long run?

Answer 3. We have conducted a thorough and independent analysis of the proposed legislation. The American Cancer Society is an evidence-based organization and a nationally trusted source of information on cancer and its causes and the American Cancer Society Cancer Action Network bases its legislative work on the evidence-based judgments of the Society. We have concluded that the proposed legislation will protect the public health and ultimately, save lives. The proposed legislation would provide the FDA with the authority and resources to effectively regulate the manufacturing, marketing, labeling, distribution and sale of tobacco products. The FDA would be authorized to restrict tobacco advertising and marketing, especially those aimed at children, including banning candy-flavored cigarettes. It would also require the tobacco companies to disclose the ingredients of tobacco products and cigarette smoke constituents. The FDA would have the authority to prohibit unsubstantiated health claims, and require larger, more informative health warnings on tobacco products. The proposed legislation would also grant the FDA the authority to take further action to ensure that tobacco products are not illegally sold to children. The public health would be much better protected with FDA regulation of tobacco than the status quo.

Question 4. Shouldn't we focus on better enforcing the dozens of tobacco regulations already on the books instead of burdening an overworked and underfunded FDA?

Answer 4. Despite the fact that tobacco kills more than 400,000 Americans each year, tobacco is the least regulated consumer product on the market today. The FDA is the only government regulatory agency that combines the public health mission with the scientific and health expertise needed to effectively regulate the tobacco industry. The manufacturing and marketing restrictions currently in place are completely inadequate, and there are no restrictions on additives or other ingredients that tobacco companies can add to the content of tobacco products. The tobacco companies market their products with unsubstantiated health claims, and mislead the public using terms such as "light" and "low tar." Furthermore, there is no mechanism for identifying misleading or fraudulent labeling or advertising claims or holding tobacco product manufacturers accountable. The proposed legislation effectively places tobacco companies under the same regulatory rubric of every other consumer product. Finally, the proposed legislation would provide funding to the FDA through a user fee paid by the tobacco industry, and will not negatively impact the other critical functions of the FDA.

QUESTION OF SENATOR BURR

Question. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer. Keeping tobacco products on the market clearly is not in the best interest of the public health. Unfortunately, there is no effective way to eliminate these products. As we learned during Prohibition, an outright ban would lead to the creation of a black market and all of the undesirable social side effects that black markets create. The fact is 45 million Americans are currently addicted to tobacco. The critical effort is to stop new smokers, who are mostly kids, from starting, to increase the access and affordability of cessation services and to give the public objectively-reviewed, factual information about tobacco products. We also must stop the tobacco industry's misleading labeling and advertising, unsubstantiated health claims, and manipulation of their product in order to keep smokers smoking and getting new users to start. The proposed legislation is critically needed to protect the public health from the harms of tobacco.

QUESTIONS OF SENATOR HATCH

Question 1. Dr. Huerta, what percentage of lung cancer is caused by tobacco usage? The reason I ask is that I am aware of a few cases where someone has been diagnosed with terminal lung cancer and never smoked a cigarette in his or her life. I was very interested in your statistics about the decrease in cancer deaths and the decrease in mortality rates and incidence from lung cancer in men. Could you please talk about this in more detail? These numbers are very encouraging news to those who have loved ones suffering from lung cancer.

Answer 1. Approximately 87 percent of all lung cancer deaths are attributable to tobacco use and smoking accounts for at least 30 percent of all cancer deaths. So while there are cases of lung cancer in nonsmokers, the vast majority are associated with tobacco use. The risk of developing lung cancer is about 23 times higher in male smokers and 13 times higher in female smokers compared to lifelong nonsmokers. Lung cancer accounts for the most cancer-related deaths in both men and women. Death rates from lung cancer for men have declined significantly from 1991 to 2003, although there is still great variation between racial and ethnic groups. After increasing for several decades, lung cancer death rates for women are approaching a plateau, but still have yet to decline. Women lagged behind men in picking up smoking, so it is not surprising we see the same lag with disease. Since 1987, more women have died each year from lung cancer than from breast cancer. This is an extremely deadly type of cancer with only a 16 percent 5-year survival rate. In 2007, an estimated 213,380 new cases of lung cancer and 160,390 deaths from lung cancer are expected.

In addition to lung cancer, smoking is associated with an increased risk of at least 14 types of cancer, including nasopharynx, nasal cavity and paranasal sinuses, lip, oral cavity, pharynx, larynx, esophagus, pancreas, uterine cervix, kidney, bladder, stomach, and acute myeloid leukemia. Smoking is a major cause of other diseases too, including heart disease, cerebrovascular disease, chronic bronchitis, and emphysema, and is associated with gastric ulcers. The health care costs associated with smoking-related diseases and deaths are astronomical. The CDC estimates that over $96 billion in direct medical expenditures are caused by tobacco each year, with an additional $97 billion lost in productivity.

Question 2. Why do you believe that the Food and Drug Administration is the proper agency to regulate tobacco? I am just not convinced that the FDA is the appropriate agency to regulate tobacco. Personally, I believe that the FDA, currently, has tremendous responsibilities imposed upon it compared to other health agencies and adding another major responsibility like the regulation of tobacco is just too much. We hear complaints all the time about the FDA not being able to do its current job and here we are, through this legislation, imposing additional responsibilities on the agency. So I'd be interested in your opinion—why is the FDA the best agency to oversee the regulation of tobacco? And please know, I do not disagree with you about the need for tobacco to be better regulated—I just don't know if the FDA is the right agency to do the job.

Answer 2. The FDA is the only government agency with the scientific expertise and enforcement power necessary to effectively regulate tobacco products and health-related claims made by the tobacco companies. The FDA can evaluate the veracity of tobacco industry claims about their products and has the ability to swiftly modify its regulations to respond to new scientific information or changes in the tobacco industry's tactics. I agree that resources for the FDA have struggled to keep pace with its critical functions. The proposed legislation ensures that the FDA regulatory functions for tobacco will be paid for by means of a user fee levied on the tobacco industry. The proposed legislation places tobacco on the same regulatory level of food and drugs, and is critically important to protect the public health.

Question 3. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes for a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 3. Tobacco use costs our Nation over $96 billion each year on direct health care costs and over $97 billion each year in lost productivity, not to mention the over 400,000 lives lost. In the unlikely scenario that a complete ban was to be enacted, the billions of dollars in public health savings would offset any loss of tax revenue by many orders of magnitude.

Question 4. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 4. The proposed legislation imposes strong, new requirements regarding the prevention and monitoring of potential black market sales and provides for a congressionally mandated study of illicit trade issues, the biggest black market threat. In addition, the user fee imposed on the tobacco companies to fund FDA regulation would amount to less than 1½ cents per pack of cigarettes, a virtually inconsequential increase. Black market sales are driven by price across State and national boundaries. The proposed legislation places restrictions on the advertising, marketing, promotion, labeling and sale of tobacco products, which should not impact the price of tobacco products.

QUESTIONS OF SENATOR COBURN

Question 1. What constituents would you recommend that the FDA require to be eliminated or reduced in cigarettes, and by how much would that reduction or elimination reduce the relative risk of tobacco-related diseases?

Answer 1. This is exactly what we want to give the FDA authority to determine. The proposed legislation would allow the FDA to use existing science and new science to identify changes to existing and new products that would reduce their harm. The tobacco companies would still be prohibited from making any unsubstantiated health claims based on any change to their product. We know the tobacco companies manipulate their products in order to keep their customers addicted and to encourage new ones to start, and we see variations in the same brand sold in different countries. The FDA is the only government agency with the resources and

scientific expertise to determine what ingredients in tobacco products or cigarette smoke constituents should be reduced or eliminated in order to protect the public health.

Question 2. How will smokers alter their behavior in response to the introduction of cigarettes with new tobacco product standards? That is, what will be the effect on cigarette consumption of smokers now knowing that the FDA is tightly regulating all the constituents and ingredients in cigarettes?

Answer 2. First of all, the new marketing and advertising restrictions would stop allowing the tobacco companies to target our youth and other vulnerable populations. These restrictions would decrease the number of new tobacco users, particularly children, since the vast majority of smokers start before they turn 18. In addition, the larger health warnings, as have been used in other countries, and the elimination of false and misleading health claims would encourage more people to quit. Product disclosure would allow the public, for the first time, to understand how tobacco companies manipulate the ingredients and additives in their product in order to increase addiction without regard for the harm of the user. Overall, the proposed legislation will help discourage new users, encourage quitting and ultimately save lives. Tobacco use is the most preventable cause of death and disease in this country and granting the FDA the authority to regulate tobacco is the key prevention measure missing in order to reduce tobacco's deadly toll on our Nation.

Question 3. In what way will reducing the nicotine levels in cigarettes improve the public's health, since we know that when nicotine levels are reduced, smokers compensate by smoking more? Won't this approach in fact hurt the public's health?

Answer 3. Most tobacco cessation products rely on the principle of weaning the tobacco user away from nicotine addiction by reducing the dosage level over time, and therefore have been effective for so many people. Reducing the addictive nicotine levels in cigarettes improves an individual's chance at stopping smoking. We know that tobacco companies have purposefully manipulated nicotine levels in order to prevent smokers from quitting. The proposed legislation would permit the FDA to determine the level of and way nicotine is introduced in tobacco products, as well as create new standards, based on the overall impact on public health. These performance standards would be the primary way in which the FDA would require tobacco products to be less harmful and less addictive. Without the proposed legislation, the tobacco companies will continue to manipulate nicotine levels to encourage new, young smokers to start and keep current smokers from quitting.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR BURR, SENATOR HATCH, AND SENATOR COBURN BY RICHARD LAND, D.PHIL.

QUESTIONS OF SENATOR ENZI

Question 1. The content of the bill before us has seen little if any change over the years, and I think we can do better. Do you have any suggestions for how the bill could be made even more effective in preventing youth smoking and helping current smokers to quit?

Answer 1. We believe S. 625, in its present form, includes the necessary tools to significantly reduce tobacco consumption among our youth and help addicted smokers break their habit. The fact that the bill has few substantive changes from versions introduced in previous Congresses does not necessitate that it be modified. Congress simply has not given the FDA opportunity to prove the effectiveness of the bill. If the bill had been enacted into law several years ago and little progress had been made in efforts to prevent or curb the use of tobacco among Americans, particularly our youth, then Congress would have legitimate reason to revisit the legislation and determine what provisions need to be strengthened, added, or removed. While probably every member of Congress would like to reduce tobacco use among children, we cannot fall prey to the trap of making the perfect enemy of the good. We believe the current provisions would provide sufficient means to scale back tobacco use significantly, especially among youth.

