AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 1108

OCTOBER 3, 2007

Serial No. 110–69

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE
44–708 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON ENERGY AND COMMERCE

JOHN D. DINGELL, Michigan, *Chairman*

HENRY A. WAXMAN, California
EDWARD J. MARKEY, Massachusetts
RICK BOUCHER, Virginia
EDOLPHUS TOWNS, New York
FRANK PALLONE, JR., New Jersey
BART GORDON, Tennessee
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
BART STUPAK, Michigan
ELIOT L. ENGEL, New York
ALBERT R. WYNN, Maryland
GENE GREEN, Texas
DIANA DEGETTE, Colorado
Vice Chairman
LOIS CAPPS, California
MIKE DOYLE, Pennsylvania
JANE HARMAN, California
TOM ALLEN, Maine
JAN SCHAKOWSKY, Illinois
HILDA L. SOLIS, California
CHARLES A. GONZALEZ, Texas
JAY INSLEE, Washington
TAMMY BALDWIN, Wisconsin
MIKE ROSS, Arkansas
DARLENE HOOLEY, Oregon
ANTHONY D. WEINER, New York
JIM MATHESON, Utah
G.K. BUTTERFIELD, North Carolina
CHARLIE MELANCON, Louisiana
JOHN BARROW, Georgia
BARON P. HILL, Indiana

JOE BARTON, Texas
Ranking Member
RALPH M. HALL, Texas
J. DENNIS HASTERT, Illinois
FRED UPTON, Michigan
CLIFF STEARNS, Florida
NATHAN DEAL, Georgia
ED WHITFIELD, Kentucky
BARBARA CUBIN, Wyoming
JOHN SHIMKUS, Illinois
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING, Mississippi
VITO FOSSELLA, New York
STEVE BUYER, Indiana
GEORGE RADANOVICH, California
JOSEPH R. PITTS, Pennsylvania
MARY BONO, California
GREG WALDEN, Oregon
LEE TERRY, Nebraska
MIKE FERGUSON, New Jersey
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
JOHN SULLIVAN, Oklahoma
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee

PROFESSIONAL STAFF

DENNIS B. FITZGIBBONS, *Chief of Staff*
GREGG A. ROTHSCHILD, *Chief Counsel*
SHARON E. DAVIS, *Chief Clerk*
DAVID L. CAVICKE, *Minority Staff Director*

SUBCOMMITTEE ON HEALTH

FRANK PALLONE, JR., New Jersey, *Chairman*

HENRY A. WAXMAN, California
EDOLPHUS TOWNS, New York
BART GORDON, Tennessee
ANNA G. ESHOO, California
GENE GREEN, Texas
Vice Chairman
DIANA DEGETTE, Colorado
LOIS CAPPS, California
TOM ALLEN, Maine
TAMMY BALDWIN, Wisconsin
ELIOT L. ENGEL, New York
JAN SCHAKOWSKY, Illinois
HILDA L. SOLIS, California
MIKE ROSS, Arkansas
DARLENE HOOLEY, Oregon
ANTHONY D. WEINER, New York
JIM MATHESON, Utah
JOHN D. DINGELL, Michigan *(ex officio)*

NATHAN DEAL, Georgia,
Ranking Member
RALPH M. HALL, Texas
BARBARA CUBIN, Wyoming
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
STEVE BUYER, Indiana
JOSEPH R. PITTS, Pennsylvania
MIKE FERGUSON, New Jersey
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
JOHN SULLIVAN, Oklahoma
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
JOE BARTON, Texas *(ex officio)*

CONTENTS

	Page
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	1
Hon. Joe Barton, a Representative in Congress from the State of Texas, opening statement	3
Hon. Henry A. Waxman, a Representative in Congress from the State of California, opening statement	4
Hon. John B. Shadegg, a Representative in Congress from the State of Arizona, opening statement	6
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement	17
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement	19
Hon. Lois A. Capps, a Representative in Congress from the State of California, opening statement	20
Hon. Nathan Deal, a Representative in Congress from the State of Georgia, opening statement	21
Hon. Darlene Hooley, a Representative in Congress from the State of Oregon, opening statement	22
Hon. Heather Wilson, a Representative in Congress from the State of New Mexico, opening statement	23
Hon. Tammy Baldwin, a Representative in Congress from the State of Wisconsin, opening statement	23
Hon. Ralph M. Hall, a Representative in Congress from the State of Texas, opening statement	24
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement	25
Hon. Steve Buyer, a Representative in Congress from the State of Indiana, opening statement	26
Hon. Tom Allen, a Representative in Congress from the State of Maine, opening statement	27
Hon. Marsha Blackburn, a Representative in Congress from the State of Tennessee, opening statement	28
Hon. Hilda L. Solis, a Representative in Congress from the State of California, opening statement	29
Hon. John D. Dingell, a Representative in Congress from the State of Michigan, prepared statement	30
Hon. Jim Matheson, a Representative in Congress from the State of Utah, prepared statement	31
Hon. Edolphus Towns, a Representative in Congress from the State of New York, prepared statement	31

WITNESSES

Richard J. Bonnie, Harrison Foundation, professor of medicine and law; director, Institute of Law, Psychiatry, and Public Policy, University of Virginia	32
Prepared statement	35
Answers to submitted questions	172
Fred Jacobs, M.D., commissioner, New Jersey Department of Health and Senior Services	37
Prepared statement	39
Answers to submitted questions	201
Alan Blum, M.D., professor, Wallace Endowed Chair and director of the Center for Study of Tobacco and Society, College of Community Health Sciences, University of Alabama	62
Prepared statement	64

Page

Risa Lavizzo-Mourey, M.D., president and chief executive officer, Robert Wood Johnson Foundation, Princeton, NJ 66
Prepared statement 68
Answers to submitted questions 206
Scott Ballin, steering committee member, Alliance for Health, Economic, and Agriculture Development, Washington, DC 71
Prepared statement 74
James Winkler, general secretary, General Board of Church and Society, United Methodist Church 96
Prepared statement 97
Henry Armour, president and chief executive officer, National Association of Convenience Stores 99
Prepared statement 101
Jack E. Henningfeld, vice president, research and health policy, Piney Associates, Bethesda, MD 105
Prepared statement 107
Answers to submitted questions 196
William V. Corr, executive director, Campaign for Tobacco-Free Kids 113
Prepared statement 115
Answers to submitted questions 189

SUBMITTED MATERIAL

Andrew C. von Eschenbach, M.D., Commissioner, Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services, submitted statement 7
U.S. Smokeless Tobacco Company, submitted statement 138
Mike Szymanczyk, chairman and chief executive officer, Philip Morris USA, submitted statement 209

H.R. 1108, FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

WEDNESDAY, OCTOBER 3, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Pallone, Waxman, Gordon, Green, DeGette, Capps, Allen, Baldwin, Engel, Solis, Hooley, Deal, Hall, Wilson, Shadegg, Buyer, Burgess, Blackburn, and Barton.

Staff present: John Ford, Ryan Long, Robert Clark, Virgil Miller, Chad Grant, Melissa Sidman, Erin Bzymek, and Brin Frazier.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The hearing is called to order. Today we are having a hearing on H.R. 1108, the Family Smoking Prevention and Tobacco Control Act introduced by Mr. Waxman. And I will recognize myself initially for an opening statement and thank everyone for being here today. I am also a cosponsor of the legislation, which aims to strengthen our Nation's regulation of tobacco products and restrict tobacco product marketing.

Every day, approximately 4,000 children try a cigarette for the first time. According to the Center for Disease Control, every day 1,140 of our children become new daily smokers. And take a minute to just think about these statistics. According to my calculations, this means that since the beginning of this year, January 1, 2007, 313,400 children have become tobacco addicts, and one-third of those kids will end up dying prematurely because of tobacco-related illnesses.

In fact, tobacco use is the leading cause of preventable death in the United States, killing more than 400,000 Americans every year. That is more than AIDS, alcohol, car accidents, murder, suicides, illegal drugs and fires combined. And tobacco use costs our health care system, both public and private, over $96 billion annually. Fourteen percent of our total Medicaid expenditure is spent on treatments for smoking-related diseases.

With such implications, it is hard to believe that tobacco products are exempt from the basic health and safety regulations that apply to other consumer products. The FDA regulates toothpaste but not

cigarettes. They monitor cereal but not chewing tobacco. And ironically the FDA regulates both over-the-counter and prescription medications to help people quit smoking yet has no authority over the cause of the addiction.

In 1996, the FDA began to implement a comprehensive rule to prevent and reduce tobacco use by children. Only 4 years later, the U.S. Supreme Court ruled that under existing law, the FDA lacks the authority to regulate tobacco products or cigarette company marketing practices. It is therefore up to this Congress to grant the FDA the authority that they need.

The 1996 rule identified that the best way to reduce the harm caused by tobacco was to reduce the number of children who became addicted in the first place. And we must build on this concept and tackle the problem on a variety of points. We must ensure that tobacco products are not marketed or sold to children. We must identify harmful elements in tobacco products. We must require more detailed warnings on cigarettes packs, and we must demand scientific proof of claims made about lower risk products.

I happen to be a parent of three children who are nearing their teens. Actually, one just turned 14 a couple days ago. And the practice of targeting young people with tobacco advertising particularly concerns me. Since the multi-state tobacco settlement in 1998, tobacco companies have increased their advertising spending by 95 percent. And they are currently spending approximately $13 billion a year. They use imagery that appeals to youth on their billboards and in their print ads. They hand out free tobacco-themed merchandise and sponsor sports and entertainment events.

All of these practices aim to draw children into a lifetime of addiction. Studies have shown that teens are twice as likely to remember tobacco advertising than adults, and they remain loyal to their brand as their addiction takes hold and they move into adulthood.

Mr. Waxman has taken the initiative and proposed a bipartisan bill that seeks to address what has become a critical public health problem. I am proud to be a cosponsor, along with many of my colleagues on the subcommittee. The bill will provide the FDA with the authority to appropriately regulate tobacco products and restrict tobacco product marketing.

The Family Smoking Prevention and Tobacco Control Act would allow FDA to monitor false or misleading advertising, as well as marketing aimed at children. It will halt tobacco sales to minors and will require tobacco companies to provide the FDA with the list of ingredients and additives in their products. And finally, it forces companies to substantiate their claims that some tobacco products are lower risk. This summer, the Senate Committee on Health, Education, Labor, and Pensions passed their version of the bill. Both the Senate bill and the bill before us today are vital pieces of legislation to curb the consumption of tobacco products, to reduce the number of children using tobacco products, and to ultimately save millions of lives.

Encouraged by the progress of our colleagues in the Senate, I am convinced that in this Congress tobacco regulation legislation will see the light of day. We are determined that it will. And I want to commend Mr. Waxman again for not only this legislation but for

so many years of attention to this issue. And I want to thank the witnesses for appearing before us today to share their experience. We look forward to your testimony, and I would now recognize the ranking member of the full committee, Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman. This is a very important hearing, and I appreciate you organizing it. I wish all the subcommittee members were here. I think everyone in the room agrees that smoking is a bad habit, and for many people, it can lead to very serious health consequences. I don't smoke. I never have. I never will, and I am going to do everything I can possible to make sure that my 2-year-old son Jack never smokes either.

I do believe that some of the provisions in the bill before us have merit. I am not so sure, however, that the Food and Drug Administration is a proper place to regulate tobacco. Even if it is, this legislation seems to me to overreach in its enthusiasm to stop smoking by giving the agency virtually unlimited discretion.

The FDA is charged generally with ensuring the safety of products. It approves drugs and devices based on safety and efficacy. This legislation would require the FDA to take on something that is both enormous and completely outside of its regulatory experience. Under this legislation, the FDA is supposed to base its decision on the very vaguest of standards: "appropriate for the protection of public health." I am not sure what that means. There is no legal definition. There is, as far as I know, not even a history that you could go through as a predicate for it.

This is the sort of vague language that is great for producing headlines, but I don't think it is going to be very good at producing constitutionally protected regulations. And, with all due respect to the authors of the legislation, we got to take a step back and really think about it before we move forward.

As of this time, the FDA doesn't even have the resources for what it is already supposed to do. We have just tasked the FDA with a new responsibility for the post-market safety of our Nation's drug supply. We now want the FDA to fix the infamous problems we are having with imported food. And this subcommittee and the Oversight Subcommittee have held hearings on that this year. It seems to me that you just can't keep piling more and more work on the FDA without giving them the additional resources and expertise to do it. Nothing in that bill does that.

In 1996, the last time the FDA attempted to regulate tobacco, it was with the intention of regulating it as a drug and to ban tobacco products all together. Quite a bit has happened to the marketing and sale of tobacco products since then. In particular, in 1998, we had the master settlement agreement. It restricted advertising. Congress also passed the Synar amendment that would require States to enforce their law prohibiting the sale of tobacco products to minors or risk losing up to 40 percent of their Federal substance abuse block grant funding.

Smoking rates, in general, since then are declining, and kids in particular are smoking quite a bit less. What hasn't changed is this particular legislation. In fact, it is basically the same legislation

that we looked at back in those days. It was a bill as far back as 2000 referred to this committee that uses, as far as we can tell, the same language. It is hard to believe that there have been no changes, no improvements, no rethinking of thoughts about this particular issue since that time.

I think it is appropriate that we have the hearing. I think it is appropriate that we listen to the witnesses before us today because it is an issue that needs to be at least discussed and debated. I am particularly looking forward to the testimony of Dr. Fred Jacobs of the New Jersey Department of Health and Senior Services.

According to the General Accountability Office and testimony before the other body earlier this year, the States have received over $52 billion in tobacco settlement payments from fiscal year 2002 through the fiscal year 2005, $52.6 billion. Of that amount, only 30 percent has gone to provide for health care services, and believe it or not, only 3½ percent has gone to tobacco control by smoking cessation programs. Three and a half percent. That is about $1.5 billion. According to a report released by the Campaign for Tobacco-Free Kids, the States have allocated from tobacco settlement payments $538 million for tobacco prevention in fiscal year 2005, which amounts to just one-third of the $1.6 billion annually that the CDC recommends. I think that is a very poor record and something that we ought to look at very closely.

A peer-reviewed article from the July 2007 "Preventing Chronic Disease" found "significant reductions in smoking prevalence among Washington residents following the implementation of a comprehensive tobacco control program funding at a level near that recommended by the Centers for Disease Control and Prevention indicate that the tobacco control programs are effective when the investment is made and States are committed to improving public health."

If we are serious about cutting the number of kids who smoke, shouldn't we insist that the States get serious about meeting the CDC's funding targets for their smoking cessation and education programs with money from the tobacco settlement?

I have a little bit more, Mr. Chairman, but my time has expired. I yield back, and again thank you for holding this hearing.

Mr. PALLONE. Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Chairman Pallone, for holding this hearing and for your leadership on this issue. I am pleased to present to the committee this bill and to have this hearing on the legislation. I am open to hear what the witnesses have to say, and I know all of us here want to learn to see if the bill needs to be changed in any way, but I think we need a bill.

Tobacco is the deadliest product on the market today when used as intended. It kills over 400,000 Americans every year. That is more than alcohol, murders, and car accidents combined, yet it is one of the least regulated of all consumer products. It is really remarkable that a cigarette is subject to less regulation than a lollipop.

The price for this vacuum of regulation is paid by all of us, most tragically by our children. In the absence of comprehensive regulation, tobacco companies can market freely to kids; even though, kids aren't allowed to buy tobacco, but they certainly find ways to get it. The industry has the unfettered ability to engineer their products to trigger quick and severe addiction. And they are able to deceive the American public about the dangers of their products. We saw that in a campaign that went on for decades.

But we have a moral obligation to do better. Chairman Pallone, Chairman Dingell, Representative Tom Davis, and I have introduced the Family Smoking Prevention and Tobacco Control Act, which will give FDA the authority to regulate the design, manufacture, marketing and distribution of tobacco products. Now, regulating tobacco is the single most important thing we can do right now to curb the deadly toll of tobacco.

By giving FDA jurisdiction over tobacco products, this bill would help to prevent the marketing and sales of tobacco to kids, enable public health professionals to know what exactly is in a cigarette and to learn what the industry knows about their addictiveness and toxicity. It would empower the FDA to keep tobacco companies from making false and misleading claims about the safety of their products. It would allow FDA to require changes to the product content or design to protect the public health by, for example, reducing the amount of nicotine to make cigarettes less addictive.

Now, some have raised concerns that FDA is not the right agency for this job. I disagree. No other agency shares FDA's strong scientific foundation, together with a public health mission and comprehensive regulatory authority.

FDA also possesses institutional familiarity with tobacco itself. Not only does FDA currently regulate nicotine as a drug in smoking cessation products, but in the 1990s, FDA actually spent years crafting a detailed framework for regulating tobacco. Ultimately the Supreme Court struck down the exercise of regulatory authority, but the groundwork was laid for a sophisticated approach to tobacco regulation.

It is true that tobacco is different from other products regulated by the FDA. We can't have a safe and effective standard. That is why the bill has a new standard appropriate for the protection of public health. There is no question FDA needs new resources to do the job, and that is why we have a user fee to help provide them with those resources.

Experts in the public health community agree that this is the right approach. The bill is supported by the Heart Association, Lung Association, Cancer Society, and over 500 other organizations. I look forward to the hearing today, and I think it is legislation that will help protect our children and grandchildren from what has been a tobacco epidemic. Thank you, Mr. Chairman.

Mr. BARTON. Mr. Chairman?

Mr. PALLONE. Yes.

Mr. BARTON. Parliamentary inquiry. The Republican sponsor of this legislation is not a member of the committee, Mr. Davis of Virginia. We had asked that he be allowed to sit in on this hearing. Has that been approved?

Mr. PALLONE. Yes, my understanding is that members from other committees can sit on the dais, but they don't participate in either opening statements or questions. But they can sit on the dais.

Mr. BARTON. Thank you.

Mr. PALLONE. So as soon as he comes in, he is welcome to join us.

Mr. BARTON. OK.

Mr. PALLONE. I recognize the gentleman from Arizona, Mr. Shadegg.

OPENING STATEMENT OF HON. JOHN B. SHADEGG, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARIZONA

Mr. SHADEGG. I thank you, Mr. Chairman, and I thank you for holding this hearing. I think it is an important discussion to have. I want to make it clear that I share the goals of the authors and proponents of this legislation to reduce the use of tobacco in this country and particularly to reduce its use by children.

My mother smoked most of her life and died of disease related to her use of tobacco, and I have deep concern about its health consequences and about its addictive qualities and share the goal of doing everything we can to reduce those incentives and that inclination in our society and to educate people about the potential harm of tobacco and the danger that it causes particularly when people become hooked on smoking at a young age.

Having said that, I would like to also express my deep disappointment that the Majority was not able to structure this hearing today in a way to create a panel so that the chairman of the FDA, Commissioner von Eschenbach, could have testified and provided his testimony. I believe that would be the most useful testimony to elucidate us, as members of Congress, and the public at large as to the fundamental question here which is what is the best mechanism to achieve the goals this legislation seeks.

I believe Commissioner von Eschenbach would, more than any other person, be able to provide insight regarding the FDA's capability and suitability to handle this task. I note that in his prepared testimony, he has shared his view that he supports the goal of the legislation to reduce tobacco use in this country but that the FDA has "concerns with the bill's proposed means to achieve those objectives."

He goes on to state that they have concerns regarding whether or not the bill could undermine the public health role of the FDA. That is his first point, whether or not aspects of the bill may be extremely difficult for the FDA to implement. And third, significant concerns about the resources that will be provided under the bill and the expectations it might create.

Mr. Chairman, I would ask unanimous consent that his testimony be made a part of this hearing at this point.

Mr. PALLONE. So moved.

[The prepared statement of Dr. von Eschenbach folows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

ANDREW C. von ESCHENBACH, M.D.
COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

October 3, 2007

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at the United States Food and Drug Administration (FDA or the Agency). I regret that I will not have the opportunity to appear before you at this hearing because the Committee was not able to resolve the issue of witness paneling within the allotted time for the hearing.

For the last three decades, I have been engaged in the war on cancer both professionally and personally. Throughout my professional career, I have been privileged to serve in a variety of roles with a similar purpose and commitment---to help assure the health and welfare of patients and the public. As many of you may know, I spent many years at The University of Texas MD Anderson Cancer Center as an oncologist, researcher, and educator. In my time as a practicing oncologist, I treated numerous patients suffering the ill effects of tobacco. I came to know first hand the life-threatening conditions caused by tobacco products and the tremendous suffering that is taking a toll on patients, their families and friends, and society as a whole. I then served for four and a half years as Director of the National Cancer Institute (NCI) before coming to FDA as Commissioner. Today, I sit before you as a physician, scientist, clinician, and regulator. As a three time cancer survivor, I am involved not just professionally but am personally committed to the fight against cancer and the resulting suffering and death. I am grateful for this Subcommittee's work in minimizing the effects of tobacco use in this country.

HEALTH EFFECTS OF TOBACCO USE

Although tobacco use has declined in this country, its effects are so detrimental that it remains one of the most important -- if not the most important -- public health issue we face. The 2004 Surgeon General's Report entitled, "The Health Consequences of Smoking," noted that during the period 1995-1999, smoking caused approximately 440,000 premature deaths in the U.S. annually, leading to 13.2 years of potential life lost for male smokers, and 14.5 years lost for female smokers. The list of diseases and conditions caused by smoking has been expanded to include abdominal aortic aneurysm, acute myeloid leukemia, cervical cancer, kidney cancer, pancreatic cancer, stomach cancer, pneumonia, periodontitis, and cataract. These are in addition to diseases previously known to be caused by smoking, including 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. Tobacco users face nicotine addiction, increased risk of cancer from consumption of carcinogens, increased risk of heart disease from exposure to chemicals, and lung disease resulting from inhaled irritants.

We concur with the Surgeon General's conclusions that measures to prevent smoking initiation need to be a multiplex, integrated strategy and initiatives need to be strong and enforced, especially among adolescents and young adults. FDA must continue to work with the drug and device industries to ensure that smokers have a variety of options to help them treat the problem of nicotine addiction.

FEDERAL AND STATE EFFORTS ON TOBACCO

FDA is privileged to be among the other Federal and state agencies that are participating in some way to reduce tobacco use. It is clear, however, that the problem remains. We must continue to be innovative in our approaches and concentrate on achieving results.

Many agencies within the Department of Health and Human Services are working to address this major public health problem. FDA has worked to help develop and approve nicotine replacement products that help smokers quit, such as nicotine gum and patches, many of which are readily available over the counter to smokers who wish to quit. FDA has approved other drug products that do not contain nicotine that help smokers quit using other modes of action, including bupropion and most recently (spring 2006) varenicline. There are a variety of other non-nicotine containing smoking cessation products in the pipeline in various stages of development.

In addition, the Centers for Disease Control and Prevention (CDC), NCI, the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the National Institute on Drug Abuse (NIDA) are all actively involved in the fight to reduce tobacco use. These agencies conduct comprehensive tobacco control and prevention programs, which serve to educate the American public on the dangers of tobacco, especially American youth. They conduct surveillance and research and collaborate with public health organizations in the prevention of tobacco use and smoking

cessation programs. Finally, the Office of the Surgeon General has been especially active in the campaign against tobacco use by following up the 2004 Report with subsequent studies on the health effects of exposure to second-hand smoke and other efforts.

The states are also engaged in a variety of methods to limit smoking. All fifty states have adopted legislation prohibiting sales of tobacco to individuals under 18. Many states also limit smoking in some public locations. Most state health departments run educational programs aimed at prevention and limiting the number of smokers.

Despite the numerous Federal and state initiatives, tobacco still claims hundreds of thousands of lives every year. This is unacceptable. We have the opportunity here to explore novel solutions to the lingering problem of tobacco.

H.R. 1108

FDA shares the goal of H.R. 1108, the "Family Smoking Prevention and Tobacco Control Act," – to reduce tobacco use in this country. We agree with the need to address this significant public health problem. But we have concerns with the bill's proposed means to achieve those objectives. The Agency has three primary categories of concern with the proposed role for FDA.

First, we have concerns that the bill could undermine the public health role of FDA. Second, we have concerns about aspects of the bill that may be extremely difficult for FDA to implement. And third, we have significant concerns about the resources that would be provided under the bill and the expectations it might create. Let me elaborate on each of those areas.

First, FDA is a public health agency, structured to facilitate and regulate the development of products that promote and protect the public health. The Agency enjoys widespread public support for its role in defining and assuring effectiveness and safety of products they consume. Our responsibility includes approving products based on scientific evidence that benefits of the product outweigh the risks. We have extensive experience in such evaluations and we have developed finely tuned methodologies.

H.R. 1108 would ask us to apply this framework to tobacco products that, when used as intended, produce disease rather than promote health. FDA cannot "approve" a tobacco product in this context, because there is no scientific context to determine benefit to outweigh the numerous risks. It will be very challenging to transform existing science into a logical regulatory structure. There is little science available to the FDA on which to base decisions on tobacco product standards (such as reducing or eliminating harmful constituents, reducing the amount of nicotine in products, or requiring changes to tobacco product components) or premarket approval.