Question 2. Certain brands are especially preferred by youth smokers, even though most advertising to children is prohibited. I can imagine that even with further restrictions on advertising as proposed in this bill, kids will still prefer certain brands, because that's the nature of fads and trends. This could further consolidate the market in the hands of the biggest players, who would then be even more well-known among youth, perpetuating the brand preferences. How does this bill address that market consolidation and youth smoking spiral?

Answer 2. While the companies that signed the Master Settlement Agreement agreed not to market to kids, there are actually few restrictions on advertising to children or anyone else in the MSA. Analysis of the MSA reveals that less than 20 percent of the marketing and promotional expenditures of the tobacco companies were affected at all. The major cigarette companies have more than doubled their marketing and promotional expenditures in the years since the MSA to an annual total of more than $15 billion,[47] or more than $40 million each day, and much of it still reaches kids. Tobacco advertising in youth-oriented magazines actually increased by more than 30 percent in the year after the MSA was signed,[48] and tobacco companies continue to reach kids through magazines, retail point-of-sale marketing, sports sponsorship, and other venues. It's no wonder that kids are almost twice as likely as adults to recall tobacco advertising.[49] Even the so-called youth prevention campaigns by tobacco companies have been shown to encourage kids to smoke.[50]

S. 625 will actually subject all tobacco companies and all brands to the same marketing restrictions, whereas that is not the case under the MSA, as not all companies are parties to the agreement. While this should create a level playing field across all manufacturers, our real concern should not be what brands kids smoke but how many kids smoke at all. Twenty-three percent of high school kids still smoke.[51] While this represents more than a 35 percent decline in high school smoking since 1997, largely brought about by price increases (due to increased tobacco taxes and MSA costs passed on to smokers) and the impact of State tobacco prevention programs, this decline has slowed or stalled in recent years, and the most recent data show a small increase in youth smoking. This stalled progress no doubt reflects the aggressive marketing by the tobacco companies.

The evidence is very clear, despite industry claims to the contrary, that tobacco marketing affects not only brand choice but initiation of smoking. A 2002 monograph by the National Cancer Institute, which reviewed the research on tobacco advertising and promotion and its impact on youth smoking, found that tobacco advertising and promotional activities are important catalysts in the smoking initiation process. The NCI report also found, based on a review of the extant research, that "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable."[52] The marketing restrictions in S. 625 are designed to reduce youth exposure to the kind of marketing that leads to increased smoking among kids.

Question 3. You indicate that your support for this bill comes from a desire to treat tobacco no differently than other consumer products. Yet this bill sets up a radically different set of standards and regulations for FDA authorities over tobacco. Can you explain to me how you believe the proposed standards for tobacco regulation are the same as for other consumer products?

Answer 3. The Southern Baptist Ethics & Religious Liberty Commission believes FDA regulation of tobacco products is long overdue. Astonishingly, tobacco products remain the most deadly but least regulated of all consumer products. The FDA can ensure the safety of everyday items, but has no authority over tobacco, a product that causes more preventable deaths than any other. Tobacco products are the only consumer products that, when used as directed by the manufacturer, kill half of their users. Thus, the standard used by the FDA to evaluate tobacco products cannot be the same standard it uses to evaluate other consumer products. S. 625 recognizes the uniquely lethal nature of tobacco products and that these products can never be "safe and effective." Instead, S. 625 appropriately applies a "public health" standard, which allows the Secretary to take actions it believes will protect the public health and reduce the number of people who suffer and die from tobacco.

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[47] U.S. Federal Trade Commission (FTC), *Cigarette Report for 2003*, 2005 [data for top six manufacturers only].

[48] Bowker, D & M Hamilton, "Cigarette Advertising Expenditures Before and After the Master Settlement Agreement: Preliminary Findings." May 15, 2000; and Fairclough, G., "Are Cigarette Ads in Magazines Angling for Teens?" *The Wall Street Journal* (May 15, 2000).

[49] National telephone survey of 510 teens aged 12 to 17 and 1,012 adults conducted by International Communications Research (ICR), March 2007.

[50] Wakefield, M., et al., "Effect of Televised, Tobacco Company-Funded Smoking Prevention Advertising on Youth Smoking-Related Beliefs, Intentions, and Behavior," *American Journal of Public Health* 96(12):2154–2164, December 2006.

[51] U.S. Centers for Disease Control and Prevention (CDC), "Youth Risk Behavior Surveillance, United States, 2005," *Morbidity and Mortality Weekly Report* (MMWR), June 9, 2006 55 SS–5.

[52] National Cancer Institute, *Changing Adolescent Smoking Prevalence*, Smoking and Tobacco Control Monograph No. 14, NH Pub. No. 02–5086, November 2001.

Although the FDA will apply a different standard to evaluate tobacco products, it will rely on the same procedures, staff expertise, and experience to analyze and evaluate tobacco products that it uses to evaluate the health impact of other products on consumers.

The "public health" standard used in this legislation will protect consumers. It will reduce smoking, especially among children, and reduce the tremendous toll of tobacco on our families. We fully support these goals.

QUESTION OF SENATOR BURR

Question. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer. We do not advocate removal of tobacco from the market, but instead believe FDA regulation is the most significant means to protect public health. A tobacco ban could prompt contraband trafficking and black market sales of the prohibited tobacco products. Additionally, a tobacco ban lacks sufficient congressional and public support, partly due to our Nation's experience with a ban on alcohol. History shows that Prohibition in the 1920s and early 1930s was not sustainable largely because alcohol consumption was a personal habit very widespread among adults. Outlawing tobacco, also a widely used product, would receive a similar negative reaction from a minority of the public. Additionally, while tobacco is an incredibly destructive product, it does not debilitate the user in the same way that illicit drugs do. A person can still perform his or her job and function safely while using tobacco. Instead, we want to find ways for people who choose to use tobacco to experience less harm from and less dependability on the product. We also want to help safeguard children from being targeted by tobacco marketing.

QUESTIONS OF SENATOR HATCH

Question 1. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes for a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 1. The Southern Baptist Ethics & Religious Liberty Commission does not possess the expertise to answer the question of revenue effects as a result of FDA regulation of tobacco. We feel confident, however, that the loss of revenue would be offset to some extent by a reduction in demand for State-funded public health and other services. Healthier people will cost the State less to care for. A healthier workforce will also lead to greater productivity, which will generate more tax revenue for the State. Additionally, families will be strengthened. More children will experience the positive benefit of having two healthy parents over the entire course of their childhood. More children in single-parent homes will experience the positive benefit of living with that parent their entire childhood. These healthier parents will have greater opportunity to provide for the financial wellbeing of their families, reducing the demand on the public welfare system. Children raised in these more stable environments will be less likely to live in poverty, and will subsequently be less likely to exhibit the effects of poverty, such as crime, poor health, lack of education, and substance abuse. It is less likely that these children, and the adults they will become, will require the same degree of care by government as a result, thereby reducing the need for tax revenue.

Question 2. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 2. This legislation will not contribute to the sale of tobacco products on the black market. Indeed, it contains provisions expressly designed to curtail illegal tobacco product sales, including the sale of contraband tobacco products. There is no reason to believe that this bill will result in additional illegal sales. Further, the

legislation gives the FDA the authority to evaluate the overall impact of any action it takes on the public health based on a population-based analysis. Thus, it is broad enough to allow the FDA to evaluate all factors, including black market sales, that impact the number of people who will die from using tobacco.

What is clear is that in the absence of this legislation and stringent regulation of tobacco products, more than 400,000 Americans continue to die each year from tobacco use. This bill provides a critical additional tool in the battle to reduce that number.

QUESTIONS OF SENATOR COBURN

Question 1. What constituents would you recommend that the FDA require to be eliminated or reduced in cigarettes, and by how much would that reduction or elimination reduce the relative risk of tobacco-related diseases?

Answer 1. The Southern Baptist Ethics & Religious Liberty Commission does not possess the expertise to recommend elimination or reduction of the various components in cigarettes. We believe the FDA needs to make those determinations.

Question 2. How will smokers alter their behavior in response to the introduction of cigarettes with new tobacco product standards? That is, what will be the effect on cigarette consumption of smokers now knowing that the FDA is tightly regulating all the constituents and ingredients in cigarettes?

Answer 2. FDA regulation of tobacco would likely cause smokers to more closely evaluate their decision to smoke and prompt many of them to abandon the habit. Most smokers have little idea of the number of carcinogens and additives within tobacco products. Disclosure of these substances and the addition of meaningful warning labels, however, would awaken many people to the dangers of tobacco use. Further, the legislation would allow the FDA to require manufacturers to adopt feasible technologies to reduce or eliminate harmful ingredients, thereby scaling back the health risks to those who continue to smoke. Reductions of nicotine levels would make it easier for millions of Americans who have tried unsuccessfully to quit smoking to actually drop the habit. Possibly most important, the legislation would help produce future generations of adults that are not addicted to cigarettes. By limiting marketing and sales of tobacco to children, countless young people will never try cigarettes and so will never begin lives of nicotine addiction.

Question 3. In what way will reducing the nicotine levels in cigarettes improve the public's health, since we know that when nicotine levels are reduced, smokers compensate by smoking more? Won't this approach in fact hurt the public's health?

Answer 3. While nicotine consumption is obviously the principle reason that people smoke, and we are concerned about addiction to nicotine in the same way we are concerned about any other addictions, we believe the more important issue relates to the chemicals, additives, and processes involved in delivering nicotine through tobacco use. We think it should be the responsibility of the FDA to determine the type and degree of danger to which smokers are exposed by the various components and additives in tobacco as they try to reach a particular level of nicotine intake.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY, SENATOR ENZI, SENATOR BURR, SENATOR HATCH, AND SENATOR COBURN BY JACK HENNINGFIELD, PH.D.

QUESTIONS OF SENATOR KENNEDY

Question 1. In your testimony, you emphasize that "FDA is the right agency and the only agency" with appropriate experience "to regulate tobacco products since cigarettes are drug delivery products at heart."

You contrast this with the lack of appropriate expertise at the Federal Trade Commission that led to its adoption of a misleading system for measuring the level of tar and other toxins in cigarettes. Please elaborate on how FDA's expertise can be used to help protect the public from the dangers of smoking.

Answer 1. The FDA was established for the primary purpose of protecting the public health through regulation of a broad range of products on the basis of their contents, designs, delivery of substances and on health effects. Its regulation through product performance standards, allowable ingredients, claims, branding representations (e.g., "fresh orange juice") and other communications are intended to serve public health. Major staffing of the FDA are the many scientists and public health experts whose mission is to contribute to the improvement of public health through science-based product regulation. They work with communications experts, legal counsel and others to ensure that products are appropriately labeled, adver-

tised and regulated so as to serve public health interests including minimizing hazardous exposures.