Associating the Agency with the approval of these inherently dangerous products would undermine the Agency's mission. Indeed, associating any agency whose mission is to promote public health with the approval of inherently dangerous products would undermine its mission and likely have perverse incentive effects. This proposed legislation would direct FDA to regulate tobacco products in a variety of ways, most significantly by the establishment of tobacco product standards, pre-market approval of new tobacco products, and standards for the sale of modified risk tobacco products. Approval of tobacco products that are dangerous to health even if used as directed runs directly counter to FDA's historical mission to protect and promote the public health by reviewing and approving products that prevent and treat disease, not products whose only impact on health is to cause disease.

In addition, the provisions authorizing pre-market approval of new and reduced risk tobacco products are of special concern. Most fundamentally, we are concerned that FDA "approval" of tobacco products may become confused with the Agency's regulation of therapeutic products such as drugs and devices. For example, the bill provides potential loopholes for "grandfathered" and "substantially equivalent" products, which will be permitted to stay on the market. We are concerned that the public will believe that products "approved" by the Agency are safe and that this will actually encourage individuals to smoke more rather than less.

As another example, the bill would attempt to apply current requirements for medical products such as drugs and medical devices to tobacco products. These include adverse event reporting, adulteration and misbranding, and record keeping. These concepts are not

applicable to inherently dangerous tobacco products. One example of the awkwardness of applying medical product standards to tobacco products is contained in the bill's definition of an adulterated tobacco product. Section 902 of the bill provides that a "tobacco product shall be deemed to be adulterated if—'(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health.'"

Tobacco products, however, are intrinsically injurious to health, i.e. adulterated according to this definition. This concept, therefore, does not fit when applied to the regulation of tobacco products. There are other examples in the bill where similar problems would arise.

The bill also appears to call for FDA to perform functions that are outside of the Agency's expertise, including, for example to investigate and prevent cigarette smuggling.

The final issue of concern that I would like to discuss today is that of resources and expectations under this bill. As I am sure you are all aware, FDA is operating in a dynamic time. We are striving to meet new challenges. Just last week, the President signed the Food and Drug Administration Amendments Act of 2007 that will allow us to continue to evolve and undertake our mission of protecting the public health. Were H.R. 1108 enacted, FDA would need to create an entirely new "tobacco center" to implement the detailed program created by the bill.

By far, the most important and daunting challenge would be to develop the expertise necessary to carry out the functions called for by this bill. FDA does not have expertise

regarding customarily marketed tobacco products and, therefore, would have to establish an entirely new program and hire new experts. Creating the appropriate organizational structure and hiring experts in the field of tobacco control and related sciences and other experts needed to staff the program at every level is considerably more challenging than simply filling identified vacancies in an existing program.

The provisions in this bill would require substantial resources and FDA may not be in a position to meet all of the activities within the proposed user fee levels. The $85 million in fiscal year (FY) 2008, $175 million in FY 2009, $300 million in FY 2010 and subsequent years of user fees adjusted by an inflation factor, is not sufficient to implement the complex program created by the bill. In addition, the bill does not authorize appropriations for start-up costs that would be associated with establishing a new product center. As a consequence of this, FDA may have to divert funds from its other programs, such as addressing the safety of drugs and food, to begin implementing this program.

Finally, FDA also would need a considerable amount of time, to implement the program created by the bill. The legislation authorizes or requires the Agency to publish numerous regulations and other documents. The bill also requires the Agency, in a short timeframe, to issue a regulation originally published in 1996 that relies on data and information that are a decade old and would need to be updated to reflect the latest science. Many of the timeframes provided, ranging from 30 days to 2 years after the bill is enacted, are unworkable especially considering the expectation that we produce these documents while we are creating an entirely new program from the ground up. These timeframes unduly and unfairly raise the

public's expectations about what the Agency could accomplish in a given period of time. In the best of circumstances when scientific results point to a clear regulatory approach, rulemaking typically involves at least a three-year process. In situations where the science is less fully developed or the issues are complex or controversial, and both are the case here, regulation development requires much more time.

CONCLUSION

I share with you the desire to reduce tobacco use in America. FDA believes it can continue to contribute to the decline in tobacco use in keeping with its primary mission by facilitating access to smoking cessation programs and therapies that have evidence of effectiveness, and by supporting sponsors who choose to pursue the development of these products. However, FDA is open to considering other roles for the Agency, if appropriate. Let me assure you that FDA is committed to joining you and other government and private organizations in efforts to minimize the devastating effects caused by tobacco use in a manner consistent with the Agency's mission.

Mr. SHADEGG. I share the commissioner's concerns. It seems to me that it is worth noting that tobacco is already regulated by numerous Federal and State agencies, including the Federal Trade Commission. I would hope the Federal Trade Commission is already taking action with regard to false or misleading claims made by tobacco companies. And if it is not, we ought to be doing oversight on the Federal Trade Commission and pushing them harder.

I have concerns about adding the regulations of tobacco to an already resource and time-constrained agency and whether or not that will achieve the goals intended. One of my concerns is that the Food and Drug Administration is there to regulate food and drugs, and I don't view tobacco as either of those. I view food as being good for you and drugs as being therapeutic and helpful. It seems to be somewhat confusing to say to an agency, which is supposed to regulate things that are good for you, is now going to regulate a product which is inherently bad for you. And I hope that is not viewed as the Government condoning the use of tobacco or expanding it.

I also am concerned about the lack of expertise within the FDA to regulate tobacco and perhaps wonder whether or not some other agency would be better to do this task.

I would note that the legislation calls for additional user fees, which may indeed be necessary to accomplish its tasks. However, I am worried that the cost of those user fees will be imposed upon the lowest income Americans and will hit them the hardest and now conflicts with the funding source advocated for the S-CHIP Program.

Let me simply conclude by saying I do think this is a worthy discussion to have. I have great concerns about whether or not this is the right agency, and I hope at some point we will be able to hear, in terms of testimony and the questioning and answering, from Commissioner von Eschenbach.

Thank you, and with that, I yield back.

Mr. PALLONE. Thank you, and next recognize our vice chair, Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing on the legislation to grant the Food and Drug Administration the authority to regulate tobacco products.

I share my colleague from Arizona's concern, and I would hope we could schedule a hearing so we could hear from the FDA particularly. And I understand the tradition that the Federal witnesses sit on their own panel, but it is no secret that cigarette smoking is the most preventable cause of death in this country. I imagine there isn't one person here today who hasn't been affected by cigarette smoking, whether personally or through the experience of a family member or friend.

The need to reduce the level of cigarette smoking in this country is a very personal issue for my family, as my wife and I watched her father and two brothers suffer severely and eventually pass away prematurely from lung cancer and smoking-related illnesses.

And I watched all three of them also try in their 40s and 50s to do everything they could to kick that habit. It was so difficult.

To know that the bulk of their health problems are by and large preventable is a sobering realization to the devastating effect of smoking. According to statistics from the CDC, approximately 21 percent of American adults are cigarette smokers. Unfortunately, many of these adults become addicted as teenagers, just like my relatives, who tried smoking out of peer pressure or simple experimentation but too quickly became hooked.

More than 1,100 teenagers under the age of 18 become regular smokers and adopt the habit that is not only deadly but extremely difficult to break. Seventy percent of adult smokers indicate they want to quit. Forty percent of smokers try to quit each year, but the addiction too often wins out over the smoker's will to quit and need to improve his or her life and health.

The recognition of the health dangers that smoking poses to the American public, both the FDA and Congress has worked for 10 years now to implement FDA regulations of tobacco products. Following the Supreme Court's 2000 ruling invalidating FDA's 1996 rule exerting regulatory authority over tobacco, clearly Congress must act to explicitly give the FDA this authority.

I am proud to be a cosponsor of the bill. The Family Smoking Prevention and Tobacco Control Act would subject tobacco products to many of the FDA's regulatory tools, such as premarket approval of new tobacco products and mandatory inspections of manufacturing facilities. The bill would also create a new user fee system imposed on tobacco manufacturer's to help the FDA absorb the cost to tobacco regulation. It seemed like in the first 10 months of this year, we have given or pointed out the FDA's lack of enforcement, whether it be the reform bill on the prescription drugs or with the food inspections that we just had a hearing last week. So we know they need additional funding.

Too many Americans have switched to certain brands based on unsubstantiated claims that these new brands will reduce the health risks we all know that are associated with smoking. It is high time that science-based agency have the authority to regulate the advertising of tobacco products and manufacturers' claim of reduced risk or reduced exposure.

This bill is a true compromise piece of legislation. Like most compromises, no stakeholder got everything it wanted. There are certainly still stakeholders with concerns about the bill. Nevertheless, I consider it victory that the American Lung Association, Tobacco-Free Kids, and Philip Morris are on the same side of the tobacco issue.

I would like to thank our colleague, Mr. Waxman, of our committee, and his Republican lead Congressman Davis of Virginia for crafting this compromise. I look forward to hearing from the witnesses and yield back my time.

Mr. PALLONE. Thank you. the gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. I appreciate the consideration for letting me go out of order. Mr. Chairman, this subcommittee has spent a fair amount of time this year talking about the FDA could or should do a better job ensuring the safety of drugs and ensuring the safety of our food supply. Indeed we passed, just 2 weeks ago, some of the most sweeping legislation to affect the FDA in probably 40 years, and I was grateful to be a part of that process.

We have talked about how the FDA could better inform the American people and about the therapeutic benefits, risks, and side effects of FDA-approved drugs. So, Mr. Chairman, forgive me. I am a little perplexed about the topic of discussion today. Used as directed, tobacco products in this country will kill 400,000 people every year when use as directed. And that is not even to address the number that are maimed and left infirm by the ravages of tobacco smoking.

I know something about whereof I speak. I was a physician for 25 years down in Texas before coming to Congress. Indeed, I am a reformed smoker. I lost both parents to cigarette-related disease. Both my parents died in their 80s of lung cancer, but perhaps the most serious problem that I saw associated with cigarette smoking was my father who was always eloquent and loquacious was rendered aphasic from a stroke at age 67 and died at age 83, never being able to utter a single word during that time. I am no proponent of cigarette smoking.

So memo to the American people: cigarette smoking is dangerous and addictive. Don't do it. If you do it, stop now. Your life will be better for it, and certainly your children's lives will be better for it. Why we need the FDA to weigh in on this is a mystery to me. We are going to hear a lot of testimony this morning, and I appreciate the witnesses who have given of their time to come give us the testimony.

Dr. Hemmingfield states that tobacco products are sophisticated drug delivery systems, engineered and manufactured to increase their potentials to cause and sustain addiction. We all agree there is no therapeutic benefit to smoking cigarettes. So why are we going to waste taxpayer dollars to regulate a product like that? What have we got next in line, crystal meth?

I know that the proponents of this bill are going to spend some time talking about how the Federal Trade Commission has failed to regulate cigarette advertisements, and maybe we could better spend our time to determine how the Federal Trade Commission could do a better job at regulating this commercial speech.

Instead of doing the one thing that could benefit public health in this country, outlawing cigarette use, proponents of this legislation would enact into law an arrangement that the courts have perpetuated by huge legal settlements to keep the gravy train flowing, and we saw that just last week with the passage of the S-CHIP bill.

We are addicted to tobacco money. Let us be honest about this. We ought to put that money where it would do some good. How about paying back the Medicare system for all of the money that

tobacco has cost the Medicare system over the years? How about paying the money to really make aggressive anti-smoking cessation campaigns? But where are we going to get our tax dollars to fund all the things that we have now committed ourselves to funding with cigarette use?

Mr. Chairman, I see my time is up. I am going to submit my whole statement for the record. It is full of valuable insight, and I encourage all members and witnesses to read it. And I will yield back the balance of my time.

Mr. PALLONE. Thank you. The gentlewoman from California, Mrs. Capps.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. Thank you, Chairman Pallone, for holding this extremely important hearing, and I want to join my colleagues in commending Henry Waxman for his tireless work on this bill and tobacco issues in general over the years. Our country owes a debt to him, and I agree with him and others that we do need to see this bill passed and signed into law.

As a nurse, I especially support this bill's approach to combating one of, if not the most, serious health problem facing our country. It is finally common knowledge that tobacco is unhealthy, dangerous, and deadly, but unfortunately it is still glamorized. Tobacco companies have purposely glamorized this product in order to attract new customers, especially a vulnerable population like young women.

If you could all please direct your attention to the posters that are pink, the poster that is pink and has flowers, you will see immediately what I am talking about. A new cigarette product manufactured in hot pink packaging and the tag line "light and luscious" is undoubtedly meant to appeal to women.

Newsweek columnist Anna Quindlen recently wrote on the deliberate effort to make Camel No. 9 cigarettes appeal to young women. She wrote about how her own daughter had tried them and described them with words like "caramel, perfume, chai tea." And just when you thought that was bad enough, check out what they came up with next. "Dressed to the nines." This ad introduces readers to stiletto style cigarettes, which are advertised as the newest, must-have fashion accessory to go along with the dress, the bracelets, and the lip balm.

While we expect this kind of sleazy marketing from tobacco companies, I have been terribly disappointed that they found a new and unexpected ally in women's fashion magazines. These magazines have historically served as legitimate sources for information on women's health, fitness, and fashion. But they have sold out the well being of their readers to help big tobacco in their search for new victims.

I was proud when 40 of my colleagues joined me in asking women's magazines to reject these ads. When not one of these magazines bothered to formally respond to our letter, we wrote again. This time, seven of them responded, but none will drop the ads. Several tried to defend themselves by pointing to their editorials on the dangers of smoking, and each made sure to emphasize that ac-

cepting the advertisements is completely legal. The publishing director of Vogue Tom Florio even wrote the following. "The goal of Congress should be to create legal guidelines for the marketing, distribution, and sale of tobacco products."

Well, there is an old saying, biblical in fact, "ask and ye shall receive." H.R. 1108 will give the FDA the authority to effectively regulate advertising. It would be wonderful if more members of the private sector would follow the lead of publications like Self magazine, which rejects all tobacco ads, but that is not the case. So we will pass a law that will enable us to better protect public health.

I look forward to hearing from our witnesses today and would like to finish with one final thought. If the Camel No. 9 advertising blitz that greeted our students at the start of school is any indication of their intentions, I shudder to think of the tricks or treats RJ Reynolds and its new friends in the magazine business have in store for our young women and girls this Halloween. I yield back.

Mr. PALLONE. Thank you. I recognize our ranking member, Mr. Deal.

OPENING STATEMENT OF HON. NATAHN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman. I am glad we are taking this opportunity today to evaluate Mr. Waxman's contribution on the issue of the FDA's regulation of tobacco products.

I think all of us have certainly been aware of the harmful and addictive effects of tobacco use and smoking, and I believe it is appropriate for us to take a look at ways to diminish the prevalence of smoking in our society. It contributes to disease and death and imposes a tremendous cost on our society as a whole.

That is especially true in the health care sector. One study has found that if all current smokers in the Medicaid Program quit, our Medicaid Program could save $9.7 billion. I am certainly sympathetic to the goals expressed by the authors of this legislation to keep our children from having easy access to cigarettes and trying to ensure that less people are in fact smoking every year.

But I do believe, however, that this issue needs the scrutiny of the legislative process. Many of the issues that require that scrutiny have been enunciated by Mr. Shadegg and by Dr. Burgess. There are many important considerations to be made in crafting the legislation, and I look forward to our witnesses' testimony on these issues.

The tobacco industry is diverse, and legislation like this will affect each sector differently. There are also considerations to be made about the country's convenience stores, and I am glad they are going to be here today to provide us with their views on this proposal.

The panels before us represent a wide range of viewpoints, and I believe their input will be useful as we evaluate the concerns that they raise and other parties have raised about this legislation. Overall, I think it should be a good hearing, and I look forward to the testimony of the witnesses. And thank you all for being here today, and I yield back my time.

Mr. PALLONE. Thank you. The gentlewoman from Oregon, Ms. Hooley.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chairman, for holding this hearing. And like many of my colleagues before me, I want to recognize Mr. Waxman for his extraordinary leadership on this issue. You have truly been a champion for protecting our children from the dangers of smoking.

I am a proud cosponsor of H.R. 1108 because I believe this bill takes important steps to improve public health. I have seen the toll on family and friends of what a lifetime of smoking can do. As a former smoker, I think it is past time that we take responsible steps to allow the FDA to regulate tobacco, like it does nearly every other product that we put into our bodies.

It is nearly inconceivable to think that the FDA has considerable authority to regulate the vegetables and fruit that we serve to our families but cannot regulate cigarettes, which are known to cause cancer and other serious health complications.

Smoking and its health effects have serious impact on women. The Center for Disease Control and Prevention estimates that more than 178,000 American women die from smoking-related diseases each year. The risk of developing lung cancer is about 13 times higher in female smokers than in non-smokers. Although we rightly put tremendous resources into treating breast cancer, lung cancer surpassed breast cancer in 1987 as the leading cause of cancer death among women.

Smoking is also associated with an increased incidence of cervical cancer and osteoporosis in women. Moreover, smoking is linked to cardiovascular disease, the No. 1 killer among women. This bill is not only beneficial for women's health, but it is also important for the well being of our children.

Every day, more than 1,100 young people under the age of 18 become regular smokers. When young people smoke, they are much more likely to become lifelong smokers than those who start smoking at a later age.

This legislation will save lives. This legislation will help reduce the incidence of teenage smoking and result in fewer lifelong smokers. Studies show that nonsmokers will have healthier adulthoods than their smoking counterparts. If we can take common sense steps to help reduce teenage smoking and ultimately improve young people's lives, then we must do so. This legislation takes those steps.

I also want to note that this legislation prohibits the FDA from banning tobacco products or reducing nicotine levels to zero. We should not and will not prohibit adults from smoking. Those who make the personal decision to smoke may continue to make that choice. This legislation simply ensures that the FDA will have authority to regulate tobacco just like it has the authority to regulate all our other food and drugs we consume.

In other words, H.R. 1108 takes common sense steps to regulate a product that is known to cause harmful health effects. Thank you, Mr. Chairman, for having this hearing.

Mr. PALLONE. Thank you. The gentlewoman from New Mexico, Mrs. Wilson.

OPENING STATEMENT OF HON. HEATHER WILSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO

Mrs. WILSON. Thank you, Mr. Chairman. I will be very brief. I wanted to thank you for holding this hearing. Like my colleagues on this committee, I want to see us reduce the use of tobacco. But I am not sure yet and what I want to learn about today is whether this bill will help or hurt in that effort.

And I am particularly concerned about overlapping responsibilities or muddying the water with respect to clarity of responsibilities in making sure that agencies have the right resources to do the tasks that we give to them.

There are a number of agencies involved in the regulation of tobacco now. This would shift those responsibilities, but it is unclear to me at this point how much or what the result would be in the ultimate goal, which is to reduce the use of tobacco.

So I look forward to the hearing today and learning more about these issues. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentlewoman from Wisconsin, Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman. I appreciate the fact that you are holding this hearing, and I appreciate our witnesses that will join us momentarily. We have heard some of the statistics this morning, but I think that many of them bear repeating. Cigarette smoking is the leading preventable cause of death in the United States, and it is responsible for about one in five deaths annually or about 438,000 deaths per year.

Smoking-related deaths account for more deaths than AIDS, alcohol, cocaine, heroin, homicide, suicide, and motor vehicle crashes and fires combined. And yet 21 percent of all U.S. adults, approximately 45.1 million people are smokers.

I am sure we could have a fascinating discussion about why people continue to smoke, knowing the serious harm that cigarettes do to their health. And while that is a conversation I think we should have, we are here today to discuss steps that we can take right now at the Federal level that will better educate Americans about the dangers of smoking and regulate the marketing and distribution of tobacco products.

I am proud to be an original cosponsor of H.R. 1108, and I thank Congressman Waxman for his tremendous leadership on this issue. I am especially pleased that H.R. 1108 will focus and prohibit cigarettes from containing any artificial or natural flavors. I am concerned about these products. Sometimes they are strawberry flavored or other candy-like flavors. And it seems to me that these are blatantly aimed at getting children to smoke, and it is really truly appalling. And I am glad that this bill puts an end to these candy-flavored cigarettes.

Additionally, I am pleased that the bill requires tobacco companies to disclose the contents of their products. Just like every other company that produces an ingestible consumer product, tobacco

companies will have to submit a listing by quantity of all ingredients and additives to tobacco, paper, and filters for each brand they manufacture. This is the right thing to do. We do it for drugs. We do it for food. We should require it of cigarettes.

Again thank you, Mr. Chairman, for holding this hearing. I look forward to our discussion today.

Mr. PALLONE. Thank you. Next is the gentleman from Texas, Mr. Hall.

OPENING STATEMENT OF HON. RALPH M. HALL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. HALL. Thank you, Mr. Chairman. And I thank Mr. Waxman for his work in this area. You know I am of a generation that remembers how the Federal Government encouraged our members and our people in the armed services to smoke by giving them cigarettes free, enticing them into the tobacco industry.

And now I see that generation that are dying out by 1,000 or 1,500 a day, and I have a hospital up in northeast Texas, the Sam Rayburn Memorial Hospital, where these old fellows are put outside the air conditioning in the heat of the summer in 100 degree weather several days in a row to smoke their cigarettes. In the winter, put out of the warmth and the care of the same area, out in the cold to do that.

I had a place built for them to smoke their cigarettes, and I got some criticism for it. But I felt as they were enticed into the situation back in the time of stress when they were thousands of miles away from home fighting for all of our freedom that they had some rights.

And I still see a gleam of that that people think they have a right to smoke and abuse their bodies, and that is a hard thing to reconcile either way. I wish we could do away with every cigarette in the world. I think we would be better off. And, of course, the world would be better off. We would have more money to spend on other health pursuits. I just appreciate you holding the hearing, and I think it will spark some continued congressional debate over the proper way to regulate tobacco.

And I would also like to thank the panelists for joining us. Your insight and your expertise will certainly guide the continued examination of the issue. Smoking-related disease is a real serious problem in the country, which deserves a fair and honest debate. And I firmly believe that we need to be doing more to reduce smoke-related diseases as we can be. I have some problems about taxing it out of existence, though I am not totally against that if that is what it takes.

My primary concern over the legislation before us today, though, is the cost of further Federal Government expansion and whether the user fees contained in the bill are just a tax increase by another name. There are many parts of the legislation I could support, but I want to make sure we think carefully about what we are doing and how we are doing it.

For example, the legislation appears to treat all tobacco products the same when it seems clear that it is a matter of common sense and science that smokeless tobacco products are different than cigarettes. They may be dangerous in themselves, but different

than cigarettes. They ought to be treated a little bit differently. We are also concerned for the tobacco retailers with over 300,000 in this country. How will the FDA regulate and enforce and adjudicate them, and how much additional staff will the FDA need? How much will this cost?

It appears Internet retailers, Native American retailers, and adult facilities are favored by the legislation. These groups share a large percent of tobacco sales and should have the same regulations as all other retailers. I hope to work with the committee on these concerns and make sure this legislation is both fair and addresses public health concerns. And, Mr. Chairman, I thank you, and I yield back the balance of my time.

Mr. PALLONE. Thank you. The gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman. In 1982, then-Surgeon General C. Everett Coop said "cigarette smoking is the chief single avoidable cause of death in our society and the most important public health issue of our time." Unfortunately, that statement is just as true today as it was when he said it 25 years ago.

Tens of millions of Americans remain addicted to smoking, and almost all of them started smoking when they were young. Also true is that most smokers today would like to quit, but they are unable to break this highly addictive habit.

I want to give a hallelujah to you, Mr. Chairman, for having this hearing and even more to Mr. Waxman for having drafted such a great comprehensive piece of legislation which I too am a proud cosponsor of.

Smoking prevention and tobacco control are issues that have been missing in action for quite some time, at least as far as Congress is concerned. I am in my sixth term on this committee, and we have a lot of hand-wringing in this committee over the years about what we do about tobacco use and smoking cessation.

When I first came to Congress, I had a mock congressional hearing in my district on teen tobacco use, and there were some low-income kids, Hispanic kids from a high school in my district, who took it upon themselves to do a study. And they did a scientific study in which they found that tobacco companies targeted advertising, billboards and other types of advertising, to low-income neighborhoods and to communities of color. These kids were so unbelievable then-Chairman Bilirakis had them come here to testify in a real congressional hearing, and they talked about their findings.

What happened after that hearing? Nothing. And then Congresswoman Bono and I introduced legislation, which we worked on for many years, on smoking cessation to add that to Medicare because it is estimated, of course, that Medicare will pay billions of dollars over the next few decades to treat tobacco-related diseases. What happened to that bill? We were told by the then chairman of the committee that we couldn't pass that legislation because it cost too

much to pay for smoking cessation programs and services, which I find incredibly ironic, given the amount that we are spending to treat lung cancer, emphysema, heart disease, and other smoking-related diseases.

In my early years in Congress, I also introduced legislation to raise the smoking age from 18 to 21 just as we had done with alcohol, and, of course, you can imagine how that went over with the committee at that time.

And then I tried to get rid of crop insurance for tobacco, which met with about the same result. And so, Mr. Chairman, I think it is really great that we are having a hearing on this bill, but I think it is even greater that we actually might do something about this problem, that we actually might pass Mr. Waxman's bill, that we actually might give the FDA the ability to regulate tobacco, which to my mind, is a no brainer.

So, Mr. Chairman, I look forward to working with you and Mr. Waxman and everybody else so that we can truly prevent teens from starting to use tobacco and prevent millions of deaths. Thank you.

Mr. PALLONE. Thank you. Next is the gentleman from Indiana, Mr. Buyer.

OPENING STATEMENT OF HON. STEVE BUYER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. BUYER. Thank you. When it comes to making decisions on behalf of a country, I utilize principle-oriented decision-making. So what I do is I put any issue through a paradigm. The paradigm goes like this. I say what is its impact upon individual liberty? Does it promote personal responsibility and accountability? Does it promote economic opportunity? Is the marketplace open, fair, and competitive? And does it protect American citizens at home and abroad. Whatever the issue, I put it in that paradigm.

So now let us take the issue that is before us. I ask the question of is what we are trying to do is regulate human behavior? I think that is what we are trying to do here. So as, I guess, we look out across the spectrum, there are a lot of things out there with regard to products that have an impact upon the human physiology. And if we are going to regulate one product, what about all these other products?

Now, if the real goal here is education and harm reduction, that is what we should be focusing on because I assure you my wife, God bless her, is driving me crazy because she goes through all the series of foods, all the bad foods, which I eat, and here are the good foods. So, let us see, she has a list. She has salt. She has refined sugar, caffeine, nicotine, alcohol, go through all that list of things that are bad for you.

Now, are we going to go down the road of saying OK, let us start regulating all of these other things? Because when I look at this, let us see, we could regulate trans fats, refined sugar, salts, alcohol, supplements, caffeine. All of these things are having an impact upon human physiology. But no, let us go ahead and let us go after nicotine.

As a matter of fact, are we really going after nicotine? Because it is really cigarettes. Because if we really wanted to have a harm

reduction strategy, we would talk about moving people from cigarettes to smokeless tobacco as a harm reduction strategy. No, that is not even taken into account in this. And with regard to advertising, yes, OK, right. They use Joe Camel and all of that. They should not have been targeting cigarettes to children, but what is the difference between McDonald's using Ronald McDonald and promoting trans fats to children. And now we are dealing with childhood obesity.

And let us go ahead and take it to the extreme. Let us see. What about all the advertising by the candy industry for the Easter bunny that also adds to what, tooth decay and childhood obesity. So then what are we going to do? We are going to outlaw Halloween, Valentine's Day, the Easter bunny. We can do a lot of things out there to regulate human behavior. Now that gets pretty ridiculous when you think about all of that.

Going back to it, the focus, I believe, what we should have is on education and harm reduction strategy. That is exactly what my wife is doing to me: taking me away from refined sugar products to Splenda. Taking me off of my Diet Dr. Pepper, which I love, and move me then to non-caffinated drinks. So I picked up Gatorade. Then she shows me how much salt is in Gatorade, and now she has me on Propel. My son calls it Gatorade for girls. That is what I drink today.

So I am on this harm reduction strategy by my wife, and that is what we should be focusing on, Mr. Chairman. I yield back.

Mr. PALLONE. I was going to ask you if your wife was a Democrat. I am sorry. I yield to the gentleman from Maine, Mr. Allen.

OPENING STATEMENT OF HON. TOM ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Mr. ALLEN. Thank you, Mr. Chairman. This is a tough act to follow. I will come back to tobacco here. I want to thank you for holding this hearing. The use of tobacco products kills over 400,000 people and costs our Nation more than $167 billion a year, based on lost productivity of $92 billion and health care expenditures of $75 billion a year.

For decades, tobacco companies have mislead the American public and Congress about the health consequences of smoking, the addictive nature of smoking, and their manipulation of nicotine levels. Perhaps of greatest concern, the tobacco companies have targeted substantial marketing efforts toward children in order to boost their profits and hook future generations on their products. An estimated 4½ million children and adolescents smoke, and another 1 million use smokeless tobacco; 15½ million kids are exposed to second hand smoke at home.

According to HHS, 1 million children will start smoking each year. One-third of those children will eventually die of a smoking-related illness. Regrettably, Maine has one of the highest teenage smoking rates in the country, despite the fact that we have reduced by 60 percent teen smoking in Maine over the last 10 years. And even though Maine leads the Nation in its commitment to dedicating tobacco settlement money to tobacco prevention and treatment, Maine still has more than one out of every five high school students smoking. That figure is unacceptably high. It is extremely

difficult to get young adults to quit smoking once they have started.

The continued efforts by the tobacco industry to market their product to young people is further evidence that despite the master settlement restrictions, this industry continues to recruit replacement smokers to keep businesses going.

I am proud to be an original cosponsor of Representative Waxman's bill, which grants the FDA the same authority over cigarettes and other tobacco products that it already has over countless other consumer products. The bill would allow the FDA to discourage children from starting smoking and encourage adults to quit in part by reigning in advertising, bolstering existing sales restrictions, and strengthening warning labels.

It would also allow the FDA to order the elimination or reduction of harmful and addictive ingredients in tobacco. Significantly the bill would require tobacco companies to disclose what tobacco products and their smoke contain. Secondhand smoke, for example, contains 250 chemicals known to be toxic or carcinogenic, according to the Center for Disease Control. Giving the FDA the power and authority to regulate tobacco products will protect our children, improve the public health, and ensure that consumers have more information about tobacco products to make better decisions.

I look forward to the testimony of our distinguished panel and yield back the balance of my time.

Mr. PALLONE. Thank you. The gentlewoman from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. I appreciate your calling the hearing today, and I am looking forward to hearing from our witnesses.

Back in the mid 1980s, I was president of the Middle Tennessee Board of the American Lung Association, and I was very involved in our smoking cessation programs, in education and awareness, asthma programs and training programs for parents. I am allergic to cigarette smoke, I have a child that is allergic to cigarette smoke, and very well aware of the harmful effects that come from cigarette smoke.

However, I think that the policy that is set forth in this bill has some serious flaws, and I do think that it misses the mark on protecting the public from tobacco. And I make these as somebody who has read the bill and just disagrees with it, disagrees with the premise on it.

We all know that the FDA is responsible for ensuring the safety of all domestic and imported food, drugs, medical devices, biologics, cosmetics. The list goes on and on, and as we have heard from countless hearings, the FDA does not have the resources to handle additional product regulation. They struggle with the intra-agency communication, and they struggled with even giving us a list of what their best practices are.

The bill grants the FDA unlimited authority to impose new, undefined tobacco restrictions and places burdensome standards on

tobacco manufacturers, farmers, sellers. The FDA is not prepared to regulate and enforce the bill's provision for the 300,000 retailers that are selling tobacco products nationwide.

Always there are two sides to every issue, and I am also concerned about the impact the bill would have on Tennessee tobacco farmers. U.S. Smokeless Tobacco Manufacturing Company has called Tennessee home for more than 75 years and employs close to 600 people through the State. The company purchase about half of all the dark tobacco grown in Tennessee from approximately 200 growers.

Many of those are in my district, and while the bill's provisions are not directed at tobacco farmers, these constituents would be negatively impacted by broad regulations that place no limits on FDA authority to regulate tobacco leaf. It is only fair to consider the impact that this bill would have on those individuals.

In 1992, Congress passed the Synar Amendment, which withheld Federal funds until States met an 80 percent compliance rate for preventing tobacco sales to minors. All 50 States are now in compliance. Since implementation, this approach has been to prevent youth usage, and those rates have declined. We should be working with our States, with manufacturers, producers, packagers, distributors, and retailers on new initiatives versus implementing an unworkable Federal layer that has no proven track record.

As you all know, we are in the midst of a debate on expansion of the SCHIP program. Many of my colleagues have voted to fund SCHIP with an increase in the Federal excise tax on tobacco. If H.R. 1108 attempts to eradicate smoking, how much would Congress have to increase the tobacco tax in order to pay for the SCHIP expansion bill?

Consumers believe that if the FDA approves a product, then it is safe. So why would we give tobacco the FDA stamp of approval? Thank you, Mr. Chairman. I appreciate the hearing, and I am looking forward to our witnesses. I yield back.

Mr. PALLONE. Thank you. The gentlewoman from California, Ms. Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Mr. Chairman, and good morning. And thank you to our witnesses for being here. In my opinion, the bill that we have before us, H.R. 1108, Family Smoking Prevention and Tobacco Control Act, I think is a bill going in the right direction and especially as it affects hundreds of thousands of Latinos. I am talking in particular about the youthful age of our community because we see a higher incidents of smoking rates amongst young Latinos and Latinas. And that is alarming for me because you think with all the money that we have spent to try to inform our community about the devastating health effects and consequences of smoking that you would see that there would be a downturn. That is not the case.

And part of it is because the tobacco industry has become very clever in targeting their message. While other corporations ignore our community and don't expand outreach in many ways to them,

the tobacco companies have done a great job, in my opinion, of targeting Latino youth. And what they have done is they are running ads in Spanish and English. They put up Spanish speaking role models, and they make it sound as though it is cool. And they actually say that, cool cigarettes. It is good to have this image of smoking the cool cigarettes while saying that somehow this is part of our culture and part of our morals or mores, put more appropriately.

And I find that rather insulting because I know that that is not the case, and it is just like the alcohol and other groups that also go way out of their way to focus narrowly to a community that is underserved in so many ways by health care insurance and has very high rates of cancer, in particular among Latinos, young males as well as Latinas.

And the statistics are there. I won't repeat them, but I do want to enter my statement into the record and just say that I am not pleased with the manner in which our corporations, in particular in this case the tobacco industry, is treating my community.

I also say that about young teens because I know Congresswomen Capps, Schakowsky, and I have sent letters to magazines that target young women and glamorizing, more or less, smoking. That somehow that is in style, and that is the way you should be if you want to be accepted by society.

So I know that there are a lot of Members of Congress that would like to see more regulation, more science, more research done, on the ill effects of tobacco and what it has on all of our community. So I yield back the balance of my time and would ask that my statement be placed in the record.

Mr. PALLONE. Thank you. I think that concludes our opening statements from the members. Additional statements for the record will be accepted at this time.

[The prepared statements follow:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding this hearing on a very critical public health issue, tobacco use, and, more specifically, on H.R. 1108, the Family Smoking Prevention and Tobacco Control Act.

The harmful effects of tobacco products and its toll on human lives have been known for decades. In spite of efforts to decrease the number of smokers, cigarette smoking remains the leading preventable cause of death in the United States. Cigarette smoking is responsible for about 1 in 5 deaths annually, or about 435,000 deaths per year. In addition to the 45.1 million U.S. adult smokers, it is estimated that each day more than 1,000 persons younger than 18 years of age become addicted to tobacco products. Not only has tobacco use claimed lives, but it also has caused serious financial losses. The use of tobacco costs the United States more than $167 billion annually in terms of lost productivity and healthcare expenditures.

In 1996, the Food and Drug Administration attempted to address this problem by issuing a final rule asserting regulatory authority over tobacco products. This rule would have made great strides in reducing the prevalence of underage smoking and use of smokeless tobacco products through strict distribution, marketing, and labeling provisions.

Unfortunately, in 2000, after several court challenges, the U.S. Supreme Court ruled that FDA did not have the authority to regulate tobacco products. Since then, there have been numerous attempts to pass legislation granting the FDA this authority.

States have done their part to address this issue. In 1998, the attorneys general of 46 States signed the Master Settlement Agreement with the four largest U.S. tobacco companies to recover billions of dollars in costs associated with treating smok-

ing-related illnesses. These funds have been used to pay for tobacco-control programs. Now is the time for the Federal Government to do its part.

H.R. 1108 has broad support from the public health community. We will look closely at this legislation and engage in a fair process that is inclusive of the public health community, industry, and other interested stakeholders.

I appreciate this hearing, Mr. Chairman. I thank Representative Waxman for his leadership on this issue. I look forward to the testimony of our witnesses and the input of our Members.

PREPARED STATEMENT OF HON. JIM MATHESON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Thank you, Mr. Chairman, for holding this hearing today on the Family Smoking Prevention and Tobacco Control Act, H.R. 1108.

I am a cosponsor of this legislation, as I have been of similar legislation since I first came to the House in the 107th Congress.

I represent the second district of Utah, where an estimated of 7.4 percent of our high schoolers smoke and an estimated 2.4 million packs of cigarettes are bought or smoked by kids in Utah each year. Not surprisingly, helping our kids to become far less likely to start smoking, we can instill in them these good habits to carry into adulthood. Indeed, only 10 percent of smokers begin after age 18. Slightly less than one-in-10 adults in Utah smoke, and that's better than half the national average of 21 percent. But we still want to do better, and we can with this legislation with its restrictions on advertising to kids, improved warning labels, and for the first time, product standards to reduce the harm of tobacco products.

In my State of Utah, the State and Federal tax burden for each Utah household to cover smoking costs is $537 each year, while the average American household is spending $630 each year for that same purpose. That's nearly $100 for each Utah family. And even that figure does not include the private health care expenditures or lost productivity caused by smoking.

Mr. Chairman, I am glad that we are moving this legislation forward—for the kids in Utah—and kids, who without this legislation, may be on their way to becoming addicted to tobacco products. There are far too many in this country.

I believe we can give the FDA the tools it needs to make cigarettes less addictive, to ban products marketed to kids such as candy-flavored cigarettes, to stop those who repeatedly and illegally sell these products to our kids, and to stop the marketing of these products to the next generation of smokers.

Thank you.

PREPARED STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, I am very concerned about the slowing down of the decline of tobacco use and the potential use of tobacco among adolescents, particularly those from homes without access to either health insurance, or adequate health care. However, while I am generally in favor of the underlying principles of H.R. 1108, I believe that we have to be careful about giving the Food and Drug Administration authority that it has demonstrated it cannot handle. By that I mean the provisions in the bill that would put the FDA in the position of inspecting and regulating hundreds of thousands of sellers of tobacco across the Nation.

I am a co-sponsor of the bill because I want to ensure that the manufacture of tobacco is appropriately regulated. However, I believe that the Synar amendment, which has been aimed at decreasing youth access to tobacco, has been working. I don't think we should willy nilly overstep State authority to regulate this aspect of tobacco when we have gotten substantial results. Under the 1992 Synar amendment, States have the authority to conduct unannounced inspections and over the past 10 years all States and the District of Columbia have reached the goal of achieving retailer violation rates of no more than 20 percent—that's sales of cigarettes to minors. That's not enough. We would like zero sales to minors, however, studies cited by the U.S. substance abuse and mental health administration show that the retailed violation rates were in the 60–90 percent range prior to the Synar amendment, so we have seen great progress.

Conversely the continued squeeze on FDA funding has prompted the agency to shut down regional offices and some field facilities to make more efficient use of limited resources. How will this streamlining by the FDA affect the proposed inspection programs in this bill? My concern is that the FDA will not have the trained inspector workforce needed to do frequent oversight. Reductions in FDA inspection oper-

ations have caused problems in areas like food safety. There are 12 percent fewer FDA employees in field offices who concentrate on food issues and safety tests for U.S.-produced food have dropped nearly 75 percent. Downsizing at FDA has also resulted in cuts in budget and staff and the FDA's field force has dropped from 4,000 in 2003 to some 3,400 today. What makes us think that added additional inspection burdens on the FDA will be successful?

Every State regulates tobacco sellers now and the States have shown the ability to reduce illegal tobacco sales. I believe that a continued partnership with States in terms of retail tobacco sales will be fruitful. I look forward to exploring whether FDA should become involved in regulation of retail tobacco sales or whether another approach that does not place the entire burden on the FDA can be workable. Thank you, Mr. Chairman and I yield back the balance of my time.

Mr. PALLONE. We will now turn to our witnesses.

I want to welcome you all, and let me indicate who we do have. First of all, on my left is Richard J. Bonnie, who is John S. Baddle professor of law and director of the Institute of Law Psychiatry and Public Policy at the University of Virginia. And second, from my home State is Dr. Fred Jacobs who is our commissioner for the New Jersey Department of Health and Senior Services, and I want to particularly welcome him not only for being here today to discuss the tobacco issue but also because of all you do on health care. And I know I have had some conversations with you about New Jersey's efforts to expand health insurance and try to provide universal health care. And just want to commend you for all that you do, Dr. Jacobs. Thank you for being here today.

And I think I already indicated that we had submitted into the record, at Mr. Shadegg's request, the statement from the FDA. So let me just mention your statements, of course, are part of the hearing record. And each of the witnesses may, in the discretion of the committee, submit additional brief and pertinent statements in writing for inclusion in the record. And so I will begin by recognizing Dr. Bonnie for 5 minutes. Thank you.

STATEMENT OF RICHARD J. BONNIE, HARRISON FOUNDATION, PROFESSOR OF MEDICINE AND LAW; DIRECTOR, INSTITUTE OF LAW, PSYCHIATRY, AND PUBLIC POLICY, UNIVERSITY OF VIRGINIA

Mr. BONNIE. Good morning, Mr. Chairman, Mr. Deal, and other members of the subcommittee. I am, as the chairman said, on the faculties of medicine and law at the University of Virginia, and I recently served as chair of the committee on reducing tobacco use of the Institute of Medicine, a component of the National Academies.

The committee's work was funded by the American Legacy Foundation, and I am here today to testify about the committee's report entitled "Ending the Tobacco Problem: A Blueprint for the Nation" a copy of which should be at your side. A summary of the report also has been submitted for the record.

As everyone here knows and has been indicated by the members, tobacco use, especially cigarette smoking, has been one of the Nation's major public health problems for most of the 20th century and continues at an unacceptable level in the 21st century. Indeed, it has become one of the world's major public health challenges.

Even though the tobacco leaf grows naturally, the tobacco problem is fundamentally a man-made problem. Cigarettes became one

of the most successful consumer products in history in only a few decades and became an ever-present icon of American life, embedded in the culture and promoted by a powerful industry.

Unfortunately, cigarettes are one of the most dangerous consumer products ever marketed. They are highly addictive and deadly, as even the tobacco companies now concede. If tobacco cigarettes were being introduced into the marketplace for the first time, there can be no doubt that they would be banned under any one of several consumer protection statutes.

Of course, banning tobacco products is not feasible or wise. The challenge the country faces today is to develop a feasible strategy for rooting out a problem that has become deeply entrenched in our economic and cultural life. There are still 45 million cigarette smokers, and another 9.7 million users of other tobacco products. Most of them regret taking up the habit and struggle to quit.

The title of the committee's report probably got your attention. Let me explain what the committee means by ending the tobacco problem. In the committee's view, the Nation's long-term goal should be to reduce tobacco use so substantially that it is no longer a significant public health problem. That doesn't necessarily mean eliminating tobacco use. The blueprint outlined in the report aims to set the Nation irreversibly on a course for achieving this objective.

Optimists might say that we are already well on our way to ending the problem. After all, the prevalence of smoking among adults has been cut in half from 42 percent to 21 percent since 1965. The prevalence of daily smoking among high school students is now at its lowest level since annual monitoring began 30 years ago. An increasing proportion of the indoor environment around the country is now smoke-free.

The tobacco companies are defending themselves in an increasing number of lawsuits, and State juries outraged by the industry's deceptive conduct have imposed very large punitive damage awards. Why not just keep doing what we are doing and wait for these historical currents to bring the problem to an end?

The IOM committee concluded that maintaining our present course will not end the tobacco problem. There are already signs that the prevalence of smoking among adults is flattening instead of decreasing, and the rate of youth initiation has hovered around 20 percent for most of the past two decades even though it is down at the moment.

The high rate of youth smoking is especially troubling because at least 80 percent of people who smoke begin to do so as adolescents when they cannot fully appreciate the grip of addiction and the future risk to their health.

Moreover, quitting after decades of use is difficult. Despite the fact that 70 percent of smokers say they want to quit and 40 percent have a specific intention to do so within the next month or so, the annual rate of cessation among people younger than 65 is low and remains low.

Meanwhile, the tobacco industry is spending more than $15 billion annually marketing its product to smokers and potential smokers in ever more creative ways, as we have just seen, while public and private resources devoted to preventing smoking and helping

people quit are dwindling. It will probably come as a surprise to most Americans, but the States use very little of the billions of dollars they are receiving under the Master Settlement Agreement to reduce tobacco use, as Congressman Barton noted earlier.

Taking these realities into account, the committee believes that the annual toll of more than 400,000 smoking-related deaths will continue well into the 21st century. It is time to change course. For four decades, the tobacco industry successfully framed a public debate around the health consequences of smoking and the illegitimacy of governmental efforts to prevent or discourage people from smoking whenever and wherever they wanted.

But that debate as I think is entirely clear from the comments made by the members, is over. The dangerous properties of tobacco and its impact on the public health are now beyond dispute. And, as our report shows, aggressive measures to reduce smoking rest on a solid scientific and ethical foundation.

The only debate now should be about how best to accommodate the legitimate interests of addicted smokers within a comprehensive national policy designed explicitly to reduce smoking and other forms of tobacco use.

In its blueprint for the Nation, the committee offers a two-pronged strategy for putting the Nation on an irreversible course toward ending the tobacco problem. This strategy involves strengthening current tobacco control measures while transforming the regulatory environment for tobacco products. This is not an either/or question. This is both.

First, we have to invest in traditional tobacco control measures. The evidence is in. These interventions do work. The report contains almost 100 pages documenting the effectiveness of traditional tools of tobacco control, such as excise tax increases, indoor smoking restrictions, comprehensive State-based programs, media-based prevention campaigns, school-based programs, and cessation therapies and services.

Specifically the committee urges States to fund tobacco control programs at the level that has been recommended by the CDC, to license all retail establishments that sell tobacco, and to ban the sale or shipment of tobacco products directly to consumers through mail order or the Internet.

The committee also urges Congress to help fund State tobacco control activities and to fund a national youth-oriented media campaign. Further, the committee recommends that all insurance managed care and employee benefits plans, including Medicaid and Medicare, cover reimbursement for effective smoking cessation programs as a lifetime benefit.

Mr. PALLONE. Mr. Bonnie, you are 2 minutes over, so I am going to ask you to summarize the rest if you don't mind.

Mr. BONNIE. I am sorry, Mr. Chairman.

Mr. PALLONE. That is all right.

Mr. BONNIE. All right, well if I might refer specifically then to the second part of the committee's strategy with regard to the change of the legal structure of tobacco control. Tobacco products, as the committee knows, are not ordinary consumer products. And for no other lawful consumer product can it be said that the ac-

knowledged aim of national policy is to suppress consumption altogether rather than to promote safe or responsible use.

And as has been noted, these products are essentially unregulated. So Congress should enact a Federal regulatory statute that is suited to the unique history and characteristics of tobacco products. There are many elements of the bill, of course, the committee did not and the national academies would not endorse any particular piece of legislation. And I am speaking on behalf of the committee.

But the elements of the bill and the goal of the bill, are fully compatible with all the recommendations that appear in the committee's report. Thank you, Mr. Chairman.

[The prepared statement of Mr. Bonnie follows:]

STATEMENT OF RICHARD J. BONNIE

Good morning, Mr. Chairman and members of the committee. My name is Richard Bonnie. I am Harrison Foundation Professor of Medicine and Law, Professor of Psychiatry and Neurobehavioral Sciences, and Director, Institute of Law, Psychiatry and Public Policy at the University of Virginia. I recently served as Chair of the Committee on Reducing Tobacco Use of the Institute of Medicine, a component of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology. The committee's work was funded by the American Legacy Foundation. Thank you for inviting me to testify today about the committee's report entitled Ending the Tobacco Problem: A Blueprint for the Nation. A summary of the report is included with my statement and submitted for the record.

As everyone here knows, tobacco use—especially cigarette-smoking—has been one of the Nation's major public health problems for most of the 20th century and continues at an unacceptable level in the 21st century. Indeed, it has become one of the world's major public health challenges.

The tobacco problem is fundamentally a man-made problem. Cigarettes became one of the most successful consumer products in history in only a few decades and became an ever-present icon of American life—embedded in the culture and promoted by a powerful industry. Unfortunately, cigarettes are one of the most dangerous consumer products ever marketed. They are highly addictive and deadly, as even the tobacco companies now concede.

If tobacco cigarettes were now being introduced into the marketplace for the first time, there is no doubt that they would be banned under any one of several consumer protection statutes. Of course, banning tobacco products is not feasible or wise. The challenge the country faces today is to develop a feasible strategy for rooting out a problem that is deeply entrenched in our economic and cultural life. There are still 45 million cigarette smokers and another 9.7 million users of other tobacco products. Most of them regret taking up the habit and struggle to quit.

The title of the committee's report probably got your attention. Let me explain what the committee means by "ending the tobacco problem." In the committee's view, the Nation's long-term goal should be to reduce tobacco use so substantially that it is no longer a significant public health problem. The blueprint outlined in the report aims to set the Nation irreversibly on a course for achieving this objective.

Optimists might say we are already well on our way to ending the problem. After all, the prevalence of smoking among adults has been cut in half—from 42 percent to 21 percent—since 1965. The prevalence of daily smoking among high school students is at its lowest level since annual monitoring began 30 years ago. An increasing proportion of the indoor environment is smoke-free. The tobacco companies are defending themselves against an increasing number of lawsuits, and state juries outraged by the industry's deceptive conduct have imposed very large punitive damage awards. Why not just keep doing what we are doing and wait for these historical currents to bring the problem to an end?

The committee concluded that maintaining our present course will not end the tobacco problem. There are already signs that the prevalence of smoking among adults is flattening and the rate of youth initiation has hovered around 20 percent for most of the past two decades even though it is down at the moment. The high rate of youth smoking is especially troubling because at least 80 percent of people

who smoke begin to do so as adolescents when they cannot fully appreciate the grip of addiction and the future risk to their health.