In fact, historically, for most food products, FDA's role was primarily to prevent adulterated products and reduce toxic exposures whether or not a specific health benefit was intended. For the last 20 years, however, FDA has conducted premarket evaluations of proposed health claims for foods. In the case of drug products the additional burden of beneficial health effect is required. In virtually all cases, some level of risk is allowed to enable benefits and/or accommodate what is feasible from a practical and commercial perspective (e.g., level of "purity" or maximum allowable standards for insect parts, pesticide residues and other contaminants such as formaldehyde in flour). In the case of drugs, most can incur serious adverse health consequence and are not considered absolutely safe (e.g., OTC pain relievers may cause more than 15,000 deaths per year) but their allowance for marketing is considered on the basis of their overall public health impact.

In sharp contrast, the FTC was established, initially as the "Bureau of Corporations" with a core mission—the regulation and protection of free and fair commercial trade through support of competitive markets and restrictions. This of course, includes advertising, branding and product claims. Moreover, FTC regulates marketing of many products which are also or primarily regulated by FDA but it generally defers to FDA on aspects of those products pertaining to health effects. In contrast to FDA's staffing by scientists and public health experts, major staffing of FTC are economists and lawyers who focus largely on issues such as compliance with the law and serving to enhance free, fair, and competitive trade—not public health.

With its focus on health protection, through regulation of tobacco products FDA will have its extensive history, expertise of its many scientists and regulators, and decades of precedents in regulation of foods, drugs, cosmetics and other substances that can be brought to bear in regulating tobacco products in such a way as to lead to decrease adverse health effects (including, in principle, addiction) and even to decrease use of some or all products.

Question 2. Even though cigarettes will never be safe to smoke and our primary goal is to stop people from smoking, you believe that it's important for the FDA to have the power to set "performance standards" regulating the ingredients in cigarettes and how they are made. Over time, FDA could require many changes in the design and contents of cigarettes currently on the market and of new brands to make them less toxic and/or less addictive by issuing performance standards. Please explain how these performance standards would benefit those who do smoke, and those exposed to secondhand smoke. Give us a few concrete examples of the type of standards that FDA might adopt.

Answer 2. The principle value of product performance standards will be to reduce or prohibit the use of added ingredients (e.g., ammonia, menthol, chocolate), materials in composition (e.g., glass fibers), and design features (e.g., hidden ventilation systems) which may increase toxicity and/or addiction. Standards may be set for ingredients in the product as well as its emissions such as constituents of "tar," and toxic gases such as carbon monoxide.

Standards that lead to decreased smoke exposure and or toxicity have the potential to reduce secondhand smoke exposure and/or the toxic consequences of secondhand smoke exposure. For example, if FDA determines that chocolate is not necessary for cigarette manufacture and consumption but may contribute to carcinogenicity and or risk of becoming addicted it could limit or ban chocolate. Similarly, if FDA determined that menthol increased toxic exposures by virtue of its own effects or by enabling deeper lung exposure of other toxins, and/or increased liability to addiction it could restrict or ban menthol. If FDA determined that hidden ventilation holes contributed to consume deception and/or adverse health effects it could ban their use or require clear demarcation and warnings. FDA could restrict nicotine content and/or form of delivery (e.g., free-base fraction). Setting standards for maximum allowable nicotine, perhaps based on current product levels is consistent with other efforts to prevent products from becoming even more toxic and/or addictive. In all of these cases, FDA actions would be based upon its science-based assessment of the potential for the standards to contribute to public health through reduction of toxic exposures.

Please note two additional clarifications regarding nicotine regulation: (1) Although it is true that nicotine is not the primary ingredient in tobacco that causes adverse health effects (other than addiction), nicotine is not without risk, and this is why nicotine in medicines such as nicotine gum is carefully regulated to ensure that levels do not exceed acceptable standards for safety. Thus, the maximum allowable dose of nicotine in nicotine gum is 4 mg of which about 2 mg is typically deliv-

ered. This is in contrast with a conventional cigarette that contains about 10 mg nicotine and can easily deliver 2–3 mg of nicotine; a "pinch" of the most popular brands of snuff can contain and deliver 10 mg or more of nicotine. (2) Although it is theoretically possible to reduce tobacco and tobacco toxin exposure by increasing nicotine levels, it is not known how much nicotine supplementation in tobacco would be required to reduce tobacco intake sufficiently to reduce adverse health effects of contaminants. Whether reducing nicotine would contribute to public health has not been determined; therefore, the bill does not compel FDA to reduce nicotine levels but appropriately gives FDA the power to regulate nicotine levels based on public health considerations.

Question 3. In your testimony you emphasize that "One key feature of the legislation is that mere compliance with a performance standard cannot be used as the basis for product claims." This is extremely important to prevent the public from being misled. What safeguards can be implemented to prevent tobacco companies from making claims based on compliance with these standards.

Answer 3. The FDA has a long history of preventing products from being misbranded and marketed (including labeling and advertising) with implicit or explicit claims that can foster inappropriate use. For example how cholesterol levels of food are communicated, the definition of "cholesterol free" and what communications are allowed in marketing (including labeling, branding, and implicit and explicit claims) has been extensively evaluated by FDA and is regulated so as not to contribute to excess exposure even if a product meets the standard for "cholesterol free." To achieve these goals, FDA has a variety of tools and precedents at its disposal: it can require sponsors to conduct studies and present data on consumer reactions and actual patterns of use, FDA can conduct its own consumer research to determine how consumers interpret communications, and FDA can require companies to collect and report findings after the product is marketed and/or collects its own data.

Thus, for example, FDA may develop its own mandatory warning stipulating that its allowance of the product to be marketed does not imply safety and in fact that the product carries a very high risk of addiction, lung cancer and heart attacks. Such a statement combined with powerful new health warnings (that will also be regulated and changed as necessary by FDA) should lead to appropriately increased consumer concerns about tobacco use, not to diminished concerns. To assure that these goals were achieved and were not undermined by unintended consequences, FDA could obtain post-market surveillance data through a variety of mechanisms at its disposal. This is all consistent with FDA's increasing requirements for risk management programs, which involve assessing potential risks, requiring marketing to be developed so as to minimize risks, and requiring that marketing efforts be designed to minimize the risks. Furthermore, post-marketing surveillance could be used to detect unintended consequences in a timely fashion so as to guide corrections in regulatory approach and marketing.

Question 4. In your testimony, you say that without FDA regulation, smokers who want to quit will increasingly turn to "new tobacco products that falsely claim (at least implicitly) to be less harmful." We are seeing more and more of these products making unproven claims entering the market today. Under S. 625, no such reduced risk claims could be made unless the FDA verified the accuracy of the claim, and determined that it would not be misleading to consumers. That is a very important safeguard for the public, is it not? Describe the type of process FDA scientists would go through to determine whether a new product really reduced the risk in a meaningful way?

Answer 4. This is among the most vital safeguards. Even though conventional cigarettes remain the most important cause of death and disease among all tobacco products, all of the major companies are investigating and test marketing products that could replace conventional cigarettes in the future. We must avoid the mistake made with "light" and "reduced tar and nicotine" cigarettes, as well as filters. These so-called innovations falsely reassured smokers, undermined prevention and cessation, and ultimately escalated annual tobacco attributed mortality, including lung cancer, in the latter quarter of the 20th century. All of this happened even as advertised tar levels declined. Preventing such a public health disaster from recurring is more likely with FDA regulation than with a perpetuation of the unregulated tobacco marketplace. This role of FDA becomes more vital with each passing day, as new products and product claims from the implicit (e.g. "Marlboro Ultra Smooth" with its "Filter Select" banner) to the more explicit (e.g. Eclipse, claiming that "compared to other cigarettes Eclipse may present smokers with less risk of cancer, chronic bronchitis and possibly emphysema.")

FDA can require full disclosure of data regarding ingredients and can require both testing by sponsors and post-marketing data collection to ensure that claims are not allowed until the agency is satisfied that they are appropriate and justified. Equally important, if allowed claims lead to unintended consequences the agency has a variety of tools at its disposal such as communications to address the problem, prohibiting sales, or immediate recall of products in the marketplace.

QUESTIONS OF SENATOR ENZI

Question 1. You state over and over in your testimony that whatever tests or standards there are, companies will use this as a marketing tool. Why will FDA regulation be any different?

Answer 1. The Food and Drug Administration is charged with protecting the public health. In its day to day regulation of a broad range of consumable products and drugs, it does this through coordinated regulation of both product contents, often through performance standards, and allowable labeling and marketing. FDA can take a wide range of actions when companies label and/or market inappropriately. For example, FDA has recalled and taken action against orange juice that was made from frozen concentrate but advertised as "fresh" and apple juice for infants that was actually artificially flavored and colored sugar water. These are but two of thousands of examples of FDA actions over the years to ensure that products are not labeled, marketed or branded in misleading ways.

The examples posed by Dr. Blum of misleading advertisements using FTC tar and nicotine ratings and descriptors such as "lights" are examples of practices that occur in *the absence* of effective product regulation. Under the legislation, FDA would have the power to prohibit these practices. As this bill makes clear, FDA's regulatory tools will include regulation of marketing, labeling, claims, and warnings to ensure that appropriate messages are communicated. FDA can also require post-marketing research and surveillance when it has concerns; it can inspect production facilities, and obtain company product manufacturing documents. Furthermore, other organizations and individuals undoubtedly will conduct post-marketing research to determine the effectiveness and appropriateness of messages and whether unintended consequences are occurring. Such data can be brought to the FDA's attention in the form of additional comments to a rulemaking record or petitions for policy change that the agency must consider.

Question 2. You said in your testimony that performance standards should be developed for all smoke constituents. I have heard figures for the number of constituents that range from dozens to hundreds. That seems like a lot of performance standards just for smoke constituents, never mind for nicotine, filters and additives. Would the result of all these regulations really be a safer cigarette?

Answer 2. The Food and Drug Administration has many tools at its disposal including the establishment of advisory committees to prioritize targets for performance standard setting, even as the World Health Organization is presently undertaking to assist nations which are implementing the International Framework Convention on Tobacco Control ("Tobacco Treaty"). Performance standards are not designed to produce a safer cigarette but to reduce the delivery of toxins in existing and new products.

Question 3. You mention the importance of stopping tobacco sales to children. Every State already prohibits the sale of tobacco products to anyone under the age of 18. These laws have been effective—reducing by half the number of children purchasing these products in the past decade. Why is FDA the appropriate agency to enforce these laws and what is gained by doing so? Don't we run the risk of derailing regulations that are already working?