Moreover, quitting after decades of use is difficult. Despite the fact that 70 percent of smokers say they want to quit, the annual rate of cessation among people younger than 65 remains low.

Meanwhile, the tobacco industry is spending more than $15 billion annually marketing its products to smokers and potential smokers in ever more creative ways while public and private resources devoted to preventing smoking and helping people quit are dwindling. It will probably come as a surprise to most Americans that the states use very little of the billions of dollars they are receiving under the Master Settlement Agreement to reduce tobacco use.

Taking these realities into account, the committee believes that the annual toll of more than 400,000 smoking-related deaths will continue well into the 21st century.

It is time to change course.

For four decades, the tobacco industry successfully framed a public "debate" around the health consequences of smoking and the illegitimacy of governmental efforts to prevent or discourage people from smoking whenever and wherever they wanted. But that debate is over. The dangerous properties of tobacco and its impact on the public health are now beyond dispute and, as our report shows, aggressive measures to reduce smoking rest on a solid scientific and ethical foundation. The only debate now should be about how best to accommodate the legitimate interests of addicted smokers within a comprehensive national policy designed explicitly to reduce smoking and other forms of tobacco use.

In its blueprint, the committee offers a two-pronged strategy for putting the Nation on an irreversible course for ending the tobacco problem. This strategy involves strengthening current tobacco control measures while transforming the regulatory environment for tobacco products.

First, we have to invest in traditional tobacco control measures. The evidence is in: These interventions work. The report contains almost 100 pages documenting the effectiveness of the traditional tools of tobacco control, such as excise tax increases, indoor smoking restrictions, comprehensive state-based programs, media-based prevention campaigns, school-based programs, and cessation therapies and services. Specifically, the committee urges states to fund tobacco control programs at the level recommended by the CDC, to license all retail establishments that sell tobacco, and to ban the sale or shipment of tobacco products directly to consumers through mail order or the Internet.

The committee also urges Congress to help fund state tobacco control activities and to fund a national youth-oriented media campaign. Further, the committee recommends that all insurance, managed care, and employee benefit plans, including Medicaid and Medicare, cover reimbursement for effective smoking cessation programs as a lifetime benefit.

If all these measures were implemented with fidelity and the efforts were sustained, the committee projects that the prevalence of smoking could be cut in half, to about 10 percent by 2025. That would mean that about 11 million fewer people would be smoking in 2025 than would be the case if current trends continue.

That would be a great accomplishment, but even if the investment were sustained for 20 years, it would not end the tobacco problem. More than 25 million Americans would still be smoking. And there remains the distinct possibility that the investment will not be sustained, momentum will be lost, and adult smoking rates will be 15 percent or higher 20 years from now.

To put the Nation on a sure course for ending the tobacco problem, we also need to change the legal structure of tobacco control. Tobacco products are not ordinary consumer products. For no other lawful consumer product can it be said that the acknowledged aim of national policy is to suppress consumption altogether rather than to promote safe or responsible use. Yet, these dangerous products are essentially unregulated. Congress should enact a Federal regulatory statute that is suited to the unique history and characteristics of tobacco products.

Congress should empower the Food and Drug Administration to regulate the manufacture, marketing, and distribution of tobacco products, and should permit the states to undertake additional interventions to complement Federal regulations in all domains except packaging and product characteristics. The committee concluded that the necessary authority should be conferred on FDA because it is the Nation's preeminent public health regulatory agency and because it is the only agency with the necessary combination of experience in product regulation and scientific expertise on tobacco-related disease and nicotine addiction. Among the key elements in the committee's proposed regulatory program are graphic package warnings modeled after those required in Canada; limiting advertising to a text-only, black-and-

white format; banning any activities by tobacco companies that target youth; and aggressive regulation of retail outlets to help reduce initiation and promote cessation.

The committee also reaffirmed recommendations by a previous IOM committee (Clearing the Smoke, 2001) that FDA be empowered to assure that any claims stating or implying that novel cigarette products reduce the risks of tobacco-related disease have a scientific basis, and that it be authorized to promulgate standards for tobacco products aiming to protect the public health. The committee specifically urges FDA to explore the feasibility of gradually reducing the nicotine content of cigarettes. The FDA already regulates pharmaceutical preparations containing nicotine, such as patches, "gum" and it seems odd, to say the least, that it has no authority to regulate the much more dangerous preparation containing nicotine that makes these other preparations medically necessary.

Some people have worried that FDA regulation of tobacco would be construed by the public as government endorsement of the safety of the product. It seems highly unlikely that such a gross distortion of public understanding could occur when public and private agencies, including FDA itself, are taking aggressive steps to discourage people from using tobacco products and to help people quit. Of course, FDA should monitor public perceptions about the dangers of tobacco use as a key component of its overall surveillance programs, and should develop or require appropriate corrective communications to counter any misperceptions that may emerge concerning the health consequences of tobacco use or concerning the effects of using specific products.

I have only touched on some of the many recommendations in the committee's report. However, the specific proposals are perhaps less important than the message and design of the blueprint as a whole. In the committee's view, it is time to transform the Nation's tobacco policy. Containing the problem is no longer good enough. The Nation should commit itself to the strong and sustained measures needed to end this critical public health problem.

I would be pleased to answer your questions. Thank you.

Mr. PALLONE. Thank you. And I should mention that your full statement is submitted for the record. We just try to keep to the 5 minutes. Dr. Jacobs, again thank you for being here.

STATEMENT OF FRED JACOBS, M.D., COMMISSIONER, NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES

Dr. JACOBS. Thank you very much, Mr. Chairman. Chairman Pallone, Congressman Ferguson, distinguished members of the Subcommittee on Health, I am very honored to be here today to testify in support of H.R. 1108, the Family Smoking Prevention and Tobacco Control Act. And I am delighted that all 10 esteemed members of the New Jersey congressional delegation are cosponsors of this important legislation that would give the Food and Drug Administration the authority to regulate tobacco products.

It has been more than 40 years since the U.S. Surgeon General first alerted the Nation that smoking is hazardous to our health. And, in my view, because smoking is the Nation's leading preventable cause of death, the FDA should have had the power to regulate tobacco products 40 years ago.

There is no greater public health threat than smoking and secondhand smoke. No other product on the market today can cause death, lifelong disability, or cancer if used as directed. Last year, New Jersey implemented its landmark indoor smoke-free air act to reduce the harmful effects of secondhand smoke, and we also raised the legal age to purchase tobacco from 18 to 19 to decrease the likelihood of students in high school purchasing cigarettes. And we increased the State's cigarette excise tax for the fourth time to $1.77 per pack, the highest in the Nation at the time.

And cigarette smoking continues to decrease among New Jersey middle school and high school students, according to the 2006 New Jersey youth tobacco survey. And current smoking rates have dropped dramatically among middle school students and among high school students since 1999. During this same 7-year period, current use of any tobacco product has also significantly declined among high school students and middle school students as well.

The New Jersey Department of Health and Senior Services has worked with community-based organizations, tobacco control advocates, and New Jersey teens to encourage young people to remain smoke-free or quit smoking if they have already started.

And the effort has paid off as the declining rates of tobacco use demonstrate. So we, in the State of New Jersey, have enacted important tobacco control initiatives in ways that will prevent illness and save lives for generations.

So I come before you today not only as the commissioner of the New Jersey Department of Health and Senior Services, but as a lifelong anti-tobacco advocate, a former chairman of the New Jersey Breaths advocacy group, and a physician who specialized in pulmonary disease for more than 45 years.

I have seen firsthand in my practice in thousands of patients how tobacco ravages the body. There are more than 4,000 toxic chemicals in cigarette smoke. 69 of them are known carcinogens. Exposure to these toxic contaminants can lead to respiratory infections, asthma, emphysema, lung cancer, heart disease, stroke, and death.

In other words, smoking causes disease in nearly every organ of the body, as former U.S. Surgeon General Richard Carmona told us in 2004 when he released the new comprehensive report on smoking and health. More than 400,000 people die in the U.S. each year from tobacco-related illnesses. That has already been discussed. And that includes 11,300 in New Jersey. And up to 62,000 adult non-smokers die each year in the U.S. from the effects of secondhand smoke, according to the U.S. EPA, and this includes up to 1,800 people in New Jersey.

It is our responsibility as public officials to protect the public health and safety. An important step we can take to provide this protection is to vest the FDA with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products and to ensure effective oversight over the tobacco industry's efforts to develop, introduce, and promote products that they claim to be "less harmful."

We must use every tool in our arsenal to promote smoking cessation, to reduce the risk of tobacco-related diseases, and to prevent our young people from becoming enticed by and addicted to tobacco products. After all, the future survival of the tobacco industry depends on addicting our children.

Up until now, education, prevention, and advertising, funded in part by New Jersey's excise tax have been our strongest tools. And we all know that despite our best efforts, we have been outmatched by the advertising power, the lobbying clout, and the ingenuity of big tobacco.

Our efforts in New Jersey are continuing. We still need to expand our outreach to smokers, encouraging them to quit and edu-

cating them about the highly effective quit services that New Jersey offers. We still need to promote tobacco use prevention among our children and teens, and we need to continue offering specialized smoking cessation programs for those teens who already smoke.

And we still need to promote and enforce tobacco age of sale laws to better ensure that licensed vendors of tobacco products do not sell to minors. And we still need to extend secondhand smoke protection in the workplace to workers on the casino floors in New Jersey.

This fall, I am traveling around the State as part of a major public awareness campaign to educate students, parents, school nurses, and pediatricians about the dangers of exposing children to the toxic effects of secondhand smoke in cars and in homes. And by the end of the year, I hope to have spoken before approximately 50 groups.

I know I am getting to the end of my time, and I just want to emphasize in the last few seconds that we as public officials need more tools in our arsenal. The Nation needs the Family Smoking Prevention and Tobacco Control Act. The FDA needs premarket authority over all new tobacco products, and the FDA needs to set national standards controlling the manufacture of tobacco products and the identification of public disclosure of ingredients in such products.

I urge you to protect the public health by approving the Family Smoking Prevention and Tobacco Control Act. Thank you very much for this opportunity to testify, and, of course, I will be happy to answer any questions. Thank you, Mr. Chairman.

[The prepared statement of Dr. Jacobs follows:]

STATEMENT OF FRED M. JACOBS, M.D.

Chairman Pallone, Congressman Ferguson, distinguished members of the Subcommittee on Health, good morning.

I am honored to be here to testify in support of H.R.1108, the Family Smoking Prevention and Tobacco Control Act.

And I am delighted that ten esteemed members of New Jersey's congressional delegation are co-sponsors of this important legislation that would give the Food and Drug Administration the authority to regulate tobacco products.

It has been more than 40 years since the U.S. Surgeon General first altered the Nation that smoking is hazardous to our health.

And in my view—because smoking is the Nation's leading preventable cause of death and disability—the FDA should have had the power to regulate tobacco products 40 years ago.

There is no greater public health threat than smoking and secondhand smoke.What other product on the market today that is unregulated can cause death, life-long disability or cancer if used as directed?

Last year, New Jersey implemented its landmark indoor Smoke-Free Air Act to reduce the harmful effects of secondhand smoke.

We also raised the legal age to purchase tobacco from 18 to 19 to decrease the likelihood of high school students purchasing cigarettes, and increased the state cigarette excise tax for the fourth time. At the time, that increase made the total tax of $1.77 per pack the highest in the Nation.

I am happy to report that cigarette smoking continues to decrease among New Jersey middle-school and high-school students, according to the 2006 New Jersey Youth Tobacco Survey.

Current smoking rates have dropped from 10.5 to 3.2 percent among middle school students and from 27.6 percent to 15.8 percent among high school students since 1999.

During the same 7-year period, current use of any tobacco products, including cigars, smokeless tobacco, cigarettes, and bidis—small, hand-rolled imported cigarettes—also significantly declined from 38.9 percent to 24.5 percent among high school students and from 18.9 to 8.4 percent among middle school students.

The New Jersey Department of Health and Senior Services has worked with community-based organizations, tobacco-control advocates and New Jersey teens to encourage young people to remain smoke-free or to quit smoking if they have already started. The effort has paid off as the declining rates of tobacco use show.

So we in the State of New Jersey have enacted important tobacco-control initiatives in ways that will prevent illness and save lives for generations.

I come before you today not only as the Commissioner of the New Jersey Department of Health and Senior Services, but also as a lifelong anti-tobacco advocate, a former chairman of the New Jersey Breathes advocacy group and a physician who specialized in pulmonary diseases.

And as a physician for nearly 40 years, I have seen first hand in thousands of patients how tobacco ravages the body.

There are 4,000 toxic chemicals in cigarette smoke and 69 of them are known carcinogens. Exposure to these toxic contaminants can lead to respiratory infections, asthma, emphysema, lung cancer, heart disease and death.

In other words, smoking causes diseases in nearly every organ in the body as former U.S. Surgeon General Richard Carmona told us in 2004 when he released a new comprehensive report on smoking and health.

More than 400,000 people die in the U.S. each year from tobacco-related illnesses—including 11,300 in New Jersey. And up to 62,000 adult nonsmokers die each year in the U.S. from secondhand smoke, according to the U.S. EPA. This includes between 1,000 and 1,800 New Jersey residents.

It is our responsibility as public officials to protect the public health and safety. And an important step we can provide for the public's health is to vest the FDA with the authority to regulate the levels of tar, nicotine and other harmful components of tobacco products and to ensure effective oversight over the tobacco industry's efforts to develop, introduce and promote products that they claim to be "less harmful."

We must use every tool in our arsenal to promote smoking cessation to reduce the risk of tobacco-related diseases, and to prevent our young people from becoming enticed by and addicted to tobacco products.

Up until now, education, prevention and advertising—funded in part by New Jersey's excise tax—have been our strongest tools. And we all know that despite our best efforts, we have been outmatched by the advertising power, lobbying clout and ingenuity of Big Tobacco.

Our efforts in New Jersey are continuing. We still need to expand our outreach to smokers encouraging them to quit and educating them about the highly effective quit services that New Jersey offers: NJ Quitline, QuitNet and the Quitcenters. We still need to promote tobacco use prevention among our children and teens. We need to continue offering specialized smoking cessation programs for those teens who already smoke. We still need to promote and enforce tobacco Age of Sale laws to better ensure that licensed vendors of tobacco products do not sell to minors. And we still need to extend secondhand smoke protections in the workplace to workers on casino floors in New Jersey.

This fall, I am traveling around the state as part of a major public awareness campaign to educate, students, parents, school nurses and pediatricians about the dangers of exposing children to the toxic effects of secondhand smoke in cars and in homes. By the end of the year, I hope to have spoken before approximately 50 groups.

But we public health officials need more tools in our arsenal. This Nation needs the Family Smoking Prevention and Tobacco Control Act. The FDA needs premarket authority over all new tobacco products. The FDA needs to set national standards controlling the manufacture of tobacco products and the identification, public disclosure and amount of ingredients in such products.

I would urge you to protect the public health by approving the Family Smoking Prevention and Tobacco Control Act.

Thank you for this opportunity to testify.

I would be happy to answer any questions.

ATTACHMENT—SUMMARY OF MAJOR POINTS

There is no greater public health threat than smoking and secondhand smoke.

We must use every tool in our arsenal to promote smoking cessation in order to reduce the risk of tobacco-related diseases, and to prevent our young people from becoming enticed by and addicted to tobacco products.

It is our responsibility as public officials to protect the public health and safety. And an important step we can provide for the public's health is to vest the FDA with the authority to regulate the levels of tar, nicotine and other harmful components of tobacco products and to ensure effective oversight over the tobacco industry's efforts to develop, introduce and promote products that they claim to be "less harmful."

New Jersey has taken a number of steps over the past two years to improve indoor air and decrease the likelihood that high school students will smoke. Last year, New Jersey implemented its landmark indoor Smoke-Free Air Act to reduce the harmful effects of secondhand smoke. New Jersey also raised the legal age to purchase tobacco from 18 to 19 to decrease the likelihood of high school students purchasing cigarettes, and increased the state cigarette excise tax for the fourth time.

Mr. PALLONE. Thank you, Dr. Jacobs. We will now have 5 minutes from the members, and I will start with myself. I am going to try to get in one question for each of you, if I can, in the 5 minutes here. Let me start with Professor Bonnie.

The FDA, in their written testimony, say that H.R. 1108 would be difficult to implement, undermines the public health roles of the FDA, and does not provide adequate resources for the agency to carry out the additional responsibilities. And I wanted to ask you, professor, did the IOM committee consider these arguments? If so, how did they reach the conclusion that the FDA is the most appropriate agency to regulate tobacco products? And how do you respond to criticisms of a bill that FDA regulation of tobacco would legitimize its use?

Mr. BONNIE. Well, I apologize again for going over my time earlier, but that is also quite a large question that you just asked me.

Mr. PALLONE. I realize that.

Mr. BONNIE. The committee did think about these matters, and I think, first of all, it should be recognized this is a challenge. Regulating this product is not like regulating other products, as I think the commissioner has indicated. And it is going to take some development of scientific knowledge and regulatory attention to develop a plan for doing so.

On the other hand, I think if the FDA is adequately resourced to do the job, there is no other agency that is better suited to do it than the FDA. It would be a challenge for any agency, but I don't know what the alternative frankly is. There is no better alternative if we are going to grapple with the regulatory challenges. I don't think the alternative is to leave the product unregulated.

The question is which agency is better suited. The committee discussed this at length and concluded that the FDA, the preeminent public health regulatory agency, has the scientific expertise to do this. As was indicated earlier, it regulates various nicotine products that are made medically necessary because of the nicotine in the tobacco products.

In addition, it has tremendous range of regulatory experience that is most directly applicable to the product itself, even though it is a different kind of product, and it presents different challenges. So I think the committee did discuss this and concluded that there really is no agency that is better suited to do it.

Mr. PALLONE. I appreciate that. I think we face the same thing with every issue. Like we just finished with PDUFA and MDUFA,

and I had a lot of criticism. I said, why are you giving additional power to the FDA because they don't do a good job? And I had the same answer which is who am I going to give it to?

Mr. BONNIE. Right.

Mr. PALLONE. So I think you are right. What about the——

Mr. BONNIE. The legitimation issue?

Mr. PALLONE. Yes.

Mr. BONNIE. We did also talk about this and commented on it in the report. I think it is a compared-to-what question. I think it might be helpful if the committee were to think about what is the situation now. Here you have this product that everyone concedes is the most dangerous consumer product ever marketed, that is essentially unregulated, and where the only form of regulation, essentially from the national government, is an invisible warning on the side of the pack.

Now, meanwhile we try very hard to get people not to smoke and to convince them not to smoke. But what do people think when a product of this kind is essentially regulated in more or less a laissez-faire manner without regulation? What inferences would they draw then?

Now, let us compare it to the situation that would exist if the Congress confers the authority on the FDA that would be represented in this bill. The FDA would be directed to serve the public health interest by aggressively regulating the manufacture, distribution, and marketing of this product.

To take a very specific example, explicitly the Act would enlarge and strengthen the public health warnings. It would also confer on the agency the authority to even strengthen them further and to provide graphic warnings, pictures of which actually appear in the committee's report.

In addition, there would be strong and aggressive efforts undertaken not only by the State governments but other private agencies, as well as by the FDA and other agencies of the Federal Government to continue to aggressively try to convince people that they should not start and that they should quit.

How in the face of all of that people would draw the inference that somehow it is being approved by the FDA in the face of all those efforts that the Government would be taking essentially escapes me. I do not think that this is really a serious problem. But even if it were to happen, the FDA should also monitor and survey through surveillance mechanisms consumer perceptions not only about smoking but about specific products. And if there were to be a problem in terms of misperceptions about the health consequences of tobacco use, then obviously the FDA should respond.

Mr. PALLONE. All right. Now, I have just a little bit of time here for Mr. Jacobs. But I wanted to ask you, you already heard some criticism about States who are not using all their money from the MSA, the agreement for tobacco cessation. Did you want to respond to that? And do you think this reflects any lack of urgency at the State level? And I guess you could also, if you could, Dr. Jacobs, explain the success that New Jersey has had with some of these anti-smoking initiatives.

Dr. JACOBS. All right, thank you very much, Mr. Chairman. Well, as you know, we were spending $30 million a year. Smokeless

States advised $45 million. We did $30 million when I was chair of New Jersey Breathes. This is back to the early part of the 21st century.

And then as New Jersey's financial troubles became known to everybody—I guess they are not a secret—a decision was made a couple of governors ago to cut this down from $30 milion to $10 million. It has been increased to $11 million. That is what is spent now on our comprehensive tobacco control program in the department, which includes things like Quitline, Quitnet, the Quitcenters, that do increase the rate of quitting by a factor of tenfold over trying alone, but still very low. It is still only about 30 or 40 percent success after 6 months because nicotine is so addicting that once you start, it is very hard to stop. And, of course, you have this additional benefit from that that it is hard.

We, of course, in New Jersey and I am sure in other States as well, have priorities when it comes to limited funding. And our particular problems with the budget gap that we have been facing and will face again next year—we just had a cabinet meeting yesterday with the Governor on this issue—makes it incumbent upon us to look to the private side, to maximize the resources we have. Myself going around and speaking to all of these groups is one way to do it. We have been very successful in getting passage of the Smoke-Free Indoor Air Act. It took 10 years of effort to do that. There are certain gaps yet, but we are working on those.

I am very proud of what New Jersey has done, and I don't think we need to apologize that we haven't spent all of the money on the Tobacco Control Act, given the financial context of that money. And it doesn't excuse the Federal Government from stepping up to the plate and doing their job as well.

Mr. PALLONE. Thank you. Recognize Mr. Deal.

Mr. DEAL. Thank you. Mr. Bonnie, did your committee or your group undertake to give any estimate as to how much the cost would be in extra funding required or additional employees at FDA if they undertook the regulatory processes outlined in this legislation?

Mr. BONNIE. No, the committee did not do cost assessment of what it would take.

Mr. DEAL. In general terms, would it be a substantial investment of resources and personnel, do you think?

Mr. BONNIE. I don't know what substantial means. I think that the committee's sense was that again some agencies should have regulatory authority here. A lot of the attention has been focused on the review of new products and particularly those products that purport to reduce exposure to toxicants or to reduce risk ultimately of tobacco-related disease.

And the challenge that it would take to gear up to conduct that kind of review and then, of course, review the products that would be submitted, it obviously would be dependent on how many applications were submitted for that kind of review.

I think it should also be emphasized though that even though that particular aspect of the bill has gotten the most attention, and of course it is the most of the pages frankly of the bill, and it is built on the foundation that the Institute of Medicine laid in a 2001 report called "Clearing the Smoke"—that very, very important

pieces of this legislation aim to reduce prevalence all together rather than the harm reduction features of the bill.

And the resources that would be needed in order to implement those portions of the bill, I think, are potentially considerably less than those that would have to be devoted to this more complex regulatory challenge. Although it, in turn, depends upon how many products would then be submitted.

So I think there is a lot of guesswork here in terms of exactly what the requirements are going to be. We do know when the agency geared up in the mid 1990s to do this what the resources were to enforce—at least initially to develop and enforce the 1996 Tobacco Rule. So there is at least that kind of evidence.

But so many of these proposals essentially would involve strengthening the warnings and doing the necessary science on that and then monitoring it. Some Federal agency should be doing that. And so I think the question would be again not about FDA but the cost of that kind of regulation, which it seems to me would be strongly supported, I think, by even members of the committee that have problems with this bill.

So again I think the committee thought that the benefits of the regulation would justify whatever cost that could be incurred, but we did not do a cost assessment.

Mr. DEAL. I believe your testimony indicated there are about 45 million people who are smokers today in this society. Is that the correct figure?

Mr. BONNIE. Yes.

Mr. DEAL. We just heard in Mr. Pallone's question and some of the comments in opening statements about the fact that States are not using a significant portion of their master settlement money for efforts to have cessation of smoking among that 45 million.

What is the suggestion as to what we do with regard to those? That is a significant number of people that we shouldn't just ignore it appears to me. Did the institute, for example, take a look at that particular issue as to what should be done in that regard and how should that be done? Should it be through the master settlement funding or what other approach, if any, should be done if it appears that States like New Jersey and others are diverting more and more of those funds to purposes totally unrelated? Was there any study done on that?

Mr. BONNIE. Yes, indeed again I am glad the congressman asked this question because the committee's blueprint does go on both tracks to try to strengthen the traditional tobacco control activities that have largely been at the State and local level. And we continue to need to be doing that; although, FDA regulation and activities could supplement what is being done.

An important part of this bill is actually to remove one of the obstacles that now exist to more aggressive regulation at the State and local level by loosening the preemption and allowing the States to engage in regulations that supplement whatever Federal regulations are adopted.

With regard to the funding of State programs, the committee did carefully look at what has been happening with the master settlement funds, also looked at tobacco excise taxes because States, of course, have been increasing tobacco excise taxes in recent years,

some of which in some States have been specifically designated for supporting tobacco control programs.

There may be constitutional limitations that may prevent set-asides of that kind in all the other States. But obviously it would be possible for the States to take a look at their revenue streamsin both cases and to devote additional monies to these tobacco control programs. And we have urged them to do that.

Another problem that is related to this, of course, is the disparities in excise taxes that ends up, of course, with possible smuggling across State lines as some places begin to increase the excise taxes even more. So what we recommended that the States do is that the States that have the lower excise taxes increase their excise taxes to the level of the top quintile of the States in order to reduce this disparity. That would have the benefit of reducing consumption and also producing these additional revenues that could be used then to fund the tobacco control programs.

So we offered that kind of strategy as a way to solve a multiple number of problems as well as, of course, the suggestion that the master settlement funds could be set aside specifically to do some of these activities. And Virginia, for example, is one of the States that actually does that.

Mr. DEAL. Thank you.

Mr. PALLONE. We will continue with some of the members, but just so everyone knows we have three votes at 15 minutes followed by two 5-minutes. So I will recognize Mr. Waxman, and then we will see how much time is left.

Mr. WAXMAN. Thank you very much, Mr. Chairman. Mr. Bonnie, you answered Chairman Pallone's question about whether FDA was the appropriate place to have this regulatory authority over tobacco. Did the IOM committee look at other agencies of the Government, Federal Trade Commission, or Center for Disease Control? And why did you decide that those agencies were not appropriate?

Mr. BONNIE. Well, we did talk about other possibilities. I might say, even as a historical matter, the IOM first looked at this question in 1994 when a committee on preventing nicotine addiction in children and youth was established, and issued a report called "Growing Up Tobacco Free" which then provided some of the scientific foundation for what the FDA did subsequently in its tobacco rule.

In that committee, this issue was also addressed, and what the committee concluded at that time, again, was that it might be that there would be alternative ways to go about it and that there might be concerns about contaminating the FDA's overall mission, as Commissioner von Eschenbach has suggested. There might be concerns about undermining the agency's overall mission by giving them authority here.

And the committee at that time thought that there might be a legitimate concern there, but the alternative that we thought was most plausible then was establish a separate agency. Now, of course, I don't think there is any interest in any member of Congress to establish a new agency.

But at that point, we had looked at the regulatory agencies and thought none of the other ones would be suitable for the broad regulatory authority that would be needed. You needed a public health

regulatory agency in order to be able to do it. Now, the Consumer Product Safety Commission, I think, thinks of itself, in some respects when it is involved in injury prevention and disease prevention activities as having a public health sort of regulatory posture.

But, of course, it is a highly under-resourced agency that, I think, if we were worried about the FDA we would have all the more worries about the Consumer Products Safety Commission, which, of course, does not have the depth of regulatory experience in any of the areas that would be relevant that the FDA does.

And, of course, the Federal Trade Commission again has a particular regulatory orientation, but it is not a public health regulatory agency with all the scientific expertise, of course, that the FDA would have.

So we actually did think about the other possible regulatory agencies and though there was really no alternative to the FDA within the existing array of Federal regulatory agencies.

Mr. WAXMAN. We talk about children being most affected. What approach do you think we could take that is directed at children as opposed to adult smokers or adults who might consider to be smokers?

Mr. BONNIE. In terms of the initiatives that the Congress should take? Well, for example—well, I guess I will mention two, I think an overall part of the strategy is, in the committee's view, to have more aggressive regulation of the retail environment, not only to tighten and enforce youth access restrictions and, of course, all the States have at some level, and that there is a Federal role that is being played there now in terms of the Synar Amendment.

Not only should those activities be strengthened but the overall retail environment and the marketing that goes on in the retail environment also needs to be more strongly addressed than is now the case. That is one of the areas where preemption under existing Federal law impedes more aggressive State action.

So one of the things, the important things that the Congress could do is to get the Federal Government out of the way of efforts of the States to engage in more active regulation of the retail environment that largely would be aimed at preventing exposure of kids to pro-smoking messages in that environment.

The other factor is to license the retailers in order to be able to set up appropriate regulatory mechanisms and, of course, the tobacco rule, if it were adopted, would set up a regulatory strategy that could support the State efforts in that area.

The second thing, of course, is mass advertising. I emphasized how important the retail environment is, and we should not forget that while we are talking about regulation of advertising in magazines, for example. But the committee, of course, did look at, as the 1994 committee did, the committee did look at the messages to which youth are being exposed in various mass media, including the magazines and recommended a text-only, black and white approach to the regulation of advertising arguing and believing that that would be consistent with the constraints of the first amendment.

So reviving the provisions of the FDA tobacco rule by granting authority to the FDA to do that and directing it, as the bill does,

to reenact that regulation would be an important part of that strategy.

Mr. WAXMAN. Thank you very much for your answers to my questions and for the terrific work that the IOM did giving us these recommendations.

Mr. PALLONE. We have 9 minutes left. Did the gentlewoman from Tennessee want to ask questions now or——

Mrs. BLACKBURN. Thank you, Mr. Chairman. I probably could go ahead.

Professor Bonnie, I did have a couple of questions for you. Litigation that is currently pending against cigarette companies, if we now had FDA certifying cigarettes as being less harmful, what will that do to some of these impending lawsuits? Did you all look at that? Have you given any thought to that?

Mr. BONNIE. I am sorry, Congresswoman, my recall about what is precisely said about this in the report is not precise. We did, in recommending stronger FDA regulation, we did take into account that, of course, there would be some questions that would be raised about what the effect of that would be on various litigation and tort remedies.

And I think in general the approach that was taken is the usual approach, I think, that is reflected in other product regulation statutes, which would be that if the State tort action, as would any direct regulatory action, were incompatible with the decision that had been explicitly made by the Federal regulatory agency, that that litigation would then be preempted by the Federal rule.

But, I think, beyond that and particularly for actions that relate to fraud and deception, as an example, that those actions would survive. I think in general that was the approach that was taken. The general attitude that the committee had with regard to preemption is that the Federal rules with regard to packages and to product regulation, direct regulation of the product by the FDA basically should have preemptive effect on State action.

Mrs. BLACKBURN. OK.

Mr. BONNIE. But all other regulations should be——

Mrs. BLACKBURN. Let me ask you this then. I think Philip Morris has more patents filed than anyone else on cigarettes that are less harmful or reduced risk. And one of the things it seems in Tennessee, whether it is intellectual property in dealing with our entertainers and our song writers, copyright, patent, intellectual property protection, is always a key component for us in these discussions.

So what is going to happen if the FDA mandates a patented Philip Morris technology for a safer cigarette, an approved cigarette? Then do you have all your other manufacturers having to pay licensing fees to Philip Morris? Have we looked at that angle if you are going to get in there and micromanage that?

Mr. BONNIE. I would love to be able to answer your question, but this is not something that the committee addressed in this report.

Mrs. BLACKBURN. So you didn't think through to the end——

Mr. BONNIE. The focus of this committee report overall was on preventing, reducing use and reducing prevalence of use. The harm reduction issue and what we should do about regulating new prod-

ucts was ancillary really to the function of this particular report. Those issues were addressed in——

Mrs. BLACKBURN. Do you have a personal thought?

Mr. BONNIE. Do I personally have a thought? No, I am not adequately informed enough to be able to answer your question.

Mrs. BLACKBURN. OK, did you think activities from like DHS and CDC and all the other agencies that are working on smoking cessation and education, should they all be drawn in under the FDA?

Mr. BONNIE. Again now I am speaking on—excuse me—trying to recall the committee deliberations so that I am speaking on behalf of the committee.

Mrs. BLACKBURN. OK.

Mr. BONNIE. And I think it is accurate to say that the committee's view was that the FDA authority here would not be in lieu of all the other efforts that would be being made by other Federal agencies.

Mrs. BLACKBURN. It would be in addition to?

Mr. BONNIE. Would be in addition to those efforts and particularly those that are designed to focus on the prevention of smoking and helping people quit. Obviously there are tremendous activities that are going on elsewhere in the Federal Government.

Mrs. BLACKBURN. OK, thank you. Mr. Chairman, I have been reading Dr. Eschenbach's testimony while I have been sitting here this morning. I am disappointed that we don't have somebody from the FDA to participate in this, and I would hope that at some point we do have the opportunity to hear from him or somebody from the agency. I yield back.

Mr. PALLONE. I would just point out that we did invite them, and I don't really understand why they are not here. But we do have their written testimony at this point that we can reference. We will now stand in recess. The two of you can stay, I hope, right? We will be back in about maybe half an hour or so and continue with the questions. And so the subcommittee stands in recess until that time.

[Recess.]

Mr. PALLONE. And the next person to be recognized is our vice chair, Mr. Green, for questions.

Mr. GREEN. Thank you, Mr. Chairman. Dr. Bonnie, the IOM report discusses some of the significant successes that the tobacco control movement has had to date. Almost all of these successes though have been on the State level. The report lists increased tobacco excise taxes, and I know Texas has dramatically increased theirs. Youth access restrictions, prevention programs, media campaigns, cessation programs, grass roots community advocating, smoking restrictions such as those implemented last year in my home town.

In fact, I congratulate my city council member, Cheryl Ovalado for her leadership on that effort. And I am proud of the work that Texas is doing on the State level, the research. In fact, it is even doing it at my alma mater, University of Houston.

Yet despite all these steps, smoking rates remain high. And the IOM report recognizes we may have hit a limit on these programs' effectiveness and further recognize that almost all these steps address the demand side of the smoke equation. Dr. Bonnie, how can

congressional efforts help address the cigarette tobacco supply problem in order to lower smoking rates? And does the available force, do they adequately meet these goals?

Mr. BONNIE. Well, I guess speaking for myself, I think I would begin by enacting this bill. But just to put what you said in context, the committee was a little bit more optimistic than your statement indicated that we might, by strengthening the steps that Texas and other States have been taking, that we might continue to make a dent in smoking prevalence.

But it would have to be sustained. It would have to be strengthened and sustained over a period of time, or backsliding is a continuing risk, and particularly because obviously the tobacco industry is—unless other steps are taken—going to continue its efforts to market the product and support smoking.

So it is for two reasons then, I think, that we need to focus on the need for Federal action not to displace but to help supplement the State actions that you just referred to. So one is on the supply side. So here obviously we have a product that basically has not been regulated, and where substantial restrictions on the nature of the product or on access to it have not yet been taken.

And in order to really do that with regard to the product, you have got to have Federal action. The State can't obviously deal with alterations in the product itself.

But in addition, I don't want to underemphasize by emphasizing the need to move to supply side because everything that we have been doing so far has been on the demand side because of basically Federal exemption. So in order to move forward, we need to begin to regulate on the supply side, but also we need to strengthen the Federal role on the demand side as well.

And this bill does that, and I think it is important to emphasize the other features of this bill that would strengthen activities on the demand side, such as the strengthening of the warnings, such as the regulation of marketing and advertising by restricting efforts to promote the use of the product.

Mr. GREEN. OK, the IOM report does not advocate the banning of the tobacco products, and I know after the House passed the CHIP program with the tax increase in it, I heard from a lot of constituents who say well, if it is so bad, don't tax it, just ban it.

Some statistics I want to make sure we get into the record that I know you are familiar with. Twenty-three percent of high schoolers currently smoke. Twenty-one percent of adults—that is about 45 million smokers—currently smoke. And 400,000 Americans die every year from their own smoking, and tens of thousands more die from second hand smoke.

Smoking kills more people than alcohol, AIDS, car accidents, illegal drugs, murders, and suicides combined. And can you explain to our committee the rationale why the IOM wouldn't just recommend just banning it in the conclusion, the prohibition of tobacco products is not appropriate?

Mr. BONNIE. Well, you can imagine, we did discuss this at considerable length because of the charge that we had about developing a blueprint for the Nation to reduce tobacco use. And one of the very first issues that we were asked to address is actually to look at the question of how would we gauge the success over a period

of time of any substantial efforts that were made to reduce use and what the goal is.

And what we concluded is that at this point, we could just talk about ending the tobacco problem as a significant public health problem with a 20-year frame of reference. It might very well be that at some point further down the path, when you have significantly reduced prevalence, that you would face the question about why not take the next step.

But clearly with 45 million smokers smoking and otherwise using other products that are addictive, it is clearly not feasible to adopt a prohibition approach. Obviously you would have to take into account the cost of trying to enforce a prohibition, the inevitable development of illicit markets and so on.

So I think nobody on the committee thought that for the foreseeable future that prohibiting these products is a feasible option. So the question then is what do you do. In order to eventually move in the direction of substantially reducing the use of the product, and there are only really two choices that we have.

One is basically to continue the regulatory environment that we now have, and the other is to engage in aggressive measures to try to discourage the use of the substance and to reduce prevalence in the way that this bill proposes to do.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. PALLONE. Mr. Buyer.

Mr. BUYER. Tell my wife I had a V–8 for lunch, all right? In her attempts to keep me healthy, she is killing me.

I went down a whole laundry list of a lot of products out there on the market today that we could regulate, and we seem to be sort of focusing on tobacco. There is a statement that was made that while tobacco is the plant, humans created this product. There is no health benefit. You could say the exact same thing as trans fats and refined sugar. Humans created those things, and we get a lot of bad effects from them. You know that. Coronary heart disease, the high insulin rates, the diabetes problems that we have to deal with with regard to our diet. And so I am just letting you know I am being very cautious and careful here with regard to the regulatory impact of this bill and what type of slippery slope are we going to take.

I would endorse the harm reduction strategy, I guess, as my wife is doing to me. And we do that through individual choice. So let me ask this question of the panel. Of the tobacco products that are out there on the market today, are there some that are worse than others, or some that are better for one's health than others?

Dr. JACOBS. Well, obviously there is a magnitude of difference in terms of the use and the abuse of cigarette smoking, and things that you inhale. Where you inhale the smoke itself is obviously more dangerous. But it is not like using other tobacco products is safe. So all of them have a risk.

The difference between tobacco products and all of the other things that you mention is that tobacco products are addicting, and they are heavily marketed because of their addicting potential. So it is difficult to stop, and you have documented evidence of the danger, particularly when it is marketed to underage kids who can't

really make a rational choice about it based on their own life experience.

So whether you deal with trans fats or refined sugars or all the rest of the items you mentioned, there, I think, an educational program is at the basis of where that ought to be addressed. And that is what we are doing in New Jersey on childhood obesity and secondhand smoke in homes. We are not going to regulate secondhand smoke in homes. We are not going to tell parents you can't smoke in your home when there are kids present. How are we going to enforce that?

But I believe strongly that if we educate people about what their conduct does in terms of harmful impact on their own children, that they will make a legitimate effort to alter that kind of conduct, such as smoking in homes and cars.

So when it comes to the specific answer to the question, which tobacco products are safer than others, there are no safe tobacco products. Some are more dangerous than others, and if we want to do a risk reduction strategy and pick the low-hanging fruit, you would go directly to cigarette smoking because that is the one that has the greatest addiction potential and the greatest harm.

Mr. BUYER. One of the challenges I have of picking FDA—and I know, Mr. Bonnie, you had to go through this decision-making process. When you look at the core mission of FDA and that they, by way of their culture, are focusing on the efficacy and safety of drugs and devices, that the culture is all about safety and health of a society. And now if we are going to take a tobacco product, and based on the testimony just now given by Dr. Jacobs, it is making choices among harm.

All right, so this is a different mindset, and so if it is about prevention and its education, there are some steps that we can take. And so let me ask you is smokeless tobacco, would that be a useful step to advocate and permit sampling of such a product if we are trying to wean people off of cigarettes?

Mr. BONNIE. You are asking me this question?

Mr. BUYER. Yes.

Mr. BONNIE. All right, well, I agree with everything that Dr. Jacobs said. So the problem is that all of these products are uniquely dangerous and are addictive. And so the slope is not as slippery, I think, as you were suggesting. And we also have to add that more than 80 percent of the users of any of these products began when they are kids, when they then not in a position really to appreciate the grip of addiction.

So for all those reasons, we need to regulate these products in order to continue to reduce the amazingly large public health——

Mr. BUYER. Let us get to the sampling question.

Mr. BONNIE. OK.

Mr. BUYER. Would you want to permit sampling as part of a harm reduction strategy to move them from cigarettes to smokeless than not at all?

Mr. BONNIE. So what a regulatory agency needs to do, and the overall goal of regulation, is to prevent and discourage the use of all these products because that is what the public health demands. We also then have to deal with the issue of when people are using the products. What should be done as a matter of regulatory philos-

ophy in order to help them make choices that will reduce the danger to them.

And I think part of the new frontier, frankly, of tobacco control is the overall issue of harm reduction and whether or not people who cannot quit should have alternatives. But to say that alternative choices will be available is not to say that all of these products would not be regulated in order to protect the public health, and it certainly is not going to be, I don't think, would be the goal of any regulatory agency to encourage people to use a dangerous and addictive product.

So I don't think that the regulatory agency, if you give FDA the authority, is going to be in the position of basically announcing to the public that our overall goal is to encourage people to use a smokeless tobacco, as an example.

The goal is going to be to regulate all of these products in order to discourage people from using them to begin with and to the extent that it could be done, to reduce the dangers associated with the use of those products.

But I can't imagine that it is going to become part of the agency's objective for exactly the reason that you said: to encourage people to think that there is a safe alternative in using these products.

Mr. PALLONE. Thank you. I recognize Mr. Gordon for a nanimous consent request.

Mr. GORDON. Thank you, Mr. Chairman. I have a bill I wish to introduce. I am involved in a hearing in another committee, like a lot of folks. So let me just quickly say I ask unanimous consent to submit a statement by the U.S. Smokeless Tobacco Company, a constituent of mine, to be included as a part of the hearing record.

Mr. PALLONE. So ordered.

Mr. GORDON. Thank you, Mr. Chairman.

Mr. PALLONE. And now I recognize the gentlewoman from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman. I want to thank both of you gentlemen for coming. You are both fabulous witnesses, and it is welcome testimony that we are hearing.

I think I will start with you, Dr. Bonnie, and chime in, Dr. Jacobs. Some people in this hearing and in general argue that the Federal Government really doesn't need to regulate tobacco because States and local governments are doing it.

And I think, Mr. Bonnie, you mentioned the Federal preemption issue a little while ago. I wanted to talk to you about my home State of Colorado because we are one of three States joining Maine and Delaware who have actually funded a tobacco prevention and cessation program at levels recommended by the CDC. And we have a comprehensive smoke-free bill that the legislature passed which prohibits smoking in workplaces, restaurants, bars, casinos.

But Colorado is not allowed to prohibit billboards with tobacco advertisements from being posted next door to a school. Is that what you are talking about, why we need Federal regulatory authority?

Mr. BONNIE. Yes.

Ms. DEGETTE. And under this legislation, would the FDA be able to issue regulations that could control the types of advertising that I am talking about?

Mr. BONNIE. I think under this legislation not only would FDA have the authority, subject of course to the constitutional constraints of the first amendment, which we could also discuss, but not only would FDA have the authority to regulate the advertising and marketing of the products, that as long as it was compatible with Federal regulation, the States would also have the authority to engage in——

Ms. DEGETTE. And I think you concluded—and, Dr. Jacobs, I am sure you would concur—that the main problem we have right now in terms of U.S. smoking is that young people are continuing to smoke and tobacco companies are continuing to target young people, correct?

Dr. JACOBS. Yes, that is right. That is not to say that you can't have an impact on the rate at which young people smoke. And New Jersey has done that. I left the numbers out of my oral testimony for the sake of time, but you have it in the written material.

So that in our State, for instance, we have a group called Rebel. It is a national movement. It is called Reaching Everyone by Exposing Lies. It is a high school group. There are 6,000 of these young kids in that group, about 300 schools. And they are the army that get out there. But once you start smoking, it would be helpful if we could ask, require tobacco companies to reduce nicotine content in cigarettes.

I think that if there is dose response curve to addiction and you move down that dose response curve, logic would tell us it is easier to wean someone off of a substance to which they have a lower addiction potential than a higher addiction potential. And the recent data of Massachusetts——

Ms. DEGETTE. Let me stop you, and I apologize. I don't have much time. That is a good thing to do, but the better thing to do would be to try to prevent them from becoming addicted to tobacco in the first place.

Dr. JACOBS. Absolutely.

Ms. DEGETTE. And part of that would be eliminating advertisements targeted directly to young people.

Dr. JACOBS. But these, of course, are not mutually exclusive goals.

Ms. DEGETTE. Right, exactly. We need to do it all. Now, I want to ask you about something I mentioned briefly in my opening statement. I told Mr. Waxman while we were on the floor voting I may be actually spurred to reintroduce this bill by this hearing. Several sessions of Congress, I introduced this legislation that I came up with. Right now, under Federal law, we tell States that they will lose Federal aid if they don't raise their drinking age to 21.

So this bill I introduced said it is exactly the same bill, but for tobacco. That if States raise their age to which retailers could sell tobacco to 21, that would seem to me to really eliminate some of the problem of these young people getting addicted. What do you think about that kind of idea?

Dr. JACOBS. We did that. Well, we didn't go to 21. We went from 18 to 19 in New Jersey to get the age of sale past high school.

Ms. DEGETTE. Right.

Dr. JACOBS. That was the idea. From 19 to 21, I think fine, but I think that was the idea. Enforcing the tobacco age of sale laws is an ongoing requirement. It is a bit of a challenge. It does take resources to do that.

Ms. DEGETTE. Right, but we do it with alcohol, and it is a challenge. But we do it. And my concept in doing this bill to age 21 is it would make it consistent with alcohol. And then instead of targeting 14-year-olds, like they do now, because the age is 18, if it is 21, maybe they are only targeting 18-year-olds. And that at least helps you capture high school students, which, I think, are a really vulnerable target group. Mr. Bonnie, did you have any comment on that? I know it is probably not part of your book.

Mr. BONNIE. Thank you. It is not. The committee did not take a position on the issue that you have just mentioned, but my own personal view would be I would be careful about this. On the one hand, as you have said, I think in terms of targeting, there is no doubt that the young adult audience of potential consumers is receiving a lot of industry attention, let us say 18 to 24 years old. And there is some indication that initiation rates among that group are not falling and may even be increasing. So it is certainly a concern from a public health standpoint.

On the other hand, I do think, as Dr. Jacobs said, that we have to worry about the practical issues of enforcement, of encouraging compliance and then promoting enforcement. And, of course, we focus on the retail outlets in terms of commercial distribution, but a lot of the distribution, of course, occurs outside the retail outlets in terms of social sources.

So I think the issue is a bit of a complicated question. My own personal advice to you would be that this is one area where local options should be available. So if the Federal Government sets the floor, as the tobacco rule did, at 18, you should allow State and local governments to experiment with higher ages, just as Dr. Jacobs said. So that would be my personal view about this matter.

Ms. DEGETTE. OK, thank you. Thanks so much for that advice.

Mr. PALLONE. The gentlewoman from California.

Mrs. CAPPS. By default I concede. Thank you both for your excellent testimony, and there seems to be an agreement in the communities now that anti-smoking campaigns are finding it difficult to compete with the purchasing power of big tobacco advertising. I want to ask each of you a different question relating to this overall topic.

Dr. Bonnie, could you please touch on what the committees found out about the effectiveness of tobacco companies' advertising? The companies argue that the goal of advertising is simply to attract current smokers to their brand, like brand competition. But I would argue that they are trying to go after new smokers as well. And I want to know your thoughts on this, and especially did you conduct any studies during your study of this overall topic specifically on the effect of advertising on children and teens?

Mr. BONNIE. Well, the committee certainly looked very carefully into the issue that you are raising. The committee, of course, did not do studies of its own.

Mrs. CAPPS. I know.

Mr. BONNIE. It reviewed the available evidence, and I think there is, I think the committee had no doubt that the effect of advertising is not just simply about brand changes. That the advertising and marketing of the products has the effect of, if not the purpose of, increasing the overall demand for the product by recruiting new users, whatever the age that they may be, and also to have the effect of encouraging current smokers to continue to smoke. And that is, I think, an often overlooked feature of this just in terms of the various messages that are being conveyed by the products by the marketing.

So I think that the committee's view, based on that evidence, was that a essential component of an overall strategy that is designed to reduce the prevalence of smoking has got to be to restrict the marketing and advertising of these products, that by its nature is designed to encourage consumption.

Mrs. CAPPS. Right, thank you. I appreciate particularly in your testimony that you talked about the vulnerability of teenagers and young children because of their lack of decisionmaking in terms of long-term effects and that kind of thing. And that also this is by nature the new market. The younger and younger, the lifespan is going to be extremely lucrative for a tobacco company and also for the adjunct advertising mechanisms that they use.

I really appreciate, Dr. Jacobs, your being here from the perspective of someone out there in the trenches, if you will, doing this work at the State level. We need the cooperation to reduce and get rid of this illness-causing habit. We need to employ every level of grass roots to the non-profit sector to, I think, I believe regulatory bodies.

I wonder if you could discuss how this particular bill, H.R. 1108, might help your State to be more effective in the kind of anti-smoking messages that actually compete with deceptive advertising. You are trying to get out there a message that runs counter to what the tobacco companies are doing through their lucrative advertising medium.

Do you think the passage of this bill could, for example, you are concerned about your young women, as I am. Do you think there would be a way to prevent publications from using ads like those for Camel No. 9 that I displayed?

Dr. JACOBS. I would hope so. Of course, Professor Bonnie is the expert on the first amendment issues here, but leaving that aside for a second, if it could be done, so that truthful advertising that wasn't deliberately targeted to a youthful age group that must be targeted by these companies if they are to survive as corporations.

Mrs. CAPPS. Exactly.