Answer 3. Model approaches to reduce access to tobacco products by persons under 18 years of age were developed by FDA in the process of its 1990s Tobacco Rule development and initial phases of implementation. I would submit that FDA understands, better than any agency, how to best achieve these goals, building on limited success in recent years to achieving the level of reduction of access that is needed in the future. An FDA program would also ensure uniform and consistent enforcement of youth access restrictions. In the past, consistent enforcement among States has been a problem.

Question 4. I think the bill sets an extremely high bar for the approval of a reduced risk product. In fact, I think it might call for clinical trials. Do you think it will be possible to get Institutional Review Board (IRB) approval for studies to determine if a tobacco product really represents a reduced risk? If that is not possible,

how else might an application for the approval of a reduced risk product be supported with data?

Answer 4. Approval of a new product for marketing and/or claims for a reduced risk product (be they new products or modifications of existing products) should be in accordance to high standards to prevent debacles such as occurred with so-called "light" and "reduced tar" cigarettes and the ongoing "snake" oil type of marketing that is occurring with some new products absent FDA regulation.

Evaluation of such products will presumably be done on the basis of review of actual ingredients (all ingredients and not just substances that the tobacco industry calls "additives" and ingredients) as well as emissions from the product to which the person is actually exposed when using the product. Therefore, this will also require chemical laboratory testing, in-vitro testing, and probably animal testing. Actual claims should be evaluated to the greatest extent possible in clinical trials involving human volunteers. At present, all over America, people are volunteering for and participating in studies involving tobacco self-administration. The studies include NIH supported studies at universities and organizations such as Battelle, and are subject to review and approval by human subjects review boards. The tobacco industry has a long history of such testing and presently supports some testing that is conducted at universities under IRB review, at Battelle, and probably in its own laboratories, although I have no way of knowing what sorts of human subjects protections are being followed in their own laboratories.

Question 5. You indicate that machine testing of factors such as nicotine yield is not an accurate indicator of what happens when a human being smokes. If that is the case, what would a product standard for tobacco be based upon? Or are you proposing these standards be based on technology you believe to be flawed?

Answer 5. I concur with leading investigators and the World Health Organization that the FTC Method and its similar international variant, the ISO or International Standards Organization method (which was based largely on the FTC method), are seriously flawed and should be abandoned. Even a preliminary examination of the method by the FDA during its Tobacco Rule development led it to the conclusion that the FTC method was flawed but at the time it issued the Proposed and Final Rules, the FTC had announced that it was taking actions to study the problem and resolve it. It was not until after the FDA lost its regulatory authority that the FTC essentially walked away from the method with an announcement on its Web site—I believe in 2001—that it would no longer disseminate the results. Yet, absent regulation, the tests are still done by the tobacco industry and provided in advertising.

New standards are under evaluation through a consortium of approximately 30 laboratories throughout the world, including the Centers for Disease Control and several NIH funded laboratories in the United States. FDA, with its extensive history in performance standard development could help ensure that new standards are accurate, fair and viable.

QUESTIONS OF SENATOR BURR

Question 1. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer 1. Although few in public health would probably disagree with the premise that the world would be better without tobacco products as they have been made, marketed and used, we have them and there is few viable ways to remove them in the near future. Most would probably also agree that the status quo is unacceptable. These are my positions as well, but what is embodied in your question is what we must do. Here my position is clear and is consistent with other leading health organizations in the United States and the World Health Organization: namely to institute science-based health-focused tobacco product regulation.

This is an effort to address the reality that at least for the foreseeable future, I do not believe that banning tobacco is viable. FDA came to this conclusion itself in the development of its Tobacco Rule in the mid-1990s. These conclusions recognize that approximately 50 million Americans are current cigarette smokers. By some estimates, nearly 40 percent of all cigarettes may be smoked by people with other psychiatric problems including depression, anxiety, thought disorder, and other substance dependence disorders and science-based medical interventions for addressing their tobacco use in the context of these other problems is in its infancy. Furthermore, for many people nicotine withdrawal is debilitating and is not compatible with their meeting occupational, social and family demands. This includes our military troops and many people in sensitive occupational positions that involve public safety. I believe that many of these people could be treated with existing pharma-

cological and behavioral treatments, but limitations in access to treatment prevent many in need of treatment from getting it.

Many health care plans do not provide adequate coverage for existing treatment and tobacco addiction rates are highest among the lower income individuals who are least likely to have any health care coverage whether they are working or not (roughly 80 percent of the approximately 47 million person without health care do not work). For many of those with co-occurring psychiatric disorder, there are still unresolved questions as to how best to treat their tobacco addiction along with other disorders. These are just the scientific, medical, and health care delivery obstacles to attempting to ban tobacco product in the near future. The social, political, and potential contraband market issues that would arise are additional issues. Much of this was discussed in a paper that was commissioned by the American Medical Association and that I co-authored a few years ago (Henningfield, J.E., Benowitz, N.L., Slade, J., Houston, T.P., Davis, R.M., Deitchman, S. Reducing the addictiveness of cigarettes. *Tobacco Control*, 7: 281–293, 1998). I note that the FDA, in its Tobacco Rule development came to a similar conclusion about banning tobacco products. Further into the future, I believe and hope that within a few decades, the cigarette as we know it today will be a relic of the past and that we will be on our way to seeing lung cancer rates at the end of the 21st century become what they were at the end of the 19th century: a medical rarity.

Question 2. Did you or did you not participate in the crafting of the World Health Organization's Framework Convention on Tobacco Control?

Answer 2. No. I served on the World Health Organization (WHO) study groups that provided scientific evaluation of tobacco and health issues in the late 1990s, and I served on the WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob) from 2000 until 2004 that was charged with providing WHO with scientific guidance on various issues that arose over the several year process of developing the Framework Convention on Tobacco Control (FCTC or "Tobacco Treaty"). After the treaty was adopted, the SACTob was reconvened with a more substantial structure as the WHO Tobacco Regulation Study Group or TobReg, and I have served since that occurred in 2004. All of my participation has been in an advisory capacity. I played no role in crafting the FCTC.

Question 3. Do you or do you not support the WHO's Framework Convention on Tobacco Control?

Answer 3. Yes. I was encouraged that former Health and Human Services Secretary Tommy Thompson signed the treaty on behalf of the United States of American in 2004, and I hope that the President will request that the Senate ratify the treaty so that the United States can join the nearly 150 other nations, representing nearly 80 percent of the world population, which have ratified the treaty.

Question 4. Is one of the main tenants of the WHO's Framework Convention on Tobacco Control to create an international, secretariat level, body that would control tobacco manufacturing, cessation programs, and production for all participating countries?

Answer 4. No.

Question 5. During the hearing, when I asked you did you support granting sovereign control of U.S. tobacco regulation to an international body, what was your answer?

Answer 5. I have not seen the transcript, but I frankly did not understand the question because it seemed that you were questioning my support of the FCTC with a question about how the treaty operates. I do support the treaty, but it does not "grant sovereign control of U.S. tobacco regulation to an international body," as I understand those terms. The treaty sets goals and develops standards as appropriate but recognizes that the more than 150 nations expected to ratify it will each need to find ways to comply that are consistent with their own systems of governance, commerce and regulation.

QUESTIONS OF SENATOR HATCH

Question 1. In your testimony, you say that we have made modest progress in reducing tobacco use and that FDA regulation of the tobacco industry have made the "progress significantly greater." Could you elaborate on that statement?

Answer 1. I will support my position with just a few examples.

Youth access: The FDA initiated a national program to reduce tobacco sales to minors. The program effectively coupled enforcement with penalties for repeat violators. At its peak, I understand that 200,000 compliance checks had been conducted

and in excess of $1 million collected from retailers who repeatedly and illegally sold cigarettes to minors. This entire system was discontinued after the 2000 Supreme Court decision to remove tobacco from FDA's regulatory authority. I do not know how many children and adolescents who could have been prevented from developing addiction, but I believe that smoking and other tobacco among our young would be substantially less today had FDA been able to sustain its program.

Warning labels: Many nations, including Canada and Australia, have adopted and evaluated much more aggressive health warnings that have been proven more effective in discouraging use and encouraging cessation among users than the decades-old approach that the United States still uses.

FTC testing and the "Light" cigarette scam: The FTC never discovered, on its own, that its testing method was seriously flawed. FDA quickly determined that it was flawed in the course of its regulation development. Furthermore it was not until the 2001 publication of National Cancer Institute Monograph 13 (Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine) that our Nation formally recognized that light cigarettes were a deadly scam today accounting for the majority of tobacco-caused deaths. Yet nothing has been done to resolve this issue. FDA could act as other nations are to ban descriptors such as "lights" and provide strong and effective warnings.

Question 2. Why does the FDA need to be the agency to regulate tobacco?

Answer 2. If you review my answer to your first question, and my answers to all of Senator Kennedy's and Senator Enzi's questions, you will see why I believe that the Food and Drug Administration is the only agency with the technical, scientific, regulatory, and legal experience for regulating products that deliver biological active substances to the body and which has the improvement of health as its primary mission. Of course it would need to coordinate various parts of the effort with other agencies, including the Federal Trade Commission, Centers for Disease Control, Department of Agriculture, Environmental Protection Agency, and the National Institutes of Health. But this type of interagency collaboration has existed for decades when it comes to FDA's regulation of foods and drugs.

Question 3. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes for a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. That is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 3. I have addressed why I do not believe banning cigarettes is right or feasible in my response to Senator Burr's first question. As to issues concerning budgetary shortfall and revenues, I simply am not qualified to answer whether the bill is passed or not and whether Congress attempts to ban cigarettes or not.

Question 4. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 4. I will address the elements of this question where I feel my expertise is relevant and defer to others on law enforcement and trade monitoring where I feel I have little to offer. As I mentioned in my explanation of why I do not support banning cigarettes and other forms of tobacco, I am concerned that this would foster contraband or "black market" sales (we also discussed this in the American Medical Association report cited above). Factors that fuel such markets are reduced access and substantially increased cost in the open market, while demand remains high. FDA regulation is expected to contribute to reduced demand and reduced consumption of tobacco products because its efforts should support prevention of initiation of use and encourage more users to quit. This should reduce pressures that foster contraband markets.

QUESTIONS OF SENATOR COBURN

Question 1. What constituents would you recommend that the FDA require to be eliminated or reduced in cigarettes, and by how much would that reduction or elimination reduce the relative risk of tobacco-related diseases?