Dr. JACOBS. I think we lose sight of that. Their corporate survival depends on their addicting our young people. That is simply the fact. So we need to do that. The other thing, of course, is to the extent that we have greater uniformity in the States, we will have less problem with importing cigarettes and other items that may be a different composition from Delaware and Pennsylvania and New York, which are freely transported now in and out of New Jersey.

Mrs. CAPPS. Thank you very much. Any other comments from——

Mr. BONNIE. I would like to comment on this first amendment question if you still have the time.

Mrs. CAPPS. I have 23 seconds. They are all yours.

Mr. BONNIE. It is a very important part of the bill, and questions have been raised about the constitutionality. The committee again looked carefully at this, and the view that we have taken, which I believe to be an accurate description of the law, is that a text-only black and white restriction of the kind that was in the 1996 and would be revived here, is fully compatible with the first amendment because it protects the core first amendment interest that users, current users of tobacco products, and the companies that are communicating with them have, in receiving information about the product, information about price, information about contents, and we end up with products that purport to reduce exposure to dangerous substances or to reduce risk, to receive information about the relative risk of the products. It is about receiving information, and a text-only, black and white format for advertising full protects the right to receive information.

What it gets rid of is the other messages that are being conveyed implicitly about what are thought to be, by the companies, benefits of using the product or perceived benefits of using the product through color and through images. And that would be restricted, and that is particularly dangerous, of course, with children.

Mrs. CAPPS. Thank you. Just to hone in on that point, you don't see constitutionally if this bill passes and all the ifs that the FDA could then regulate against such kind of advertising as I demonstrated in the posters?

Mr. BONNIE. That is the committee's view, and I think eventually, if and when, and certainly it will go to the Supreme Court if it is adopted. My view is that if this case is properly and well argued that—based on current case law at least—that it would survive constitutional review.

Mrs. CAPPS. Thank you very much. I yield back.

Mr. PALLONE. Thank you. Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. It is great to have a panel here with two lawyers and a doctor, even if one of them is the same person. That is a fascinating discussion about the first amendment. I never really thought about it in those terms, so the first amendment would apply to a PDF file that it is black and white and not to a larger font size, a bolding or italicized print. Maybe we ought to make that applicable to political advertising, and our lives would all be a lot easier over the next 2 years. What do you think? In political advertising, do you think we ever use that penumbra of psychological influences in political advertising to try to sway the voting public one way or the other?

Let me ask a question. I apologize for being gone during most of the question and answer period. You heard my comments as the hearing got underway this morning. Dr. Jacobs, in your testimony, the statement "we must use every tool in our arsenal to promote smoking cessation." And I think we probably both agree the biggest tool we have in our arsenal is don't ever start. It is the most effective way to lead to smoking cessation. But why do we even allow it? Why do we even have cigarettes? Why do we even allow them

to be a legal entity in this country? If we are really serious about using every tool in the arsenal, wouldn't we just outlaw cigarettes?

Dr. JACOBS. I guess if that was a feasible idea. Certainly from a public health standpoint it is a toxic, class A carcinogen. We would outlaw it the same way you outlaw the free sprinkling of asbestos fibers around the room. It is the same thing, but I think, as Professor Bonnie has pointed out in the IOM report, with 45 million addicted people in the United States right now, there would be substantial resources that would have to be brought to bear on that in order to accommodate that particular large population.

I think from a public health standpoint, I would like to get rid of cigarettes. They don't do any good to anybody except the people who sell them, I guess.

Mr. BURGESS. Well, they do us a lot of good because of the tax revenue that we collect off of them.

Dr. JACOBS. They do, and, you know, it is an interesting point you raise because in one of the budget hearings we have at the legislature in New Jersey, someone asked me that very question. They said, Dr. Jacobs, you are advocating people stopping smoking. What happens if they all stop and the hundreds of millions of revenue we have are gone? What are you saying about that?

Well, listen, you are talking to the chief public health officer in the State. My goal is to stop people from smoking. If we do it, you will have to find the money some place else, but you are never going to get me to say we are going to encourage people to keep smoking because we need the money. That is simply not a balance we can have.

That is not to say that the revenue isn't put to important uses. It is. But you don't use money to fund the functions of government by going ahead and killing people who are actually using that particular substance. So I think you cannot make that argument.

Mr. BURGESS. Well, on the issue of using every tool in the arsenal to promote smoking cessation, should we earmark a portion of the funds that we collect from the tobacco companies to really aggressive steps toward alleviating that burden of addiction from the 47 million people who are so addicted? We have new medications such as Chantix, the new medication that is out there that apparently has the ability to block at the receptor level, so a very powerful tool now that is within the hands of practitioners.

Yet I will tell you, as a practitioner, as an OB/GYN practitioner, if I told someone they need to stop smoking, very rarely would I be able to get them into a program that their insurance company would participate with them and lead them to a state of smoking cessation.

So to say to the smoking public we want you to stop and not provide them the tools to stop when we are collecting money from the company that we want to help them stop purchasing, it just seems to me that we should really be digging down and aggressively promoting smoking cessation activities rather than having the FDA regulate tobacco.

Again, I raise the question that was partly in jest, but partly, if we are talking about a delivery system, crystal meth is—I mean it is an ideal delivery system if your goal is to get high from methamphetamine. They don't rely on any penumbra of advertising ac-

tivities. They just simply make a much more addictive product, put it out there, and it sells itself.

Well, why don't we do something to help break that cycle of addiction, and rather than focusing on the FDA regulating tobacco, why don't we put those monies toward smoking cessation activities? It would seem to be a much more judicious use of our time and effort.

We just gave the FDA enormous new power. Probably not in the last 40 years has the FDA had the tools at their disposal that we just gave them last month, and now we are going to saddle them with something that is virtually impossible. And on top of that, it just thwarts their mission at every turn.

Mr. BONNIE. Well, I think that—No. 1, I don't think either of these things are mutually exclusive. I think we should be doing both. And No. 2, I don't share your philosophy that the FDA is somehow outgunned in all of this or underresourced. If they are underresourced, then I think that there is a remedy for that in the Congress.

If you have a Food and Drug Administration that has a goal and a mission, then they have to be adequately resourced and funded to do that goal. And if they are not adequately funded and resourced, then it is, I think, the responsibility of the Congress to see to it that they are. Not just in this, but in everything else they do.

Mr. BURGESS. Correct, but, Doctor, their mission is to see that the drug supply and the food supply in this country is safe, that drugs are safe and effective. You can't argue that nicotine is ever going to be safe. It is always effective in that it causes addiction, but it is never going to be safe.

Mr. BONNIE. Well, I don't disagree with that. I don't think it is ever going to be safe in the present form certainly. And I don't know what the future will bring in terms of nicotine therapy, but neither do you. We just don't know.

Mr. BURGESS. I would be willing to live without it as a country. That is a trade-off I would readily accept.

Mr. BONNIE. But I don't know that at this stage of the game that we can make the kind of choice, particularly the comparison with crystal meth. Crystal meth, of course, is not a legal product. I know you are saying this in jest, but this is not a legal product. Tobacco cigarettes are a legal product. They are sold by legal outlets after being manufactured legally in the United States, with certain age groups excepted.

That being the case, there is a responsibility, if you are authorizing the sale in a legal structure, to at least have some relatively fair level playing field between those who are looking to improve the public's health by reducing consumption and those who have a corporate responsibility to increase consumption. And that is not a level playing field now.

Mr. PALLONE. We are 2 minutes over so I will—let me move on.

Mr. BURGESS. But Mr. Bonnie sat here faithfully——

Mr. BONNIE. All right, quick points. Obviously the regulatory criteria would be different under this bill and not safe and effective. There is no reason that a single agency can't have different responsibilities where the regulatory criteria are different in order to deal

with different types of social problems. And I do think that a public health agency's mission could accomplish both of those things.

Mr. BURGESS. But it could just as well be accomplished by the Federal Trade Commission and not even come under the preview——

Mr. BONNIE. Well, I think a public health agency like the FDA has the public health expertise to do it that the FTC would not have. Second, on the dependency on the money, which I think you are right, that this is one of the problems of relying upon the tobacco excise taxes to fund other social programs.

I think we would never end up reducing smoking substantially overnight and presenting this problem of getting off the addiction that public agencies have to tobacco revenues. It would obviously be over a longer period of time if we are aggressively implementing a policy to reduce the prevalence of smoking. And clearly State agencies can project what the revenues and can become less dependent on.

Mr. BURGESS. I don't disagree with him, but I think it would be a lot more aggressive——

Mr. PALLONE. Gentlemen, we are up to 3 minutes. I got to cut you off here, gentlemen. Let us move on to the next question. Mr. Engel of New York.

Mr. ENGEL. Well, thank you, Mr. Chairman. I want to thank you for holding this hearing. It is very important, and I am proud to be a cosponsor of this bill. It just boggles my mind that so many people still don't understand the damage that they do to their health and their life by smoking. And I think it just makes sense to give the FDA the broad regulatory authority over manufacturing, distribution, and marketing of the use of tobacco products. I just think it is good, plain common sense, and we ought to pass this bill forthwith.

Mr. Bonnie, this book that we have here, the IOM discusses some of the concerns raised by certain portions of the public health community, including some we will hear in our next panel of witnesses. The committee outlines of the concerns, and I am going to quote it. It is that quote that "the proposed regulatory framework making reduced exposure or reduced harm claims in section 911 is too demanding and may impede the development of reduced exposure products by stifling innovation and retarding competition with safe products."

And that is a quote; however, ultimately the IOM concludes, and I am going to quote it again "the fears about this legislation are overstated and that Federal tobacco product regulation is an essential element of the long-term strategy for achieving substantial reductions in tobacco use, in tobacco-related morbidity and mortality." That is a quote, so you came to that conclusion even after looking at the other side. So can you please explain how and why the IOM reached its conclusion?

Mr. BONNIE. All right, so the IOM, as you quoted, considered the objections that have been raised to giving the agency Federal regulatory authority. And again I want to emphasize that there is a whole series of aspects of this bill that do not involve—that give the agency authority over the manufacture, marketing, and distribution of these products, that do not involve the issue of sup-

posed risk reduction products and that are essential components of a strategy designed to reduce tobacco use.

Again I mention the issue of strengthening warnings and regulating the retail environment. Those are very, very important parts of this bill.

With regard to the issue of regulation of supposedly reduced risk products, the committee consulted not only the members who have economics background, but actually consulted other economists to think about what the potential incentive effects could be for adopting a regulatory program, such as that is envisioned in the bill in light of the criteria.

And the argument has been that the criteria by requiring scientific evidence to support the claims that they want to make, that the criteria are so demanding that it would lock in benefits that some companies may now have, and it would discourage competition because of what would have to be done in order to substantiate those claims. The committee's view was that the claims need to be substantiated in order to avoid the kind of disaster that we had with regard to the light and low tar cigarettes in the past where people were mislead into believing that they were actually smoking a safer product.

So substantiation of the claims is a non-negotiable item. They should be substantiated, or they should not be made, and then the issue is well how demanding is that going to be in terms of encouraging innovation. And the committee's conclusion was that actually this might liberate more competition, particularly by niche small companies that were actually trying to develop these products rather than deter it.

Mr. ENGEL. Thank you. Let me ask you about another recommendation that the committee has recommended. All insurance, managed care, and employee benefits, including Medicare and Medicaid, cover reimbursement for effective smoking cessation programs as a lifetime benefit. Did the committee look at the cost associated with this recommendation?

Mr. BONNIE. I think yes. With regard to the recommendations about prevention and cessation activities, I think that here is a situation where in every case when you look at the cost effectiveness of the intervention to reduce prevalence by reducing initiation and my promoting cessation. The public health benefits are so astounding for doing so that they do, in every case, substantially outweigh the costs of actually engaging in these activities.

And cessation is actually, as Congressman Burgess said earlier, the benefits of cessation are very, very, well established if you can actually increase the demand for cessation and to provide the reimbursement that people need in order to be able to do it. It is the most undeveloped part of our tobacco control strategy. So we definitely looked at the costs of those interventions.

Mr. ENGEL. Thank you. Makes sense to me. Dr. Jacobs, I am wondering if I can ask you one quick question. Is there anything in this bill that would impede the progress of States in their attempts to decrease the prevalence of tobacco use?

Dr. JACOBS. I don't think so. I think the bill itself will, of course, give us more tools in terms of having the Federal Government weigh in on this issue in a more level comprehensive way, so that

those States that don't have to begin at ground zero. You have already set a floor of regulation, which you can, if you need to, you can add to and build on. I think that would be the main value for us.

Mr. ENGEL. OK, thank you very much. Thank you, Mr. Chairman.

Mr. BUYER. Mr. Chairman, in a question I had for Mr. Bonnie in the discussion with regard to harm reduction strategy, we had the discussion about reduced risk products and components and the need to educate about alternatives. I had asked the question on sampling but never received a response with regard to whether sampling should be permitted or not. And I would ask that he address that. Is that permitted, Mr. Chairman?

Mr. PALLONE. Let me say the following. I didn't realize that Mr. Engel still had the time.

Mr. ENGEL. No, I am finished, Mr. Chairman.

Mr. PALLONE. You are? Thank you. Now, you want to ask an additional question?

Mr. BUYER. No, what I am asking, Mr. Chairman, is with regard to the ban on sampling that is in the bill, I had asked Mr. Bonnie about sampling, and he was not responsive to that. And I had asked that he be given time to be responsive.

Mr. PALLONE. If you would quickly, because we have to move on.

Mr. BONNIE. All right. Well, I think actually it will be very quick because the provision of the bill that you are mentioning is what now? What is the provision of the bill?

Mr. BUYER. That does not permit sampling as part of a harm reduction strategy. You testified that we should, with regard to regulatory scheme or schematic, permit alternatives out there with regard to products and components for people to transition from cigarettes to something else. If we are going to do that, shouldn't we permit sampling so they know what to go toward?

Mr. BONNIE. Mr. Chairman, I would be happy to respond to this question in writing afterwards.

Mr. PALLONE. Sure, that would be great. And let me mention to——

Mr. BUYER. We still don't get an answer.

Mr. PALLONE. Well, he is going to——

Mr. BONNIE. Well, the committee actually did not address this question at all.

Mr. PALLONE. Yes, we would be happy to have you——

Mr. BONNIE. And I would be happy to do it on my own in writing.

Mr. PALLONE. And let me also mention that you may get additional questions from other committee members within the next 10 days or so that we would ask you to respond to as well. Thank you both. I apologize to Dr. Jacobs. I didn't get an opportunity to talk to you at all today because I would have liked that opportunity. But I came in here. It has been real busy, so hopefully I will give you a call, and I can come to Trenton in the near future.

Dr. JACOBS. Any time, Mr. Chairman.

Mr. PALLONE. Thank you. Thank you, both. And I would ask the next panel to come forward. OK, I think we are ready to begin. I want to thank you all for being here. Let me just introduce everybody. I will start on my left. I guess there is a slight change be-

cause Dr. Blum maybe has to leave early. First we have Dr. Alan Blum, who is a professor, and Wallace Endowed Chair in Family Medicine at the College Community Health Sciences for the University of Alabama, where he is also director of the Center for Study of Tobacco in Society. And then we have Dr. Risa Lavisso-Mourey, who is president and CEO of the Robert Wood Johnson Foundation in Princeton, New Jersey. And then we have Scott Ballin who is an attorney, steering committee member for the Alliance for Health, Economic, and Agricultural Development in Washington. Mr. James Winkler, general secretary of the General Board of Church and Society for the United Methodist Church. Mr. Henry Amour who is president and CEO of the National Association of Convenience Stores, and Dr. Jack Hemmingfield, who is vice-president for Research and Health Policy, Piney Associates in Bethesda, Maryland. And then last is Mr. William Corr, who is executive director of the Campaign for Tobacco-Free Kids. And again I would say we ask you to limit your comments to 5 minutes. Your written statements will be made part of the record in their entirety, and we may ask additional questions in writing for you afterwards within 10 days or so. So we will start with Dr. Blum.

STATEMENT OF ALAN BLUM, M.D., PROFESSOR, WALLACE ENDOWED CHAIR AND DIRECTOR, THE CENTER FOR STUDY OF TOBACCO, SOCIETY, COLLEGE OF COMMUNITY HEALTH SCIENCES, UNIVERSITY OF ALABAMA

Dr. BLUM. Thank you, Mr. Chairman, members of the committee. The mission of the FDA is to ensure the safety of medications that treat disease, not substances that cause it. I feel strongly as a practicing family physician who has devoted the past 30 years to curbing the smoking pandemic, perhaps a longer continuous period than anyone else in this room, that an overstressed FDA is the wrong agency at the wrong time to regulate tobacco products.

And I am proud this afternoon to report that yesterday the congress of delegates of the American Academy of Family Physicians, the largest subspecialty medical organization in the United States, considered the arguments against and for the bill and decided to withdrawal its endorsement of this bill, pending strengthening and amendments.

By having to promulgate manufacturing and health standards for cigarettes under H.R. 1108, the FDA will be communicating the perception that cigarettes are now safer to smoke. Since smoking prevalence is directly proportional to the degree of perceived harm from smoking, FDA sanction of cigarettes may lead to an increase in smoking prevalence.

The tobacco industry will most certainly take advantage of this bill to tell consumers through TV, newspapers, and the Internet that cigarettes are now regulated by the same agency that oversees our food and medicine.

Indeed, Philip Morris, maker of the world's top selling cigarette, Marlboro, is already testing the waters. It is setting a new standard for chutzpah by enlisting the Nation's doctors and spreading the company's deceitful propaganda. For the first time in more than half a century, a cigarette maker is communicating directly to physicians by means of personal letters offering to supply unlim-

ited copies of "If You Decide to Quit Smoking" a 52-page booklet that avoids mention of the word addiction, contains a total of three sentences that refer to diseases caused by smoking, and includes 17 color photographs, all of healthy, smiling people, and none of persons made ill from smoking or of their diseased hearts or lungs.

Television ads for Philip Morris's Youth Smoking Prevention Campaign have been condemned as cynical and ineffective by the very health organizations that have joined with Philip Morris in backing this bill. Yet the company touts this program and its recruitment of college students at career fairs on university campuses across the country and half-page ads such as this in the campus newspaper that I am from, even though the only jobs it offers these students are on the Marlboro sales team, delivering fresh cigarettes to supermarkets, convenience stores, pharmacies, and bars.

A student at one of these career fairs told me that Philip Morris is a great company. They don't just sell cigarettes. They help prevent smoking.

Such tactics aimed at burnishing the company's nicotine-stained image among doctors, parents, college students, and university officials will flourish with the enactment of this bill. FDA regulation of tobacco products under H.R. 1108 would provide an unprecedented, unmerited legitimacy to cigarette makers, sending the message to consumers that cigarettes, however problematic, are now Government sanctioned.

William Godshall, the most effective tobacco control advocate ever to work for the American Cancer Society, cites the more than 400 cigarette brand products on the U.S. market today, each with differing amounts of chemical additives and thousands of poisons in the smoke. He rightly questions the feasibility of correlating smoking-related deaths and diseases with the brands of cigarettes consumed, which the FDA would have to do if it is to make any valid assessment and recommendation about individual tobacco products.

As Dr. Michael Siegel at Boston University's School of Public Health has pointed out, the public is simply not aware that there are over 4,000 poisons in cigarette smoke, including more than 40 cancer causers. If a consumer were informed that one such poison or two carcinogens had been reduced or removed from a cigarette brand, as Philip Morris intends to do, then he or she is going to infer that the problem is being taken care of or even solved. This ignores the dozens of other cancer causers in the cigarette and the other diseases cigarettes cause.

In short, there is no evidence that tinkering with the levels of various components of cigarette smoke will result in a safer product, yet this is precisely the strategy that Philip Morris is counting on through H.R. 1108 to perpetuate the myth that research can discover a safe cigarette.

Assisted by the University of Virginia and Duke University, which have taken over $40 million from Philip Morris, the company is on track in its plan to turn back the clock half a century to the Frank Statement to Cigarette Smokers issued by the tobacco industry in 1954, which pledged aid and assistance to the research effort into all phases of tobacco use and health.

At this year's annual shareholders meeting of Philip Morris, company CEO Louis Camilleri praised this bill and promised that the company's new $350 million research center will solve societal problems raised by tobacco.

FDA regulation, a new safe cigarette research center, lucrative research grants to a docile, academic community are the sheep's clothing that this wolf has donned to deceive the public and to ensure Marlboro's continued sale success.

Does anyone with even a rudimentary knowledge of public health believe in the wisdom of yet another quest for a safe cigarette? The only safe cigarette is an invisible cigarette.

Tobacco control advocate David Sweanor goes further, arguing that Philip Morris is trying to preserve the status quo by preventing effective competition from noncombustible tobacco products.

Lastly, primary prevention, not taking up cigarettes in the first place, is universally agreed upon as the answer to end the tobacco pandemic. Reducing demand through paid mass media education is the cornerstone of primary prevention, yet nothing in this bill addresses or encourages major multimedia anti-smoking campaigns. Indeed, by creating the impression that the cigarette pandemic is being addressed by the Federal Government, this bill could be a disincentive for State and local governments to devote additional anti-smoking resources. We need to fight smoke with fire, not symbols, not ineffective bills crafted with the secretive input from America's biggest cigarette company.

This bill is a godsend for Philip Morris. No one else will benefit.

[The prepared statement of Dr. Blum follows:]

STATEMENT OF ALAN BLUM, M.D.

The mission of the Food and Drug Administration (FDA) is to ensure product safety and to approve medications that treat disease, not substances that cause it. By all accounts, the FDA is struggling with the challenge of regulating an expanding universe of products and threats. It is the wrong agency at the wrong time to undertake oversight of tobacco products.

By having to promulgate health standards for cigarettes, the FDA will be communicating the perception that they are now safer to smoke. Thus H.R. 1108 will increase doubt among consumers that cigarette smoking is truly injurious and lethal.

The tobacco industry will most assuredly take advantage of this bill to remind consumers through the broadcast and print media and the internet that cigarettes are now regulated by the same agency that oversees the safety of our food and medicine.

Industry leader Philip Morris, maker of the world's top-selling cigarette, Marlboro, is already testing the waters. It's setting a new standard for chutzpah, by enlisting the Nation's doctors in spreading the company's deceitful propaganda. For the first time in more than half a century, the cigarette giant is communicating directly to physicians by means of personal letters offering to supply their waiting rooms with unlimited quantities of If you decide to quit smoking—-a 52-page booklet that avoids mention of the word "addiction," contains a total of three sentences that refer to diseases caused by smoking, and includes 17 color photographs, all of healthy, smiling 20-somethings and none of persons made ill from smoking or of their diseased hearts and lungs.

TV ads for Philip Morris' Youth Smoking Prevention campaign have been rightly condemned as cynical and ineffective by some of the very health organizations that have joined with Philip Morris in backing this bill. Yet the company touts this program in its recruitment of college students at career fairs on university campuses across the country (as well as on its Web site *www.cantbeattheexperience.com*), even though the only jobs it offers these students are in the Marlboro sales force, delivering fresh cigarettes to supermarkets, convenience stores, pharmacies, and bars.

Such tactics aimed at burnishing the company's nicotine-stained image among doctors, parents, college students, and university officials will flourish with the en-

actment of this bill. FDA regulation of tobacco products under HR 1108 would provide an unprecedented and unmerited legitimacy to cigarette makers and would send the misleading message to consumers that cigarettes, however problematic, are now government-sanctioned.

William Godshall, perhaps the most knowledgable and effective tobacco control advocate ever to work for the American Cancer Society, sees a parallel between the countless medications and food products overseen by the FDA and the more than 400 cigarette brand variations on the US market, each with differing amounts of scores of chemical additives and thousands of poisons in the smoke. He rightly questions the feasibility of correlating smoking-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.

The public is not generally aware that there are over 4000 poisons in cigarette smoke, including more than 40 cancer-causers. If a consumer is informed that one such poison or carcinogen has been reduced or removed from a cigarette brand, then he or she is going to infer that the problem is being taken care of or even solved. This ignores the dozens of other cancer-causers in that cigarette. In short, there is no evidence that tinkering with the levels of various constituents of tobacco smoke will result in a safer product.

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. Moreover, it would be highly unethical to conduct such ongoing research on persons who smoke without providing constant cessation interventions. Having served as a member of the University of Alabama Institutional Review Board, which oversees research protocols to ensure the protection of human subjects, I cannot imagine that prospective comparison studies of different cigarettes would be approved by any legitimate scientific institution.

Yet this is precisely the strategy Philip Morris is counting on to perpetuate the myth that research can discover a safe cigarette. Assisted by the University of Virginia and Duke University, which have thus far accepted over $40 million from the manufacturer of Marlboro in the past year, Philip Morris is on track in its plan to turn back the clock half a century to the "Frank Statement to Smokers" issued by the tobacco industry (in reaction to the myriad scientific studies implicating smoking in a host of diseases), which pledged "aid and assistance to the research effort into all phases of tobacco use and health."

In his remarks to shareholders at this year's annual meeting of Philip Morris, Louis Camilleri, ceo of its parent company, boasted of his support of this bill and promised that the company's new $350 million research center in Richmond will seek to solve "societal problems raised by tobacco." FDA regulation, the research center, and related grants to universities and medical schools make up Philip Morris' formula for Marlboro's continued sales success.

Does anyone with even a rudimentary knowledge of public health seriously believe in the wisdom of yet another quest for a safe cigarette? Philip Morris has played this game before with its earlier cigarette research centers in the 1950s and 1970s (One of the most complete and fully integrated facilities for tobacco research in existence anywhere in the world. Its every detail has been designed for translating the scientific theories and findings of basic research into practicalities.).

It is deja vu all over again, and proponents of this bill are wittingly or unwittingly aiding and abetting the biggest member of Big Tobacco in institutionalizing junk science.

Philip Morris' endorsement of both the FDA bill and the Institute of Medicine report supporting FDA regulation is eerily reminiscent of the Tobacco Industry Research Committee's Frank Statement of 1954: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business...We always have and we always will cooperate closely with those whose task it is to safeguard the public health...In charge of the research activities of the Committee will be a scientist of unimpeachable integrity and national repute. In addition there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science, and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities. This statement is being issued because we believe the people are entitled to know where we stand on this matter and what we intend to do about it."

And in 2007: "Philip Morris USA believes regulation of tobacco products by the FDA could potentially create a new framework within which manufacturers can refocus their efforts to pursue reduced harm products."

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.

Primary prevention—-not taking up cigarettes in the first place—-is universally agreed upon as the answer to end the devastating health toll caused by smoking. Reducing demand through paid mass media education is the cornerstone of primary prevention. Nothing in this legislation addresses or encourages major multi-media anti-smoking campaigns. Indeed, by creating the impression that the cigarette pandemic is being addressed by the Federal Government, the bill could be a disincentive for state and local governments to devote additional resources.

We need to fight smoking with fire, not symbolic, tokenistic regulation. This bill is a godsend for Philip Morris. No one else will benefit.

Mr. PALLONE. Let me just mention to everyone that we have a 15-minute vote and then two 5-minute votes. So we probably have time for Dr. Lavizzo-Mourey, and then we are going to have to take a recess. So I recognize Dr. Lavizzo-Mourey.

STATEMENT OF RISA LAVIZZO-MOUREY, M.D., PRESIDENT AND CEO, ROBERT WOOD JOHNSON FOUNDATION, PRINCETON, NJ

Dr. LAVIZZO-MOUREY. Thank you, Mr. Chairman, Ranking Member Deal, and members of the subcommittee. Thank you for the opportunity to testify on the need for H.R. 1108, the Family Smoking and Prevention Control Act.

I am Dr. Risa Lavizzo-Mourey, the president and CEO of the Robert Wood Johnson Foundation, which is the largest philanthropy in the country, devoted exclusively to improving the health and health care of all Americans. For more than a decade, the Robert Wood Johnson Foundation has worked successfully to reduce the prevalence of tobacco use using a two-pronged approach.

First we have focused attention on policies and programs that are most effective, and second we have focused attention on action-oriented evidence-based policies aimed at preventing people from starting to smoke, helping current smokers to quit smoking, and protecting nonsmokers from the serious health harms of secondhand smoke.

Our Nation has made significant progress in reducing tobacco use, especially at the State and local level. However, tobacco is still the leading cause of preventable death in this country. And we have heard the statistics this morning. I won't go into them, but they are in my written testimony.

Most troubling is that our progress in reducing smoking has stalled among youth and adults in recent years. The good news, however, is that there is strong consensus among our Nation's public health experts on what actions are needed. Both the Institute of Medicine, as we have heard already, and the President's Cancer Panel have reached the same conclusions in their issued reports this year.

An effective national strategy to reduce tobacco use must include a dual approach. First, stepped-up initiative at the local and State level, such as smoke-free air laws, tobacco price increases, public education and cessation practices preventing kids from smoking and protecting nonsmokers, and helping smokers quit.

And second, the opportunity that is before you today: enactment of Federal legislation granting the FDA authority over tobacco products.

Mr. Chairman, the FDA regulation is especially needed to address the continuing problem of tobacco marketing that appeals to children and misleads the public about the health risks and undermines the efforts of smokers to quit. Unfortunately, there is abundant evidence that the tobacco industry continues to engage in harmful practices, and I want to cite just a few examples that demonstrate how the industry continues to appeal to children and target vulnerable populations.

We all remember the 1998 State Tobacco Settlement and the tobacco industry's promises to stop marketing to children. What has happened since then? Well, since 1998, the total marketing expenditures by the tobacco industry have doubled, reaching $13.4 billion in 2005, according to the FTC. This is nearly $37 million a day to market addictive and deadly products.

Cigarette advertising increased in youth-oriented magazines, as frequently as 2 years after the settlement. And even today, tobacco companies continue to run ads in magazines portraying smoking as cool and glamorous.

The settlement, as you know, did not restrict in-store advertising and tobacco companies know that 75 percent of teens visit a convenience store at least once a week and therefore they have increased their advertising and promotions in these stores. Science tells us that this kind of marketing works. In fact, a study supported by the Robert Wood Johnson Foundation and published this May in the journal called Archives of Pediatrics and Adolescent Medicine has found that the more the cigarette industry markets to teens, the more they are exposed to cigarette advertising in retail stores, the more likely they are to smoke. The study also found that restricting these retail marketing practices would reduce youth smoking.

In addition, the tobacco companies have regularly introduced new candy, fruit-flavored products. For example, recently R.J. Reynolds introduced a flavored version of Camel with very enticing names. These kinds of youth-oriented practices work. We know that they work and the tobacco companies have a long history of targeting other specific populations, most recently, marketing to women and girls as we have already heard with Camel No. 9, the same kind of notorious efforts that we have long eschewed. Camel No. 9 continues the tobacco industry's long history of targeting women and girls beginning back in 1968 with "You've come a long way, baby." I can tell you as a physician, even though they say smoking is glamorous, there is nothing at all glamorous about the increased death rates from lung cancer that have occurred as a result of this legacy of marketing to girls and women.

The tobacco companies have similarly targeted African-Americans and Hispanics, especially children in these communities, and one of the most egregious and recent examples is Kool Mix, a marketing campaign that used a hip hop theme.

Mr. Chairman, let me just conclude by saying the FDA is uniquely qualified to achieve the goals because of its regulatory experience, the scientific knowledge and public health mandate this agency has. Thank you.

[The prepared statement of Dr. Livizzo-Mourey follows:]

TESTIMONY OF RISA LAVIZZO-MOUREY, M.D.

Chairman Pallone, Ranking Member Deal, and Members of the Subcommittee, thank you for this opportunity to testify about the need for H.R. 1108, the Family Smoking Prevention and Tobacco Control Act. I am Dr. Risa Lavizzo-Mourey, President and CEO of the Robert Wood Johnson Foundation, the Nation's largest philanthropy devoted exclusively to improving the health and health care of all Americans.

For more than a decade, the Robert Wood Johnson Foundation has worked successfully to help reduce the prevalence of tobacco use through a two-pronged approach. First, we have funded research to learn which policies and programs are most effective. Second, we have focused attention and fostered action on evidence-based policies aimed at preventing people from starting to smoke, helping current smokers quit and protecting non-smokers from the serious health harms of second-hand smoke.

Tobacco use is still the leading cause of preventable death in our country—causing more than 400,000 preventable deaths in the United States each year, sickening millions more, reducing the productivity of our workforce and undermining our Nation's economic competitiveness due to $100 billion a year in tobacco-related health care bills.

Today we are asking you, the Congress, and the Federal Government to provide the leadership needed to address this significant threat to the health of our Nation. One of the most important things you can do now would be to give the FDA authority over tobacco products.

Our country has made significant—although by no means sufficient—progress, especially at the state and local level. A growing number of states and localities have increased taxes on tobacco products, enacted smoke-free air laws that cover all workplaces and public places, and funded tobacco prevention and cessation programs. Collectively, we have also made great strides in getting effective tobacco cessation treatments into clinical practice and through state and national quitlines, and many health and health care policy changes have boosted access to and use of evidence based treatments.

The best measure of progress is that fewer Americans, both youth and adults, are smoking. Youth smoking rates have declined by 37 percent since peaking in 1997, and adult smoking rates have steadily declined as well.

But we have not yet turned the corner on this pervasive health threat which continues to take an enormous toll in health, lives and money in our country. Nearly one in four high school students still smokes and nearly 21 percent of all Americans remain addicted to this deadly product. Most troubling of all is the fact that our progress in reducing smoking has stalled among both youth and adults in recent years.

Our challenge today, Mr. Chairman, is to resist complacency and for all levels of government to redouble efforts to reduce tobacco use. The good news it that we know what to do, and there is a strong consensus among our Nation's public health experts about the science-based actions that must be taken. As both the Institute of Medicine and the President's Cancer Panel recommended in landmark reports issued this year, this strategy must include both stepped-up initiatives at the state and local level and enactment of Federal legislation granting the FDA authority over tobacco products.

As the IOM concluded, "Incremental reforms" will not end the Nation's tobacco problem. A more fundamental shift must occur. It is time for Congress and other policymakers to change the legal structure of tobacco policy, thereby laying the foundation for a strategic initiative to end the Nation's tobacco problem—that is, reducing tobacco use to a level that is insignificant from a public health standpoint."

These expert conclusions regarding FDA authority are critical.

Mr. Chairman, there are many reasons why we need FDA regulation of tobacco products in addition to and in support of the ongoing efforts to reduce tobacco use at the state and local government. I will name two:

- FDA authority over tobacco has a high probability of stopping tobacco marketing that targets our children and undermines the effective prevention measures in states and communities.
- FDA authority over tobacco has a high probability of stopping tobacco industry practices that undermine efforts to help smokers quit. These include the manipulation of tobacco products to make them more addictive and the deceptive marketing of light and low-tar cigarettes and other so-called "reduced risk" products.

Mr. Chairman, we all know that the tobacco companies continue to engage in these harmful practices today.

While the 1998 tobacco settlement, known as the Master Settlement Agreement or MSA, curtailed some tobacco marketing to children, the MSA addressed less than 20 percent of all tobacco marketing expenditures. Federal Judge Gladys Kessler found last year that tobacco companies continue to market in ways that appeal to young people and continue to recruit children as new tobacco users. In Judge Kessler's words: "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."

The tobacco companies have circumvented MSA restrictions by dramatically increasing overall marketing expenditures and constantly finding new ways to market their products, many of which appeal to kids. Between 1998, the year of the MSA, and 2005, the last year for which data is available, the major tobacco companies nearly doubled their total marketing expenditures from $6.9 billion to $13.4 billion, according to the Federal Trade Commission. That is nearly $37 million each and every day—much of it appealing to kids.

There are many examples of how the tobacco companies continue to market in ways that appeal to children:

• The MSA did not place specific restrictions on advertising in print media, such as magazines. As a result, cigarette advertising increased in youth-oriented magazines in the two years after the MSA, and tobacco companies continue to place magazine ads that portray smoking as cool and glamorous.

• The MSA did not restrict in-store advertising. Knowing that 75 percent of teens visit a convenience store once at least once a week, the cigarette companies have increased their advertising and promotions in and around these stores. In fact, retail marketing now makes up about 90 percent of all cigarette marketing expenditures, according to the Federal Trade Commission. Science tells us this kind of marketing influences youth behavior. A study supported by the Robert Wood Johnson Foundation and published this May in the journal Archives of Pediatrics and Adolescent Medicine found that the more cigarette marketing teens are exposed to in retail stores, the more likely they are to smoke. The study also found that restricting these retail-marketing practices would reduce youth smoking.

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

• Since the MSA, the tobacco companies have regularly introduced new candy and fruit-flavored tobacco products that clearly are intended as starter products for new tobacco users, most of whom are children. The R.J. Reynolds company, for example, introduced new flavored Camel cigarettes with names like Twista Lime, Warm Winter Toffee and Mocha Mint. A 2005 Harvard School of Public Health study concluded, "Flavored cigarettes can promote youth initiation and help young occasional smokers to become daily smokers by masking the natural harshness and taste of tobacco smoke and increasing the acceptability of a toxic product." Survey data reveal that youth are almost twice as likely as adults to be aware of these flavored products and their advertising, and youth smokers are much more likely than older ones to have tried them.

Unfortunately, this youth-oriented marketing works. According to the 2005 National Survey on Drug Use and Health, more than 81 percent of youth smokers prefer the three most heavily advertised cigarette brands—Marlboro, Camel and Newport. Numerous studies have found an association between tobacco marketing and youth smoking initiation and progress to regular use. As the National Cancer Institute found in a 2002 report, "the conclusion that there is a causal relationship between tobacco marketing and smoking initiation seems unassailable."

In addition to targeting youth, the tobacco companies also have a long history of targeting specific populations that have had historically lower smoking rates, and that tobacco companies regarded as potential new "customers," including girls and women and African American and Hispanic youth.

The most recent example of tobacco marketing to women and girls is R.J. Reynolds' Camel No. 9 cigarette introduced earlier this year by the same company that brought us the notorious Joe Camel. The Oregonian newspaper has aptly called Camel No. 9 "Barbie Camel.". Camel No. 9 comes in a shiny black box with a tiny pink camel and pink and teal borders. Ads in the most popular fashion magazines associate Camel No. 9 with everything a teenage girl aspires to be: glamorous, sophisticated and beautiful. And then there are the promotional giveaways: berry lip balm, cell phone jewelry, cute little purses and wristbands, all in hot pink.

Camel No. 9 continues the tobacco industry's long history of targeting women and girls, dating back to the "You've Come A Long Way Baby" campaign Philip Morris

launched in 1968. These campaigns have cynically equated smoking with independence, sophistication and beauty and preyed on the unique social pressures that women and girls face. The marketing of cigarettes as "slims" or "thins" and later as "low-tar" and "light" also played into young women's concerns about weight and health.

As a physician, I can tell you that there's nothing glamorous or beautiful about cancer and heart disease, which have been the main consequences for women. While death rates for most cancers have declined among women, rates have skyrocketed for lung cancer. Since 1987, lung cancer has been the leading cancer killer among women, surpassing breast cancer. Heart disease is the overall leading cause of death among women, and smoking accounts for one of every five deaths from heart disease. Altogether, more than 178,000 women die of tobacco-related diseases each year. This is the lethal legacy of the tobacco industry's targeting of women and girls.

The tobacco companies have similarly targeted African-Americans and Hispanics, especially children in those communities. One of the most egregious recent examples is Brown & Williamson's marketing campaign for Kool cigarettes, called Kool Mixx. This hip-hop themed campaign featured images of musicians, disc jockeys and dancers on cigarette packs and in advertising. It even included radio giveaways with cigarette purchases.

Again, the evidence is powerful that this targeted marketing works, especially on children. Take Lorillard's Newport cigarettes, which have been marketed to African Americans longer and more heavily than any other brand. While about 42 percent of African-American adults who smoke prefer Newport, 80 percent of African-American youth smokers prefer this brand.

This marketing has a devastating impact on the health of African Americans. While African Americans smoke at roughly the same rates as whites, they die at a higher rater from smoking-caused diseases. African American men bear an especially high burden of death and disease, with lung cancer rates almost 40 percent higher and average death rates about 30 percent higher than for white men.

The tobacco industry has similarly targeted Hispanic communities. As they have done with women and African Americans, the industry has sought to associate smoking with the culture, music and aspirations of the Hispanics and Latinos. One recent ad campaign for Kool cigarettes featured multicultural images, concerts with Latino musicians and aspirational slogans such as "It's about pursuing your ambitions and staying connected to your roots." It is truly offensive that the tobacco industry would exploit ethnic communities to sell a deadly and addictive product.

Mr. Chairman and members of the Subcommittee, these examples make it abundantly clear why the FDA needs the authority and resources to effectively regulate tobacco products and their marketing. With the authority that you can give, the FDA can finally stop tobacco marketing and sales to children; eliminate special flavored cigarettes that appeal to and target youth smokers; prevent tobacco companies from deceiving the public about the health risks of their products and undermining efforts to help smokers quit; and take other necessary steps to protect public health and save lives. These steps will significantly enhance state and local efforts to reduce tobacco use and help address the tobacco industry's targeting of specific populations, resulting in an excess burden of disease borne by many of the most vulnerable among us. The FDA is uniquely qualified to help achieve these goals because of its regulatory experience, scientific knowledge and public health mandate. With the powerful public health combination of FDA authority over tobacco products and enhanced efforts at the state and local level, we can achieve the goal that the Institute of Medicine has set for us—to eliminate tobacco use as one of the most pressing public health problems in the United States.

Thank you for your attention to this issue and the opportunity to testify.

Mr. PALLONE. Thank you, and I apologize. We are going to have to take about half an hour break for the 3 votes and then we will be back. Thank you all. The committee stands in recess.

[Recess.]

Mr. WAXMAN [presiding]. The subcommittee will come back to order. Chairman Pallone is managing a resolution on the House floor and asked me to chair the continuation of the hearing from this morning.

Mr. Ballin, I think you are next. Is that right?

Mr. BALLIN. Yes, sir.

Mr. WAXMAN. There is a button on the base of the mic and we will have the clock going. Of course, all of your full statements will be in the record and we would like to ask you if you could to keep to the 5-minute time.

STATEMENT OF SCOTT BALLIN, ATTORNEY, STEERING COMMITTEE MEMBER, ALLIANCE FOR HEALTH, ECONOMIC, AND AGRICULTURE DEVELOPMENT, WASHINGTON, DC

Mr. BALLIN. Mr. Chairman, it is an honor to be here today. In some ways I think I have come full circle on this issue. I testified before this subcommittee in support of FDA oversight way back in the early part of the 1990s and had the privilege to work with Congressmen Mike Synar and Bob Whittaker at that time, both who served on this subcommittee and who were the first to introduce legislation to give the FDA regulatory authority over tobacco products, and I would be remiss if I did not recognize you who I worked with over the years and your staffs. You have been a leader not only on this issue but on many other tobacco-related issues, and I commend you for that continued leadership today as well.

I think I am here supposedly as a minority witness but I would rather be thought of as a witness for both the majority and the minority because I am here to encourage both parties to work together in crafting FDA legislation that will serve the public health and establish a regulatory structure that will serve those needs 10 to 15 years down the road. This legislation is long overdue and Congress needs to act and act soon. FDA is the right agency to regulate tobacco products. I know that some of my colleagues probably think that our suggestions today with some amendments will detract from the focus of this legislation but I think there are some things that need to be considered as this subcommittee looks at the amendments that will have to be addressed by this committee during a markup.

The testimony we have submitted for the record today hopefully will be of some assistance to members of the committee from both parties as well as from those from both the tobacco and non-tobacco States. We have patiently waited 15 years for enacting of this critically important legislation and spending a few more weeks to make potential improvements would in our opinion be time well spent.

Our organization, AHEAD, was formed as an outgrowth of a project funded by the Robert Wood Johnson Foundation that brought public health advocates and growers together in the mid–1990s to talk about contentious tobacco issues. I personally learned a great deal from that experience about the critical importance of dialog and engagement, and if there is anything I want to emphasize today in my testimony, it is that challenging views, opinions and behaviors as well as listening and looking for opportunities for changes can have a significant and positive effect on outcomes.

I am not going to go into details as to why this legislation is needed. We heard a lot of that this morning, and for me personally and for our organization, AHEAD, oversight by FDA is a given. AHEAD strongly agrees with much of what has been said and articulated by the other witnesses here today in support of FDA. I think that where we may have some differences of opinion is how best to move forward to accomplish our shared goals and objectives.

My experience over the last several years has led me to conclude that in addition to giving the agency authority, we also need to have great engagement between the stakeholders to discuss the complex issues, debate and dialog those issues which many of those issues were raised this morning. Some of these discussions can and will obviously take place at FDA as part of the regulatory process but even that may take some time, and I strongly support and encourage discussions outside of the legislative process to address some of these issues as has been done this morning during some of the discussions and dialogs with this committee.

Good decisionmaking can't be done in a vacuum and we can't merely rely on using the tobacco industry's past bad behaviors as an excuse for not challenging or engaging them in the dialog. Stakeholders need to look beyond their own agenda if for nothing other than to understand what other factors, both positive and negative, need to be considered. We need more interaction between the scientific research community, experts in advertising and marketing, agronomists, tobacco and pharmaceutical companies, scientists, producers as well as the consumer who often gets left out of these discussions. Today's environment isn't just about big tobacco's past and potential future abuses. It is also about changing the competitive environment between the tobacco companies, old and new, pharmaceutical industries and the biotech companies. It is also about technological advances in making it feasible to reduce and remove toxins and pesticides from tobacco leaf.

Our suggestions for this legislation are contained in our testimony but I would like to just sort of review them very quickly. First, we would like to say and suggest that all tobacco and nicotine products be brought under the same umbrella at FDA through maybe a center on tobacco and nicotine and that there should be classification panels similar to the medical device panels used to review combustible products, non-combustible products and therapeutic products. We also suggest regulating products based upon risks and relative risks and intended uses so that users of tobacco and nicotine products are fully informed about the products they use. We also support expanding and upgrading the scientific advisory committee to include experts in agronomy and plant technology, labeling and marketing and consumer affairs. We also would suggest that there be greater interagency cooperation, and that was alluded to earlier this morning.

Conspicuously absent from today's hearings are the tobacco and the pharmaceutical companies. It would be of great interest to hear from them publicly and for the record as to where they stand on a number of the issues pertaining to the FDA regulation. The so-called tobacco industry is no longer the monolithic giant it once was, and as long as tobacco remains legal, the industry must be more transparent and accountable in what they do.

Also missing from today's hearing are the voices of the tobacco producers who produce the tobacco that goes into tobacco products and also is used in nicotine products, and I hope that there will be a time that they can also come to this committee. We also encourage this committee to contact the Agriculture Committee and ask them to hold some hearings on the importance of agricultural pro-

duction of tobacco, looking at the health and safety issues related to that aspect because that will impact FDA regulation.

Mr. Chairman, I would like to thank you in particular for your leadership on this and we look forward to working with you in the future.

[The prepared statement of Mr. Ballin follows:]

Statement of AHEAD (Alliance for Health Economic and Agriculture Development)

Concerning FDA Regulation of Tobacco Products

Subcommittee on Health
Committee on Energy and Commerce

October 3, 2007

The Alliance is an informal organization whose purpose is to educate, stimulate, and facilitate discussions with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, pharmaceutical and biotech interests about a spectrum of issues related to the production, processing, manufacture, sale, distribution, labeling, marketing and use of tobacco and tobacco products. The Alliance is an outgrowth of the *Southern Tobacco Communities Project* established in the mid-1990's through a grant from the Robert Wood Johnson Foundation that brought the public health community and growers together to engage in a civil dialogue about tobacco. That dialogue led to the issuance of a set of ***Core Principles*** in 1998 and the presidential commission report **Tobacco at a Crossroad** in May of 2001. The Steering Committee members serve as individuals, each of whom has significant and unique experiences in dealing with tobacco related issues.(For more information: see www.tobaccoatacrossroads.com or call 202 686-8898)

Statement of AHEAD (Alliance for Health Economic and Agriculture Development) Concerning the Need for FDA Regulatory Oversight of Tobacco

On behalf of the Alliance on Health Economic and Agriculture Development (AHEAD), I am pleased to provide this testimony to the Subcommittee on Health concerning the need for FDA regulation and oversight of tobacco products.

This is an issue that has languished in Congress for far too long. It is now over 15 years since I had the privilege of working with two members of this Subcommittee, Congressman Mike Synar (D-OK) and Congressman Bob Whittaker (R-KS) in introducing what was the first legislation in Congress to give FDA regulatory oversight over tobacco products. And I also want to express my deep appreciation to Congressman Waxman for his years of work on not only this issue but many other tobacco issues that came before this Subcommittee when he was Chairman.

Today while the goals and objectives of FDA oversight remain much the same as they were in the early 1990's, at the same time much has changed in the tobacco environment which needs to be considered in crafting any legislation. The legislation being discussed today is virtually identical to legislation introduced in the last three Congresses, and not much different than the McCain legislation of almost 10 years ago.

The Alliance would like to provide the Subcommittee with some broad and specific recommendations and suggestions on how this legislation can be improved upon and made more workable.

First and foremost, the Alliance has taken the position that the FDA is the appropriate and must logical agency for overseeing the manufacture, sale, distribution, labeling and marketing of tobacco products. Several of the Alliance's Steering Committee members have been involved and worked on this issue for more than 15 years, both via the administrative route by petitioning the FDA and working within the FDA, as well as via the legislative route. The views and positions of the Alliance have been guided by the work of the Southern Tobacco Communities Project (funded through a grant from the Robert Wood Johnson Foundation) , a set of core principles issued and adopted by the public health community and tobacco growers (1998) and the presidential commission report, Tobacco at a Crossroad, (May 2001). On the issue of FDA for example, the **Core Principles Statement** noted:

> That it is in the best interests of the public health community and the tobacco producer community that FDA should have authority to establish *fair and equitable* regulatory controls over the manufacture, sale, distribution, labeling (including country of origin) and marketing of tobacco products, both domestic and foreign, comparable to regulations

> established for other products regulated by the FDA. Such regulations should have as their goal the protection of public health and assurances that users of tobacco products are provided with *full and complete information* about the products they are using.