Answer 1. I believe that it would be premature to make specific recommendations for ingredient elimination, although I believe that many toxicants should be reduced if not eliminated. In fact, today's marketed products deliver highly toxic substances in quantities that vary widely across cigarettes, and includes carbon monoxide gas, tobacco specific nitrosamines, heavy metals, nitrosamines, agricultural residues (e.g., from pesticides and fertilizers). I believe that standards could be developed based on what the market place has already shown to be feasible. Under FDA's direction advisory committees could supplement internal evaluations to examine a wide range of substances. For example, added ingredients (e.g., ammonia, menthol, chocolate), materials in composition (e.g., glass fibers), and design features (e.g., hidden ventilation systems) which may increase toxicity and/or addiction should be considered. Standards may be set for ingredients in the product as well as its emissions such as constituents of "tar," and toxic gases such as carbon monoxide. Standards that lead to decreased smoke exposure and or toxicity have the potential to reduce secondhand smoke exposure and/or the toxic consequences of secondhand smoke exposure. For example, if FDA determines that chocolate is not necessary for cigarette manufacture and consumption but may contribute to carcinogenicity and or risk of becoming addicted it could limit or ban chocolate.

In the first few years, I would not expect to see disease risk fall substantially, if at all, due simply to performance standards on ingredients, and that is why this aspect of regulation should be seen as simply one of my elements of comprehensive tobacco control that are needed short run and long run to reduce tobacco use and associated disease.

Question 2. How will smokers alter their behavior in response to the introduction of cigarettes with new tobacco product standards? That is, what will be the effect on cigarette consumption of smokers now knowing that the FDA is tightly regulating all the constituents and ingredients in cigarettes?

Answer 2. The effects will depend at least in part on how radically and how quickly products are changed and the nature and effectiveness of accompanying communications. The mid-century wholesale adoption of the niche market for cigarettes with filters is a powerful lesson in how quickly and massively tobacco users can adjust their behavior when there appears to be a health benefit. Unfortunately, in that case, lack of oversight of the health consequences (as FDA would have) meant that the filters provided reassurance to smokers but not necessarily actual health benefit. Fortunately the FDA has considerable experience in health communications and marketing regulation. However, many aspects of consumer behavior will be affected by the behavior of the tobacco industry itself as well as other factors such as increasing adoption of clean air laws by communities, cities and States.

Question 3. In what way will reducing the nicotine levels in cigarettes improve the public's health, since we know that when nicotine levels are reduced, smokers compensate by smoking more? Won't this approach in fact hurt the public's health?

Answer 3. As discussed in the American Medical Association commissioned paper cited above, and my testimony, I concur with the WHO and the FDA's own conclusion, in its 1990s Tobacco Rule which does not support near-term reduction of nicotine in cigarettes. We do not yet have the science base, the treatment infrastructure, the education or other elements in place to enable such action. Furthermore, with FDA regulation AND increased commitment to comprehensive tobacco control as outlined in reports by the Centers for Disease Control and Prevention and the WHO, it may not be necessary to eliminate nicotine from tobacco products. However, I believe it is vital that FDA have the power to reduce nicotine levels to below a threshold level of addiction as one of its regulatory approaches. But the agency will need to be in a position to help drive the science and to monitor progress and effect of regulation—intended and unintended—and to thereby determine if such an approach would be warranted.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY, SENATOR ENZI, SENATOR BURR, SENATOR HATCH, AND SENATOR COBURN BY GREGORY CONNOLLY, D.M.D., M.P.H.

QUESTION OF SENATOR KENNEDY

Question. You conducted a study into how consumers perceived the implied claims tobacco companies are making about the reduced health risks of their products. Can

you elaborate on what the public understanding is when they see these claims, and would you give use a few examples of the types of claims currently being made.

Answer. We examined smokers' responses to advertisements for potentially reduced exposure tobacco products (PREP), light cigarettes, and regular cigarettes. A convenience sample of 600 adult smokers reviewed one actual advertisement for each type of product. Smokers ranked the products on health risk, amount of tar, and carcinogenicity, and identified the messages they perceived the advertisements to convey. Smokers perceived PREP products as having lower health risks and carcinogens than Light or regular cigarettes.

Although no advertisements explicitly said that the products were healthy or safe, advertisements for PREP products and light cigarettes were interpreted as conveying positive messages about health and safety. Most smokers believed that claims made in cigarette advertisements must be approved by a government agency. The results indicate that advertisements can and do leave consumers with perceptions of the health and safety of tobacco products that are contrary to the scientific evidence. Explicit and implicit advertising messages may be strengthened by the perceived government endorsement. This supports the Institute of Medicine's recommendation to regulate the promotion, advertising, and labeling of PREP tobacco products and light cigarettes. Effective regulation should focus on consumer perceptions resulting from advertisements rather than the explicit content of advertising text.

Example of PREP advertising we studied include Eclipse. It used the slogan "The best choice for smokers who worry about their health is to quit. Here's the next best choice." Although this was not an explicit claim smokers perceived it to equate with a claim for reducing their risk of disease.

A second ad was for Omni. The slogan for this brand was "There's only one brand that significantly reduces carcinogens. Made you look!" Although this ad only referenced a reduction in cancer causing agents and not a reduction in actual cancer risk it still was perceived by smokers as a claim of reduced cancer risk.

QUESTIONS OF SENATOR ENZI

Question 1. The bill assumes tobacco industry user fees will pay for the regulation of the tobacco industry. The prescription drug user fee program also housed at FDA levies over $300 million per year in user fees to support over 1,500 employees. This is on top of hundreds of millions in appropriations and appropriations-funded employees for the drug center. A standard drug review takes 10 months. In contrast,, this bill would require the review of a reduced risk product, with an entirely different standard for approval, in 6 months. In addition, there are over 5,000 brand styles on the market today. The "health information" required for each brand or sub-brand under section 904 is extensive. I think it would take a lot of FDA employees to go through that data, never mind to do reviews of new products, otherwise it would just get warehoused and not be of much use to anyone. What is the basis for the user fee levels set in the bill, and how do we know if that is enough to support what the bill requires?

Answer 1. The user fees in the bill would be used among other things to conduct needed independent research on conventional tobacco products and potentially reduced (tobacco) exposure products (PREPS). The bill would ramp up user fees from the initial amount to $300 million per year, equal to the drug user fee program housed at the FDA. This level of funding appears adequate to carry out the provisions of the bill. This level of funding is not far different from what tobacco manufacturers are expending for research they conduct on PREPS. If FDA did regulate PREPs, the industry research would most likely be made available to the FDA and complement FDA funded research. The bill would also require the industry to conduct the bulk of testing on the design and emissions of conventional brand styles that are in the marketplace. There may be 5,000 brand styles in the market but realistically only 1,000 are actually sold based on certifications by the New York Fire Prevention Office of Reduced Ignition Propensity Cigarettes in New York.

Also, Canada requires extensive testing of toxic constituents in the tobacco and in smoke and CDC already receives ingredient lists for the companies as does Texas by brand. If these jurisdictions already receive this information, it should not be burdensome for FDA.

Question 2. The data in your testimony regarding the targeting and uptake of menthol cigarettes to African-Americans, particularly young people, is amazing. This practice is abhorrent. However, section 909 of the bill that you support permits menthol to remain on the market. Why shouldn't menthol also be banned along with the rest of the flavored additives? Would you support changing the legislation to disallow menthol along with other flavorings? If not, why not?

Answer 2. The bill will not include menthol in the list of banned "candy" flavors given the long history of menthol use in tobacco products. However, the FDA could reduce or ban menthol through a performance standard. Menthol is in all cigarettes at some level but only at high levels in brands that are advertised as mentholated. If FDA found menthol alone or high levels had an adverse effect on the public health, the Agency could reduce or ban it.

Question 3. FDA's role is to assure the safety and effectiveness of medical products, not to tinker at the margins of regulating a product known to be harmful. What kind of public health message would we send if we directed FDA to regulate the tobacco industry and approve tobacco products?

Answer 3. In our research we conducted among a panel of 600 smokers, the vast majority believed a governmental agency approved the content of advertisements, including data on levels of toxins on PREPs. The FDA bill would protect consumers from current applied claims for reduced harm which they believe are explicit claims and approved by a governmental agency. FDA regulation will be an end to such claims.

Question 4. In your testimony, you suggest that States lack the resources to aggressively counter tobacco use. How can that be possible given the levels of funding provided by the MSA?

Answer 4. In my testimony, I stated that States lacked the resources and legal reach to regulate tobacco products. The resources would be both the scientific expertise as well as financial resources. If other States as Massachusetts did, assert FDA-like jurisdiction on tobacco products, the industry would likely litigate. Also, it may not be in the national interest to have 50 different approaches to tobacco product regulation.

QUESTION OF SENATOR BURR

Question. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer. The United States banned the sale of alcohol in the early part of the last century. The action did have a positive public health impact but also created unintended consequences of increased crime and other social problems. Given the fact that 45 million Americans smoke, this history would argue against an immediate, total ban of cigarettes. The legislation would allow FDA to gradually "wean" smokers off conventional tobacco products while providing alternate nicotine delivery devices that do not cause significant harm. This would be considered as a possible approach for the FDA.

QUESTIONS OF SENATOR HATCH

Question 1. You have been repeatedly quoted as saying that the legislation would initially give "Philip Morris a market advantage over its business rivals" but eventually the bill "could turn Marlboro into lard: legal but no one uses it." (Quotes are from a story in the Richmond-Times Dispatch, February 26, 2006.) Would you explain what this initial, if temporary, market advantage would be?

Answer 1. The legislation empowers the FDA to curtail aggressive marketing of tobacco products to youth. After the Master Settlement Agreement, R.J. Reynolds Tobacco continued to advertise in magazines popular with youth, introduced candy flavored brands popular with young people, targeted black youth with new menthol brands and most recently young females with brands like Camel No. 9. To the extent the FDA bill restricts such reckless marketing, RJRT would lose market "advantage" to Philip Morris. However, in the long term, the FDA bill should result in reduced sales of all brands regardless of the company and improve the public health.

Question 2. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes from a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 2. First, no one is advocating a ban on cigarettes tomorrow and passage of such a law is extremely unlikely if not totally unrealistic. Making a projection on the State budgetary impact of a ban is equally unrealistic. If the current bill is enacted, the bill will result in a reduction of cigarettes sales and there is no doubt that the economic benefit in health or savings far out weight tax losses. We do not know what the reduction would be until the final bill is enacted and implemented. Cigarette consumption fell 50 percent between 1993–2004 in Massachusetts. The decline in Massachusetts taxes was offset with increases in the State tax rate and a redirection of consumer resources from cigarettes to healthy goods and services.

Combined current Federal and State taxes are small in comparison to the economic burden that smoking has on the U.S. economy.

Question 3. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 3. There is a general provision in the bill for the FDA to seize mis-branded cigarettes which one would assume to be smuggled cigarettes not in compliance with standards established by the FDA. The provision of this law could be used to address contraband cigarette sales if the FDA law resulted in an increase in contraband sales. In 1978, Congress passed the Contraband Cigarette Act which has been effective in reducing contraband cigarette sales. This law could be used to address any smuggling possibly created by the bill.

QUESTIONS OF SENATOR COBURN

Question 1. What constituents would you recommend that the FDA require to be eliminated or reduced in cigarettes, and by how much would that reduction or elimination reduce the relative risk of tobacco-related diseases?

Answer 1. According to the Surgeon General's 2000 Report, tobacco manufacturers should eliminate or reduce a toxic constituent to the lowest level technically feasible but not make a claim that such reductions reduce health risks unless scientific study shows this. One example is the removal of tobacco specific nitrosamines (TSNAs) which cause cancer. Currently, smokeless tobacco manufacturers have reduced TSNA levels in smokeless tobacco that they promote as PREPs but don't do so for conventional brands which have up to 20 times the level of TSNAs than PREPs. The FDA could require them to do so for all products. Removing or reduction in toxins could take into account a fixed timetable for smokers to adapt to the changes.

Question 2. How will smokers alter their behavior in response to the introduction of cigarettes with new tobacco product standards? That is, what will be the effect on cigarette consumption of smokers now knowing that the FDA is tightly regulating all the constituents and ingredients in cigarettes?

Answer 2. Based on the New York experience with reduced ignition propensity Cigarettes (fire safer cigarettes) which were the only cigarette allowed for sale in the State as of July 2004, there will likely be little or no effect on smoker behavior if product design is changed. We examined cigarette consumption before and after the RIP requirement in New York and found no difference in consumption indicating product acceptance. FDA could take the same approach with requirements on other design features and allow time to phase in such changes so that consumers could adapt to the products.

Question 3. In what way will reducing the nicotine levels in cigarettes improve the public's health, since we know that when nicotine levels are reduced, smokers compensate by smoking more? Won't this approach in fact hurt the public's health?

Answer 3. We do not know how increasing or decreasing nicotine will affect the public health. As part of FDA regulation, research will be conducted to find this answer before nicotine levels are changed. Increasing nicotine and decreasing toxins in smoke or in the body doesn't necessarily correlate with a reduction in disease outcomes. For example, cardiovascular disease may be induced at very low doses of toxins.

On the other hand, nicotine could be reduced to a level that is non-addictive (.3mg/g of tobacco), a level found in tomatoes. This could result in complete cessation of conventional cigarettes and a switch to nicotine products that have been shown not to cause harm.

RESPONSE TO QUESTIONS OF SENATOR ENZI AND SENATOR HATCH BY LISA SHAMES

U.S. GOVERNMENT ACCOUNTABILITY OFFICE,
WASHINGTON, DC. 20548,
March 15, 2007.

Hon. EDWARD M. KENNEDY,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC. 20510.

Hon. MICHAEL B. ENZI,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC. 20510.

Re: Posthearing Questions Related to the Regulation of Tobacco Products

DEAR SENATORS: On February 27, I testified before this committee at a hearing addressing the regulation of tobacco products. This letter responds to your request that I provide answers to followup questions asked after the hearing. Senator Enzi's and Senator Hatch's questions, along with my responses, follow.

QUESTIONS OF SENATOR ENZI

Question 1. In 1998, as the Senate debated a major tobacco bill, I offered an amendment that would have directed the money paid into the National Tobacco Trust Fund by manufacturers and importers to Medicare, Medicaid and tobacco control and prevention. Half the money would have gone to Medicare, 25 percent to Medicaid, and 25 percent to tobacco control and prevention activities. Although the legislation eventually failed, I wonder what would have happened if we had applied that breakdown to the Master Settlement Agreement (MSA) funds. Are any States spending 25 percent of their MSA money on tobacco control and prevention activities?

Answer 1. For fiscal year 2006, five States—Wyoming, Maine, Arkansas, Oklahoma, and Montana—reported that they planned to allocate over 25 percent of their MSA funds on tobacco control and prevention, with Wyoming reporting 35.9 percent of their funds, Montana reporting 26.1 percent, and the others falling in between.

Question 2. I'm interested in determining what portion of "health" spending by the States under the MSA is going toward the care of smokers and former smokers, and what portion is going to other health priorities. Can you discuss the breakdown of the "health" category of State spending?

Answer 2. While States provided examples of health programs, they generally did not provide a further breakdown of the percentages allocated to each specific example. However, Medicaid and insurance-related programs were two commonly-cited examples.

Question 3. I learned a lot about the MSA and how States are spending the funds from your testimony, and much of what I learned worries me. Can it really be true that States would actually receive a decrease in MSA money if smoking goes down? It seems to me that is a perverse disincentive for States to do right with this money.

Answer 3. The tobacco companies' annual payments are adjusted based on several factors contained in the MSA, including fluctuations in the volume of cigarette sales, inflation, and other variables, such as the participating companies' share of the tobacco market. Declining tobacco consumption alone would result in lower MSA payments than originally expected. Tobacco consumption has declined since the MSA was signed in 1998—by about 6.5 percent in 1999 alone—mostly attributed to one-time increases in cigarette prices by the tobacco companies after the agreement took effect. Analysts project that, in the future, tobacco consumption will decline by an average of nearly 2 percent per year.[53] As a result, tobacco consumption is estimated to decline by 33 percent between 1999 and 2020.

However, the MSA also includes an inflation adjustment factor that some analysts have estimated increases payments more than any decreases caused by reduced consumption. The inflation adjustment equals the actual percentage increase in the Consumer Price Index for the preceding year or 3 percent, whichever is greater. The effect of these compounding increases is potentially significant, especially given that

[53] Cigarette consumption peaked in 1981 and has been declining since.

the payments are made in perpetuity. Assuming a 3-percent inflation adjustment and no decline in base payments, settlement amounts States receive would double every 24 years.

Also, several tobacco companies' interpretation of the provision that addresses participants' market share led them to lower their payments in 2006. Under this provision, an independent auditor determined that participating tobacco companies lost a portion of their market share to non-participating companies. An economic research firm determined that the MSA was a significant factor in these market share losses. Based on these findings, several participating companies reduced their fiscal year 2006 payments by a total of about $800 million. Many States have filed suit to recover these funds.

In addition to the annual payments States receive, the MSA requires that a Strategic Contribution Fund payment begin in 2008 and continue through 2017. The base amount of each year's Strategic Contribution Fund payment is $861 million, which will be adjusted for volume and inflation and shared among the States. Strategic Contribution Fund payments are intended to reflect the level of the contribution each State made toward final resolution of their lawsuit against the tobacco companies. They will be allocated to the States based on a separate formula developed by a panel of former State Attorneys General.

QUESTIONS OF SENATOR HATCH

Question 1. There has been a growing tendency both at the Federal and at the State level to use monies generated from tobacco taxes for a variety of legislative purposes that are not directly connected to anti-smoking campaigns, some of which are very legitimate initiatives. Let's assume two scenarios. First, Congress bans cigarettes tomorrow and the ban works. We are no longer able to rely upon any revenues, either at the Federal or the State level, from the sale of tobacco. If such a ban took place, what would be the budgetary shortfall that we would have to make up? Second, let's assume the legislation before the committee is enacted, which is intended, among other things, to result in a reduction of the sale of cigarettes. What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 1. While we have not conducted an analysis of the economic effects of a cigarette ban or of the current bill on tax revenues and MSA payments, the revenue stream from the MSA, excluding securitized proceeds, has been over $5 billion annually for several years.

Question 2. Unfortunately, one of the consequences of the increased regulation of cigarettes, as well as an increase in the cost, has been a burgeoning black market in cigarettes. Again, the legislation is intended, among other things, to discourage smoking, as well as the smoking of cigarettes at current levels of nicotine. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 2. We have not studied the provisions in this bill. However, we reported in 2004 that cigarette smuggling, particularly of counterfeit cigarettes, is a significant problem. However, because of the clandestine nature, the extent of cigarette smuggling into the United States is impossible to measure with any certainty.[54]

We appreciate the opportunity to comment and hope that these responses are of assistance. If you have any additional questions, please do not hesitate to call me at (202) 512–3841.

LISA SHAMES,
Acting Director,
Natural Resources and Environment.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR BURR, AND SENATOR HATCH BY ALAN BLUM, M.D.

QUESTIONS OF SENATOR ENZI

Question 1. Do you think FDA regulation of tobacco lends legitimacy to the [tobacco] industry?

[54] GAO, Cigarette Smuggling: Federal Law Enforcement Efforts and Seizures Increasing GAO–04–641, (Washington, DC.: May 28, 2004). Counterfeit cigarettes are those produced without the authorization of the trademark holder.

Answer 1. The tobacco industry should be fully expected to take advantage of this bill to remind all Americans through television, radio, the print media, package inserts, the U.S. Mail, and the internet that cigarettes are now regulated by the same agency that ensures that food and medicines are safe.

Philip Morris is already testing the waters, and setting a new standard for chutzpah, by attempting to enlist physicians in the distribution of the company's propaganda to their patients. For the first time in more than half a century, Philip Morris is communicating directly to doctors by means of personal letters (example attached) offering to supply unlimited copies of a booklet on stopping smoking. *If you decide to quit smoking* . . . (cover attached) does not mention the word "addiction," contains a total of three sentences in its 52 pages that mention diseases caused by smoking, and is illustrated with 17 color photographs, all of healthy, smiling people and none of persons made ill from smoking or of tobaccogenic diseases.

Philip Morris' Youth Smoking Prevention advertisements on television and in booklets directed to parents (*Raising Kids Who Don't Smoke*, cover attached) have been reviled by health organizations such as the Campaign for Tobacco Free Kids as both ineffective and inappropriate. The company touts this program to college students at job fairs on university campuses across the country (as well as on its Web site (*www.cantbeattheexperience.com*), even though there are no entry-level Youth Smoking Prevention positions. To the contrary, the jobs offered to college students are exclusively summer internships and territory sales managerships that involve the distribution of cigarettes to upwards of 150 convenience stores, supermarkets, pharmacies, bars, and other retail outlets.

In half-page color advertisements in college newspapers urging students to meet with company recruiters at career fairs, Philip Morris boasts that it is "unique in how we face our particular challenges and responsibilities" (copy of advertisement attached, from *The Crimson White*, University of Alabama, February 9, 2007, page 5: "'I want a MARKET LEADER. An INNOVATOR. Someone who'll stretch my limits. And you're telling me TOBACCO?' YES. And we're telling you United States. We not only lead a major consumer products category in this country—we do it with a brand that's recognized as one of the 10 most valuable in the world. We're also unique in how we face our particular challenges and responsibilities. That's why we've helped redefine how products are marketed . . . with innovative, experiential and one-to-one programs for our adult consumers. So now—how about telling us more about you? See us on campus at the Career Fair Wednesday, February 14th, 9am–3pm Bryant Conference Center." CANTBEATTHEEXPERIENCE.COM. PHILIP MORRIS USA)

Such practices aimed at burnishing the company's nicotine-stained image among physicians and parents and increasing the size of its youthful sales force—direct mail to the medical profession, propaganda campaigns aimed at parents, and recruitment advertisements in college newspapers—would remain unregulated by this bill and protected by the first amendment.

FDA regulation of tobacco products would provide an unprecedented, unmerited, health-related legitimacy to manufacturers of cigarettes and would send a misleading message to consumers, namely that cigarettes, however unsafe, are government-sanctioned.

By promulgating health standards, FDA will be fostering the perception that cigarettes are now safer to smoke. The public is not generally aware that there are more than 4,000 solid and gaseous poisons in tobacco smoke, including more than 40 cancer-causers. Nor are most consumers of cigarettes likely to understand epidemiology. If consumers are informed that nitrosamines (powerful carcinogens) have been reduced or removed from cigarettes, then they are going to infer that the problem is being taken care of or even solved. This ignores the dozens of other cancer-causers. Neither the technology to remove carcinogens from cigarette smoke nor the science to prove that the removal of any toxin from cigarette smoke reduces mortality yet exists. Such studies would take decades to detect any reduction of harm from tobacco use, and the ethics of conducting such ongoing research on persons who smoke without providing frequent cessation interventions would be called into question. Having served as a member of the Institutional Review Board (IRB) of the University of Alabama (overseeing research protocols to ensure the protection of human subjects), I cannot imagine that prospective comparison studies of different tobacco products would be permitted by any scientific body.

Since smoking prevalence is directly proportional to the degree of perceived harm from smoking, FDA sanction of cigarettes will lead to an increase in smoking prevalence, compared to what would have occurred in the absence of this legislation.

Question 2. Do you believe that getting FDA regulation of tobacco up and running will take substantial time and commitment from HHS and FDA leadership? What

is FDA's track record when they are asked to produce many new complex regulations simultaneously?

Answer 2. I agree with Senator Kennedy that the Food and Drug Administration has been a model for the world to follow in ensuring the safety and efficacy of medications. I greatly admire his longstanding efforts, as well as those of Representative Waxman, the late Senator Kefauver, and other legislators, to strengthen the watchdog powers of the FDA over the pharmaceutical industry.

By all accounts, however, the FDA is in a state of turmoil. Unprecedented bipartisan criticism has rained down on the agency for several years, as its failings and foul-ups have mounted. These troubles culminated in the sentencing of the most recent former FDA Commissioner for his conviction on ethical conflict-of-interest violations on the very day of the HELP Committee's hearing on this bill.

The current FDA Commissioner, Dr. Andrew von Eschenbach, has publicly questioned the wisdom of giving the FDA the power to regulate tobacco. "When a product, when used as intended, results in death, it's hard for me to say how to regulate that as being safe and effective," he told Bloomberg News on March 6, 2007. In an interview on the same day with the Associated Press, Dr. von Eschenbach warned that if the FDA were to accept the mandate of the bill to reduce nicotine levels in cigarettes, consumers would tailor their smoking habits to maintain current levels of the addictive drug:

> "We could find ourselves in the conundrum of having made a decision about nicotine only to have made the public health radically worse. And that is not the position the FDA is in; we approve products that enhance health, not destroy it," said Dr. von Eschenbach, a cancer surgeon . . . "What I don't want to see happen is that we are in a position where we are determining that a cigarette is safe."

For his candor, Dr. von Eschenbach has been criticized as "misinformed" by the chairman/ceo of the Campaign for Tobacco-Free Kids in a March 6, 2007 press release.

Senator Kennedy's earlier bill, The Tobacco Product Education and Health Protection Act of 1990 (S. 2795), which I was privileged to testify in favor of, was closer to the mark in establishing a separate Center for Tobacco Products.

The FDA has a disappointing and alarming recent history of compromised consumer safety. For instance, considerable shortcomings have been exposed in the FDA's regulation of medical devices, including artificial heart valves, coronary artery stents, heart defibrillators, and artificial joints. FDA policy is to permit brands to be marketed that are "substantially equivalent" to other models that have been approved. As a result, failures of these less-tested brands—and resultant fatalities—are more likely to occur. This has been the case with defibrillators, and since only health facilities (among all sorts of public places in which a host of cheap, shoddy models are installed) must regularly test devices and report failures, the FDA does not even know the magnitude of the problem.

In contrast to the time when the FDA prevented drugs like thalidomide from reaching the market for the treatment of nausea of pregnancy, today the pharmaceutical industry has regained the upper hand through aggressive marketing and ineffective regulation. For example, in 2006 two separate congressional committees examined the FDA's handling of antidepressant medications in pediatric patients because of an increased association between these drugs and suicide attempts. The FDA had failed to make public the recommendation of its own scientific reviewer that there be an intensive risk management strategy if these drugs were to continue to be prescribed to adolescents and children. Similarly, although some medications used for hyperactivity in children have been removed from the market in Canada, the FDA has been slow to restrict the use of these drugs.

In several recent instances, the failure of the FDA to obtain complete and accurate data from companies on the incidence of adverse effects of top-selling medications has undermined public confidence in the impartiality of the agency. After one manufacturer, AstraZeneca, was found to have withheld information that its cholesterol-lowering medication Crestor may have caused a higher incidence of muscle damage, liver damage, and kidney failure than similar drugs, the company purchased full-page ads in major newspapers that claimed, "The FDA has confidence in the safety and efficacy of Crestor," In response, Representative Henry Waxman wrote in a letter to the FDA, "Either AstraZeneca is misleading the public about Crestor's safety, or the FDA is giving the company private assessments that conflict with the agency's public position" ("Crestor Ads Draw Fire; FDA Could Act." *USA Today*, December 8, 2004).

Such failures by the FDA to obtain and act on reports of adverse drug effects may be the tip of the iceberg. The FDA's latest annual report on mandatory monitoring

of drugs approved for the market found that 899 of 1,259 post-approval studies had not even been started. ("Many Drug Studies Not Begun, FDA says." *Los Angeles Times*, February 2, 2007, page A20).

Similar serious post-marketing safety concerns have been raised about medications for weight-loss (Meridia), acne (Accutane), and asthma (Serevent).

Perhaps the most thorough failure of the FDA occurred with the COX-2 inhibitor drugs for arthritis (Vioxx, Celebrex, Bextra), which became the most promoted, prescribed, and consumed class of medications in spite of the fact that they were no more effective and were far less expensive than older, over-the-counter drugs, and in spite of the manufacturers' knowledge of an increased incidence of cardiovascular problems attributed to these new drugs. In this instance, in 2004 a glaring conflict-of-interest was revealed to have occurred in the agency, wherein an FDA scientist who worked with pharmaceutical companies on drug approvals also had authority over FDA's drug safety office.

Other allegations of problems at the FDA in recent years have included rampant conflict-of-interest and pro-pharmaceutical industry bias among scientific advisory panel members; the lack of checks on bovine hormone and antibiotic use in cattle that has led to bacterial contamination of meat; the failure to prevent contamination of animal feed and the resultant increased risk of mad cow disease and Jacob-Creutzfeld disease in humans; inadequate inspections of produce and other food; the failure to end the practice of gifts to prescribing physicians by pharmaceutical companies; insufficient attention to questions about the safety of dietary supplements, sleep medications, and hormone replacement therapy in women, among other classes of drugs; influenza vaccine shortages due to the failure to plan for the replacement of a contaminated facility in the United Kingdom; mixed messages on the safety of breast implants; the relative ease with which certain prescription drugs with potentially harmful consequences have been able to receive over-the-counter status; and the failure to limit off-label uses of drugs or to enforce its own rules on prescription drug advertising.

To its credit, during the brouhaha over the COX-2 drugs, the FDA commissioned the Institute of Medicine (IOM) to assess the drug safety system. On the basis of its investigation, in September 2006 an IOM committee reported on numerous serious problems at the FDA, including the scarcity of post-approval data. Earlier in 2006, the Government Accountability Office also found that the FDA lacks a clear and effective process for oversight of post-market safety issues. The IOM proposed 25 recommendations for overhauling the agency. Although the FDA pledged to adopt the necessary reforms, the *Wall Street Journal* reported on March 3, 2007 that a study commissioned by the agency itself found that its new system for detecting adverse effects of medications has failed. ("Report Blasts FDA's System to Track Drugs. *Wall Street Journal*, March 3–4, 2007, page A1–A2).

Senator Enzi's observation that the FDA is struggling with the challenges of regulating an expanded universe of products and threats is accurate. The FDA is already tasked with duties related to public health, drug importation, food safety, and bioterrorism, any of which could ramp up demands for FDA resources. It makes no sense to give this overextended agency yet another huge mission. I also agree that getting FDA regulation of tobacco up and running will take substantial time. Given its present inability to solve its own myriad problems, the FDA would be the wrong agency at the wrong time to undertake oversight of tobacco products.

William Godshall, a public health professional and founder of Smokefree Pennsylvania, is a leading advocate of the harm reduction approach to tobacco control, whereby consumers of cigarettes are encouraged to switch to noncombustible tobacco products if they cannot otherwise stop smoking. He sees a parallel between the hundreds of medications overseen by the FDA and the more than 400 different brand variations of cigarettes on the U.S. market, each containing differing amounts of scores of chemical additives and thousands of smoke constituents; and he therefore questions the feasibility of correlating tobacco-related deaths and diseases with the brands of cigarettes consumed, which the FDA would have to do if it is to make any valid assessments and recommendations about individual tobacco products.

FDA's track record in dealing with complex and controversial regulations is problematic at best. But this reason should not, per se, rule out FDA regulation of tobacco if such regulation would likely result in major reductions of tobacco-related illness and death. Regrettably, S. 625, if enacted, would not provide this public health benefit.

Addendum: As a former member of an FDA advisory panel (on immunologic devices), I support the mission of this agency and appreciate the dedication of its staff. However, a personal experience may help to illustrate the disappointment and frustration I anticipate would result were the FDA to undertake the regulation of tobacco products.

In the April 3, 1981 edition of the *Journal of the American Medical Association*, I wrote an editorial that was the first to state the case for the removal from the market of phenylpropanolamine (PPA), a stimulant with actions similar to ephedrine and the amphetamines that was an ingredient in heavily advertised over-the-counter weight loss remedies and cold pills (Phenylpropanolamine: An over-the-counter amphetamine? *JAMA* 1981;246:1347–48). Several medical journal articles had reported individual cases of hypertension and hemorrhagic stroke attributed to PPA (even in small doses and even among young persons) in Australia and the United Kingdom.

In October 1981 the Center for Science in the Public Interest, a Washington-based nutrition education group, petitioned the FDA to ban dietary aids containing PPA. In the mid-1980s, *The Medical Letter*, an independent review of medications, joined in the call for a ban on PPA. Ubiquitous advertising for the diet pills (e.g., Dexatrim) and decongestants continued unabated. Not until 1991, by which time a total of 44 cases of stroke in PPA users had been reported to the FDA, did the agency convene a public hearing on the drug, but pressure from the manufacturers of PPA-containing OTC products prevented any action from being taken.

In October 2000 Public Citizen's Health Research Group, which estimated that as many as 510 to 1,020 cases of hemorrhagic strokes had occurred in persons using PPA-containing products, petitioned the FDA for an immediate ban on all uses of PPA in OTC products, including appetite suppressants and cough and cold preparations. Finally, on December 22, 2005 the FDA reclassified PPA as not safe or effective and ordered the removal of PPA from all drug products.

Cigarettes are already known to be responsible for an estimated 500,000 deaths each year in the United States. Yet, as Senator Coburn points out, with enactment of this bill Congress would be sidestepping its responsibility to take direct action against cigarettes by not granting the FDA the authority either to remove them from the market or otherwise seriously limit their sale. Cigarette manufacturers have far greater financial resources and influence than makers of PPA. If it took nearly 25 years for the FDA to heed calls for a ban on this dangerous drug, then can we truly expect the agency to take any immediate and decisive actions that will significantly inhibit cigarette sales?

Question 3. [C]ould this bill serve to create a significant legal defense by the industry to counter product liability and tort lawsuits by plaintiffs?

Answer 3. The bill would serve to create a significant legal defense by the tobacco industry to counter product liability and tort lawsuits by plaintiffs. In court, the industry would remind jurors and judges alike that tobacco products are now regulated by the same agency that ensures the safety of food and medicines.

The bill would end the prospect of meaningful punishment of the tobacco industry and the achievement of reform through litigation. Punitive damages for victims, or classes of victims, of tobacco-caused death, disease, and suffering would end due to the shield provided by the FDA.

In previous tobacco litigation, cigarette manufacturers have successfully argued that they are sufficiently regulated and thus there is no need for further steps to deter future misconduct. The industry gained considerable public relations value from the Master Settlement Agreement (MSA) and would gain additional mileage from FDA regulation. Analogous to its having cited the MSA numerous times in court over the past decade, including the Department of Justice case, the industry would claim that the Federal Government has assumed jurisdiction over all aspects of tobacco operations, including manufacture, new product introductions, health claims, health standards, ingredients, additives, constituents of smoke, nicotine, advertising, access, and marketing (which would be true) and that there is thus no need for any further injunctive relief or punitive damages to deter future bad behavior: it is now all under FDA's control. And from a public perception, cigarette manufacturers would be right.

The important point is not whether the bill actually gives the tobacco companies immunity or protection from litigation. Rather, it is whether or not the companies can use the fact of being regulated by FDA to achieve *de facto* immunity by exploiting the public perception that the problem is being solved.

Tobacco industry investment analyst Bonnie Herzog wrote in her March 5, 2007 report that the bill could "prevent future litigation." Tobacco industry investment analyst David Adelman wrote in his February 15, 2007 report that the bill gives the industry, "an additional and potentially effective legal defense." Analysis of internal Philip Morris documents (e.g., Bates numbers 207573345/3346 and 2081523647, accessible at University of California, San Francisco Legacy Tobacco Documents Library) suggests that this is a key goal the company hopes to achieve with FDA regulation.

Question 4. Does anything in the proposed legislation address anti-smoking programs? Does anything in the proposed legislation help smokers quit?

Answer 4. Nothing in this legislation addresses anti-smoking programs or encourages these programs to be offered to the public. In fact, the bill will likely have a chilling effect on State and local anti-smoking programs because it will shift the entire focus to the Federal regulatory level. It will create a perception that the problem is being handled by the Federal Government, which will deter many State and local legislatures from taking on this issue.

In addition, there is nothing in the proposed legislation that will help current smokers quit. In fact, the legislation will likely make it much more difficult for smokers to quit because it will create a false sense of security. Knowing that cigarettes are now stringently regulated by the FDA and that the products now have an FDA seal of approval, many smokers will be under the illusion that the product is now somehow safer. This will result in many consumers continuing to smoke, rather than quit. Tobacco companies have long been able to accomplish this by marketing filtered cigarettes, then "low-tar" cigarettes, then "light" and "ultralight" cigarettes. These much-touted innovations did not confer any reduction in the risk of disease. Yet they successfully addressed the health concerns of many if not most smokers, who would otherwise have attempted to stop smoking but who decided to continue because of the false inference that such products were safer.

Indeed, according to Professor Michael Siegel of Boston University School of Public Health (personal communication, March 3, 2007), this legislation is likely to result in increased, not decreased, deaths from tobacco products for the following reasons:

a. The bill will make it virtually impossible to research, develop, introduce, and market new potentially less hazardous tobacco products. It essentially freezes the market as it is and entrenches existing high-risk products into the market. It puts an end to any meaningful possibility of harm reduction as a tobacco control approach.

b. It will undermine current and future litigation: the companies will be able to argue successfully that they are already regulated to stave off injunctive relief and substantial punitive damages in litigation by appealing to jurors' perceptions that the problem is being solved. The grossly exaggerated claims by health organizations supporting this bill of the bill's positive impact on public health are only contributing to this perception.

c. It will reduce the public's perception of the inherent harmfulness of cigarettes. By promulgating health standards, FDA will be giving the public the perception that cigarettes are now safer to smoke.

d. Most importantly, there are no documented mechanisms by which the legislation will save lives. Health groups supporting this bill have not produced a single evidence-based argument of how it will save lives.

Dr. Siegel points out that there are only three ways that this could occur:

First, the bill could save lives if the performance standards reduced the relative risk of smoking-related diseases. There is no evidence whatsoever that this is the case.

Second, the bill could save lives if it encouraged the research, development, and marketing of actual reduced risk products. But the bill does the opposite by setting up an almost impossible barrier to the creation of such products.

Third, the bill could save lives if it reduced youth smoking. It has been well-documented that youth access restrictions, implemented in actual widespread practice, do not reduce youth smoking. The very access restrictions that could potentially reduce youth smoking have been precluded by the bill (namely, raising the legal age of purchase and restricting the types of establishments, such as pharmacies, that sell cigarettes).

[Research has also documented that the kinds of marketing restrictions imposed by the bill are not effective in reducing youth exposure to cigarette advertising. There are too many avenues for the tobacco companies to market their products, and anything short of a near-total ban on advertising and promotion of tobacco products (which would violate the first amendment) is unlikely to have a substantial effect on youth smoking. Even major changes in policy, such as removing advertisements completely from youth-oriented publications, would not reduce youth exposure to advertising to any meaningful extent.]

Fourth, the bill could save lives if it reduced adult smoking by reducing demand for cigarettes. The bill won't do that by increasing competition in the marketplace, and it won't do that by increasing the public's perception of the inherent risks of cigarettes.

Question 5. I believe that people shouldn't smoke. I also believe that the best way to achieve this is by reducing demand, not tinkering with the supply. We reduce demand by preventing people from smoking in the first place, and helping current smokers quit. Do you agree with this approach?

Answer 5. The best approach to address the smoking pandemic is to do all we can to reduce the demand for cigarettes. The supply-side approach makes little sense because cigarettes are an inherently dangerous product, and there is no evidence that tinkering with the levels of various constituents of tobacco smoke will result in a safer product. We simply do not know the specific constituents that are responsible for the diseases or the relative contribution of each constituent, alone and in combination. Nor do we have any evidence for a decreased relative risk associated with product changes that either eliminate or reduce one or several components of tobacco smoke.

QUESTION OF SENATOR BURR

Question. How is keeping tobacco products on the market in the best interest of the public's health? Please provide a direct answer to this question.

Answer. As former FDA Commissioner David Kessler has noted, as long as there are 50 million Americans addicted to nicotine, taking tobacco products off the market would not be prudent. Among other adverse effects, such a prohibition would dramatically exacerbate the black market.

Prevention is universally agreed upon as the answer to end the devastating health toll caused by smoking. Reducing demand through paid mass media education campaigns is the cornerstone of primary prevention. Regrettably, this bill is by no means likely to reduce consumption, since it will normalize cigarettes and create the illusion of safety.

QUESTIONS OF SENATOR HATCH

Question 1. What provisions are included in the bill that will enable the FDA to combat not only the illegal sale of cigarettes in general but the possibility of a rise in the illegal shipment of cigarettes into this country?

Answer 1. With regard to contraband, Professor David Sweanor of the Faculties of Law and Medicine of the University of Ottawa notes (personal communication, March 11, 2007) that section 921 of the bill institutes a form of "track and trace" for tobacco products. Had such a system been in place, the major tobacco companies would not have been able to develop the infamous "transit trade" that allowed cigarettes to get "lost" and show up untaxed in various jurisdictions. He commends this aspect of the bill but believes this is addressing the last war.

According to Professor Sweanor, the problem now is not cigarettes that originate from the major cigarette manufacturers but rather from counterfeiters and Native American reservations who can produce fake branded cigarettes for a few cents a pack. Although the legal authority exists to stop such practices, the bill does nothing to address these alternative sources of contraband. Thus the growing problem of fake Marlboros from Asia or Mexico, or anything else that enters the pipeline other than from the major manufacturers, is not addressed. The goal should be to anticipate where the contraband will originate and to take measures to stop it. This bill does not do that.

Question 2. If such a ban took place, what would be the budgetary shortfall we would have to make up? What is the budgetary shortfall we can expect if the current bill is enacted at both the Federal and State level?

Answer 2. Since the bill would have a negligible effect at most in reducing smoking, the budgetary shortfall would be little to none.

A *ban on cigarettes* would reduce annual Federal cigarette tax revenue by about $7.5 billion* (calculated at the Federal excise tax rate of 39 cents a pack for 19 billion packs sold), annual State and local cigarette tax revenue by about $13 billion, and annual tobacco settlement payments to States by about $8 billion. Thus cigarette prohibition could reduce Federal and State revenue by about $28.5 billion a year.

It is possible that reduced health costs for tobaccogenic diseases and fires might offset such lost revenue. However, since this *bill* is unlikely to reduce cigarette consumption, its enactment is certain to increase the already massive amounts of Fed-

*Since Federal cigarette tax revenue is a small fraction of 1 percent of total Federal Government taxes ($2.5 trillion a year), it does not have a meaningful impact on the Federal revenue situation.

eral and State Government expenditures spent on the treatment of cigarette-caused disease and disability.

[Whereupon, at 12:10 p.m., the hearing was adjourned.]

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