The presidential commission report **Tobacco at a Crossroads** noted:

> In the long run, effective regulation by the FDA benefits everyone, including farmers. It will save lives. Independent science based decisions by the FDA designed to protect public health by taking all *reasonable steps* to reduce the harm of tobacco products now being sold and *promote* the introduction of less harmful products will create *fair* standards and will provide *predictability* to farmers and industry (pages 42-43)

In the spirit of civil and transparent dialogue, the Alliance offers constructive suggestions for restructuring and improving the legislation now pending before this Subcommittee. This testimony is provided in two parts, the first of which focuses on some broader recommendations concerning how tobacco products (and other nicotine products) should be regulated under the FDA. Part II deals specifically with specific language changes to the legislation in a number of areas.

PART I

1. **A Separate Chapter under the FD&C Act for all Tobacco and Nicotine Products**
2. **Tobacco and Nicotine Scientific and Surveillance Committee**
3. **User fees to fund tobacco and nicotine research**
4. **More effective coordination between governmental agencies**
5. **Providing incentives to develop lower risk products (tobacco and nicotine)**
6. **Tobacco Agriculture**

1. A Separate Chapter under the FD&C Act for all Tobacco and Nicotine Products

As noted above the tobacco environment has been changing and will continue to change. It is clear that we are dealing with a market place in which there is increasing competition and overlap between a spectrum of diverse tobacco based products, pharmaceutical products, as well as tobacco producers, and tobacco and pharmaceutical manufacturing interests. Many in the public health community, the research community, the tobacco industry and the pharmaceutical industry increasingly speak in terms of the need for a more ***coherent and rational tobacco and nicotine policy.*** A restructured regulatory scheme would allow the FDA to prescribe labeling and marketing requirements for all nicotine containing products based upon risks, relative risks and intended use of those

products, allowing the consumer to fully understand the risks and relative risks of products available to them – from the highly toxic combustible products (cigarettes), to significantly lower risk noncombustible tobacco based products, to even lower risk nicotine replacement therapies (NRT). Several recent studies have shown significant consumer misunderstanding about the risks and relative risk of those products – something that needs to be rectified. For a long time it has been convenient to look at all tobacco products as being equally harmful – clearly a supposition that is not supported by the science or even common sense. There has also been a tendency to separate tobacco from other nicotine products used for cessation of cigarette smoking even though most (if not all) of the products on the market today have one thing in common – they contain *nicotine derived from tobacco*. The challenge and more importantly the opportunities that we face whether as health advocates, scientists, policy makers, producers, manufacturers (broadly speaking) or consumers is to consider the most effective way in which to take **all** of these products and craft a coherent and workable regulatory policy that will allow these products to be regulated in a consistent manner based on their risks, relative risks and intended use.

Our first recommendation is to bring all tobacco and nicotine products under the **same regulatory umbrella** as part of a separate Center at the FDA. This Center could be named the Center for Tobacco and Nicotine. Within this framework it would make sense given the wide spectrum of risks and relative risks associated with tobacco and nicotine products, that we use a model similar to one used under the medical device section of the FD&C Act by establishing three distinct categories and panels to review, classify and recommend labeling and marketing requirements and allowances for products. (This type of model was one considered by the Institute of Medicine in its report **Clearing the Smoke**) These three categories would be:

a) Combustible products (Cigarettes, cigars, little cigars, pipes etc)
b) Noncombustible tobacco and nicotine products (for recreational use), including tobacco based products as well as nicotine based products which are not used for therapeutic purposes.
c) Noncombustible tobacco and nicotine products for therapeutic use, including products containing nicotine derived from tobacco (i.e. patches, gums, lozenges, inhalers), and tobacco based products that would be used for therapeutic purposes (no products currently on the market).

The panels would be composed of a spectrum of 'experts' in the fields of public health, pharmacology, addiction, biotechnology, advertising and marketing, good manufacturing practices, agronomy etc. Any interested party would be allowed to petition a panel for the reclassification of a product, a variance on the regulatory requirements for a product or even removal of a product not meeting regulatory specifications. New products would be subjected to pre-market approval. Regulations for both categories and individual products would be based on the 'risk' profile of the category and of the product.

2. Tobacco and Nicotine Scientific and Surveillance Committee

To assist the FDA and the Tobacco and Nicotine Classification Panel(s), we suggest that provisions in the currently proposed Tobacco and Scientific Advisory Committee (sec. 918) be expanded and also include surveillance functions. These two areas in particular have and will continue to have significant ramifications on the ability of the agency to do its job in not only reviewing products but also in determining how the public (both the individual consumer and the population as a whole) may be using such products. There is no doubt that the science pertaining to the production, manufacture and marketing of tobacco and nicotine products will continue to change. Major changes in curing techniques and biotechnology impacting on tobacco and nicotine products is already on here or just over the horizon.

Surveillance is a crtical component of any tobacco and nicotine regulatory effort. In addition to making sound scientific based policy and regulatory decisions, we regard surveillance as one of the top two or three functions that will be needed to be carried out, and one that will play an important role in deciding how the spectrum of tobacco and nicotine products should be labeled and marketed to ensure that any users of these products are interpreting the information in a way that allows them to fully understand the risks and relative risks of those products.

Having a 'high level ' advisory committee in place, with representation from a broad spectrum of experts, to assist FDA (and other agencies) in their efforts will go a long way towards ensuring that policy is being made with the most up to date scientific and surveillance data.

3. User Fees to Fund Tobacco and Nicotine Research

There has been some growing discussion within the public health and scientific communities as to how the tobacco industry could participate and/or be required to fund research that will have short term and long term effects on the reduction of disease and death caused by the use of tobacco products. Many are concerned about the misuse of science by the industry and therefore have opposed any measure that would leave the industry in charge of research funding decisions. It might therefore, be useful to consider using a portion of the 'user fee' to fund tobacco and nicotine research. An Office on Tobacco and Nicotine Research established in the Office of the Secretary could be used to set priorities and allocate funding to such agencies as the NIH and CDC in carrying out both research and surveillance efforts.

4. More Effective Coordination Between Governmental Agencies

One of the things that is often ignored or forgotten is that oversight and control over the manufacture, sale, distribution, labeling and marketing of tobacco and tobacco products

does not and cannot rest within any one agency or even one department. The current legislation does recognize this to a certain extent but we believe the interagency functions should be strengthened. Strengthening these functions would not only benefit the FDA but would benefit other departments and agencies that deal with tobacco as well. We would recommend that these functions be strengthened by establishing a broader and more comprehensive Interagency Tobacco and Nicotine Coordinating Committee within the government that ensures ongoing cooperation, communication and integration on a variety of issues. While an interagency committee already exist it has not be used as effectively as it could or should be. The proposed Interagency Tobacco and Nicotine Coordinating Committee should include representation from such Departments and agencies as **HHS** (FDC,CDC,NIH,CMS etc.), **USDA, EPA,FTC,ATF,USTR, and DHS**.

5. Providing Incentives to Develop Lower Risk Products and Medications

Both the Institute of Medicine (IOM) and several organizations within the public health community (as well as the presidential commission report) have called for incentives and the encouragement of industry (broadly speaking) to develop scientifically based lower risk products. Yet there are no provisions in the legislation for using competitive forces (in a regulated environment) for stimulating change in the tobacco industry, the pharmaceutical industry, biotech industry etc. and the products they manufacture. Consideration should be given to incorporating incentives into the legislation or in committee report language suggesting ways that such efforts could be achieved. One obvious and often cited example is to tax products based upon their risks and relative risks; higher taxes for combustible products, lower taxes for noncombustible products, and no or a minimal tax on medicinal and therapeutic products. Other 'incentives' could come in the form of 'tax credits" or expedited review (and greater leeway in marketing) for new products that have a science based expectation to lower risks.

6. Tobacco Agriculture

Over two years ago, Congress provided growers with an industry-funded tobacco buyout. At the same time, Congress intentionally or unintentionally repealed most of the tobacco program, leaving domestic and foreign tobacco virtually unregulated. In an environment in which tobacco is considered an inherently dangerous product, such action makes little sense, especially when considered the recognized need for FDA oversight over manufactured products. All stakeholders must realize and consider that what is done (or not done) at the production level has significant impacts on the health and safety of the final product.

For example: How do different growing technologies and curing processes impact the nicotine levels and other characteristics of the plant? What are technologies that exist to remove tobacco specific nitrosamines (TSNA's)? What pesticides and other chemicals are being used, and should we be reducing those pesticide and chemical applications? What should US producers do to move towards production standards that will have a positive effect in reducing the level of risk posed by tobacco currently on the market? Where does the nicotine in both tobacco and nicotine products come from? What role can genetically modified tobacco and geonomics play in not only reducing risks associated with tobacco products but also in the development of medicines and industrial enzymes? What incentives and training should be given to producers to begin changing their methods of production to meet the challenges of the 21st century? What system do we need to monitor tobacco production both here in the US and abroad? What kind of authorities and structures need to be restored at the USDA (such as a permanent Tobacco Advisory Board) to ensure that there is continuity and consistency between the regulation of the manufactured products by the FDA and what is needed to be done by the USDA (as well as other agencies such as EPA).

Whether one wishes to acknowledge it or not HR 1108 does have consequences on producers of tobacco and it would be prudent for Congress to carefully and fully consider these ramifications (both positive and negative) as it moves forward with the FDA legislation.(See recommendations in Part II). We would also encourage this Committee to officially request the House Agriculture Committee to hold hearings on these important issues – issues that not only impact domestic tobacco production and health issues here in the US but could have significant ramifications globally as well. While other agricultural commodities have integrated regulated strategies between USDA, FDA, and EPA tobacco does not. It's time that is changed.

PART II

Specific suggestions for modifications to S. 625 and HR 1108

AHEAD also provides the following specific suggestions for modification in the legislation. **As before we hope that all parties interested in this important legislation will take the time to consider these suggestions and to work towards finding *common ground* that will most effectively and fairly establish a workable and flexible process under which tobacco and tobacco products (and nicotine products) will be regulated in the coming years.**

SUMMARY OF PROPOSED CHANGES

1. Sec. 2. Findings: Add a number of findings to the legislation that reflects a changing environment in which tobacco and nicotine products are produced, processed, manufactured, labeled and marketed.

2. Sec.3 Purpose: Add language that emphasizes that enforcement authority of the FDA be both flexible, and ***fair*** and that there should be incentives for the development of science- based lower risk products. Add a new subparagraph (8) that ensures that adult users are fully and accurately informed about the risks, relative risks, and intended uses of tobacco and nicotine products.

3. Sec.4 Scope and Effect (page 15): Although the language is designed to ensure that FDA does not infringe upon USDA's authorities, the current language references 'existing law'. Many of the provisions of the previous existing law designed to ensure integrity of tobacco were repealed -- leaving a serious void. This section needs clarification.

4. Sec. Definition (pages 16-17): Keep definition of tobacco product as defined in lines 12-18 and strike the exemptions in lines 18-23. A restrictive definition (as currently in legislation) is a *disincentive* for the development of new scientifically based tobacco based products that could lower the risks associated with other high risk tobacco products.

5. Sec. 900- Definitions (page 23): Modify the definition of a 'smokeless product' to include all tobacco based products that consist of cut, ground, powdered, compressed or leaf tobacco that are intended to be used in a noncombustible form.

6. Sec. 901 Limitation of Authorities (pages 23-24: While indicating that producers (growers) should not be subject directly to the provisions of FDA authority, the legislation provides an exception that would subject producers to the requirements of the Act if the producer is also a tobacco manufacturer or *controlled* by a manufacturer. In a post buy out environment this in effect could subject almost all growers, warehouses and cooperatives to the requirements of the Act. This sections needs careful reconsideration.

7. Sec.906(d) General Provisions.(pages 45-56): Consider striking this section as it seems to (except for a few limitations) provide the Secretary with very broad authority to regulate tobacco products with only a showing that it is in the interest of public health. At a minimum if this section is retained, added a new subparagraph (C) which would further clarify what must be taken into consideration. The limitations (906(d)3) concerning face-to-face transactions, minimum age of sale and matchbooks could be moved elsewhere in the Act.

8. Sec. 907(a)(3) Tobacco Product Standards (pages 54 and 59): Add a new subparagraph (C) on page 54 that requires consideration of *consumer acceptability* and that tobacco users will use such products as alternatives to higher risk products. Also, revise and add new sub-paragraphs (2) and (3) under the section, Consideration by Secretary (page 59) to require consideration of the impact of standards on tobacco producers, processors and other small businesses and to again require consideration of *consumer acceptability* of the products required to meet the performance standard.

9. Sec. 911 Modified risk Tobacco Products pages 85-100): Revises requirements to be more consistent with the language and intent of the IOM report Clearing the Smoke and the presidential commission report Tobacco at a Crossroad. Allows the Secretary to promulgate rules and regulations for tobacco product *categories* (in addition to individual products for which an application has been filed) that will allow users of tobacco to differentiate between the risks and relative risks of such categories. Under Sec.911(l) amend to use IOM language specifying the criteria to be used by the Secretary in establishing guidance and standards (including involvement of tobacco manufacturers.)

10. Sec.918 Tobacco Products Scientific Advisory Committee (pages 109-11): Add three additional voting members including an expert in agronomy and tobacco plant technologies; an expert in labeling, marketing and consumers affairs; an expert in harm reduction. (Note: Failing to add an expert in agronomy and tobacco plant technology we suggest making the grower representative a voting member).

* * * * *

1. Sec. 2 FINDINGS (pages 2-13)

We encourage the Subcommittee to conduct a careful review of the findings that will more adequately reflect the current environment surrounding the production, manufacture, sale, distribution, labeling and marketing of tobacco and nicotine products.

We also suggest adding the following findings:

> **New technologies are available (and are being developed) that will allow tobacco and tobacco products to be developed that are lower in risk.**
>
> **Tobacco manufacturers should be given incentives and encouraged to develop and market products that can be reasonably expected to reduce the risk of disease compared with many of the tobacco products currently on the market.**
>
> **Tobacco producers should be given incentives to produce, cure, and process tobacco that is lower in tobacco specific nitrosamines, toxins and pesticides and that can reasonably be expected to reduce the risk of disease.**
>
> **The Congress should enact and the USDA should implement tobacco agriculture policies that will compliment FDA oversight that will ensure that**

both domestic and foreign tobacco meet minimum health and safety standards, and that product standards don't create competitive disadvantages for American tobacco producers.

Stakeholders, including scientists, public health organizations, tobacco manufacturers, pharmaceutical and biotech companies, tobacco producers, governmental agencies and others should be encouraged to engage in transparent, open debate and dialogue about issues pertaining to the production, manufacture, sale, labeling and marketing of tobacco and tobacco products.

It is in the interest of users of tobacco and nicotine products that the Congress establish a more coherent tobacco and nicotine policy that will allow consumers to understand the risks, relative risks and intended uses of all tobacco and nicotine products.

2. Sec. 3 PURPOSE (pages 13-15)

On page 14 line 3-6 revise to read:

(4) to provide new, flexible, and fair enforcement authority to ensure that there is effective oversight of , and incentives for, the tobacco industry's efforts to develop, introduce and promote less harmful tobacco and nicotine products.

On page 14 insert a new subparagraph (8) (and re-designate all paragraphs thereafter)

(8) to ensure that adult users are fully, accurately and truthfully informed about the risks, relative risks and intended uses of all tobacco and nicotine products.

On Page 15 lines 12-17 the current legislation reads:

(b) AGRICULTURAL ACTIVITES. – The provisions of this Act (or amendment made by this Act) which authorizes the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to

affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

Comment: The current provisions of the legislation would and do allow the FDA to have influences indirectly over tobacco production through such things as performance standards and modified risk requirements. In addition because the Congress repealed important tracking, monitoring and testing provisions that were part of the 'tobacco program' when the buyout was passed, there is virtually **no** "existing law regarding the growing, cultivation, or curing of raw tobacco". This could give the FDA the green light to have even more authority and the ability to indirectly or directly affect requirements at the production level. This section therefore needs to be carefully written to ensure that FDA does not have excessive and undue influence over tobacco production. Authorities should be restored to the USDA and FDA, USDA (and other agencies) should work cooperatively. Growers should be part of the process not victims of the process.

3. Title I - Authority of the FDA - Sec. 101 pages 16-17 (Definition of Tobacco Products)

On page 16, strike lines 18-23.

Comment:

In our testimony submitted to the HELP Committee we suggested that the definitions of tobacco (and nicotine) products be revised as part of our broader suggestion that all tobacco and nicotine products be brought under a single regulatory umbrella at the FDA (under a separate chapter) that will allow for a more coherent tobacco and nicotine policy to be implemented.

The Institute of Medicine, many in the public health community and the presidential commission report have all called for the development of new lower risk tobacco products. (See for example, the Principle Recommendations, of the IOM report which states that **Manufacturers have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related disease**.) Yet this legislation, by selectively restricting what is and what is not a tobacco product (even when the product is composed of tobacco) prevents the development of many new and potentially lower risk tobacco based products --- products that could help reduce the disease caused by the use of more toxic products. Competition (with incentives) to develop new products (coupled with fair and effective regulations) may be in the best interests of the public health, tobacco and nicotine users, manufactures and even producers. It should be up to

the FDA to determine if a tobacco product meets the regulatory requirements of the Act.

If Congress chooses to continue to keep tobacco and therapeutic nicotine products under separate sections of the FDCA, then **at a minimum** we suggest that subparagraph (2) , lines 18-23 be stricken from the legislation. This will encourage tobacco companies , biotech companies and even pharmaceutical companies to develop tobacco- based consumer products (not therapeutic) for which there is a reasonable expectation (based on scientific evidence) that such products will reduce risks.

4. "CHAPTER IX- TOBACCO PRODUCTS

Section 900 – Definitions:

On page 21 lines 14-18, amend the definition of smokeless tobacco *Section 900 (16)* to read:

> "(16) SMOKELESS TOBACCO. – The term smokeless tobacco means any tobacco based product that consists of cut, ground, powdered, compressed or leaf tobacco that is intended to be used in a noncombustible form.

Section 901 FDA Authority Over tobacco Products (Scope)

Comment:

Page 23 (line 24) - 24 (lines 1-23) "Limitations of Authority" intends that the provisions of the Act "shall not apply to tobacco leaf that is not in the possession of the manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producers of tobacco leaf without written consent".

Under the "Exception" (B) line 11 , if a tobacco producer of tobacco leaf who is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer".

In a post buyout environment where there will undoubtedly be more realignment of producers and industry such that the lines between them will increasingly become blurred, it is feasible that all tobacco producers, warehouses, or cooperatives who enter into any kind of a contractual relationship with a manufacture could/will be subject to the provisions of the ACT.

"Subparagraph (C) – Rule of Construction" line 17 also indicates that "nothing in this Chapter shall be construed to grant the Secretary authority to promulgate regulations of any matter that involves the production of tobacco leaf or a producer, thereof, *other than activities by a manufacturer affecting production*". Again, while well intended, the post buy environment will more than likely see increased contractual and business relationships between producers and manufacturers such that all tobacco producers could be subject to the requirements of the Act. This is also a likely scenario given that the FDA will be establishing performances standards, good manufacturing practices, and setting regulations governing reduced risk products that through the manufacturer or by other means will affect (directly or indirectly) all tobacco producers in the US.

These provisions must be carefully reconsidered and rewritten to ensure that the tobacco producers does not find him or herself subject to direct or indirect authority of the Act unless it is accomplished in a fair and equitable manner and under conditions which producers are directly and actively involved in the setting of standards and requirements. For example, the Act should clearly state that any regulations which would indirectly require growers to change the leaf that they produce should be done with both the involvement of growers and in consultation with the USDA.

Sec. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS ----Section 906(d) RESTRCTIONS. (page 45, line 20-24, page 46 lines 1-17).

Comment:

This section, 906(d) RESTRICTIONS (pages 45 and 46), would give the Secretary almost opened ended, unlimited authority to establish regulations and restrictions *"on the sale and distribution of a tobacco products, including restrictions on access to, and the advertising and promotion of the tobacco product, if the Secretary determines that such regulations would be appropriate for the protection of the public health*".

While the Secretary does have to make a finding of the risks and benefits to the population as a whole, including users and non-users of tobacco products taking into account; the increased or decreased likelihood that those will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products, it would seem that given the public health risks of tobacco the Secretary could effectively impose such restrictions on all tobacco products (including products that might be considered lower in risk) that would make access to all tobacco products even to adults excessively restrictive.

In addition, this section talks about restrictions on the sale distribution, access to and advertising of tobacco products' in general terms, not in terms of children and adolescents but in terms of the adult populations as well.

Does this subsection (with the exception two limitations on face- to- face transactions and minimum age of sale) in effect given the Secretary such broad authority as to allow the Secretary the ability to supercede many of the other provisions of the Act?

Given the extensive requirements concerning the manufacture, sale, labeling and marketing of tobacco products covered under many sections of the legislation this section could and should be eliminated. The 'limitations' noted under 906(d)3, could be moved elsewhere in the legislation.

At a minimum, the public health standard used for making a "finding as to whether a regulation would be appropriate for the protection of public health" should also require the following new subparagraph (C)

(C) the risks, relative risks and intended uses of the spectrum of tobacco products from those using the most harmful tobacco products (combustible products) to those who would use lower risk products (including noncombustible smokeless tobacco products and pharmaceutical nicotine)

Section 907. TOBACCO PRODUCT STANDARDS.(Pages 53-64)

Comment:

One of the reasons that tobacco growers and public health organizations joined together in support of FDA oversight over tobacco products has been the potential for producers to work under a system under which there are fair and realistic standards established that would give US producers a more competitive role in producing tobacco leaf (as well as the final manufactured product) that has fewer toxins, pesticides, and meets other health and safety standards when compared with leaf that is produced overseas. While standard setting in the legislation is in terms of the manufactured tobacco product, there is no question that there is an indirect (if not direct) effect on US producers. For that reason and others we therefore suggest the following modifications to Section 907.

907(a)(3) TOBACCO PRODUCT STANDARDS (Page 54)

After subparagraph (B), (lines 21-23) add the following:

(C) the increased or decreased likelihood that the product will be consumer acceptable and that an existing user of tobacco will use such products as alternatives to other higher risk products on the market.

Revise subparagraph (E) CONSIDERATION BY THE SECRETARY.- page 59 as follows:

(E) Consideration by Secretary.--
The Secretary shall consider all information submitted in connection with a proposed standard including information concerning the:

(1) Countervailing effects of the tobacco product standards on the health of adolescent users; adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter
(2) The direct and indirect impact of the standards on tobacco producers, processors and other small businesses to be able to comply with the standard.
(3) The consumer acceptability of the product or products for which the tobacco standard is required.

Section 911. MODIFIED RISK TOBACCO PRODUCTS (Pages 85-100)

Comment:

Another reason that many growers have joined with the public health community in supporting FDA regulatory oversight of tobacco products has been the prospects for the development of lower risks tobacco products. This section of the legislation is therefore of particular interest and concern, both from the standpoint of public health and how US producers can effectively play a positive role. The provisions of this section seem to be more determined to keep lower risk products off the market rather than in giving industry ***incentives and encouragement*** to develop lower risk products especially given the significant dangers associated with products currently on the market. This includes the 'standards' that must be met in order to bring a product onto the market.

Section 911(b)(2) SOLD OR DISTRIBUTED (pages 85-86)-- establishes what the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' entails. Several issues here should be noted. While the banning of such descriptors such as 'light' , mild (Subparagraph ii, page 86) etc is essential does this also mean that truthful meaningful statements such as "this is a smoke free tobacco product", or 'this is a smokeless tobacco product' will also be prohibited? How would such restrictions be considered under the First amendment and in particular how would recent decisions made with respect to health claims on food products impact on the circumstances under which claims on tobacco product would be allowed or disallowed? Descriptors which are

misleading and deceptive should be prohibited --- and already are by the Act's 'misbranding' section (903) --- but those that are accurate, truthful and non-misleading should be allowed under controlled circumstances, even if requiring explanatory, clarifying labeling and disclosures.

More problematic is subparagraph (iii) page 86-87 which would conclude that a tobacco product is a reduced risk product even in situations in which 'the tobacco manufacturer has taken any action directed to consumers *through the media or otherwise*, other than by means of the tobacco product's label, labeling, or advertising that would be reasonable be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances. This provision would seem to suppress any and all discussion, debate, dialogue and publication of scientific findings, studies etc.

Subsection 911(d) FILING. (pages 87-88)

This section lays out some of the requirements for the filling of an application for a modified risk tobacco product. Revise (d)6 to read:

> **"(6) data and information on who the targeted potential users of the product are and how consumers are expected to use such product.**

Comment: As with several other sections, the concern is that there seems to be a required showing on how consumers actually use the product even before the product is put into the market place. The focus should be, as we noted above,on the *expected* intended use of the product. The surveillance requirement that will involve industry, FDA etc should provide the data to determine if the target audience and the messages contained in the labeling and marketing of the product are having their intended effect as contained in the application.

Subsections 911 (g) and (h) (page 89-96 lines)

Comment:

These sections establish the basis and criteria on which the Secretary can approve an application for a modified risk tobacco product when the applicant has demonstrated that such product, as it "*actually* used by consumers will--- (A) *significantly* reduce harm and the risk of tobacco related disease to individual users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do no currently use tobacco products". The legislation as drafted is problematic in

that it requires a showing of an outcome that can't be evaluated unless and until such products are allowed on the market (putting the cart before the horse). As we noted above, issues pertaining to 'actual use' should be part of the surveillance provisions under the legislation. It also sets the standards for allowing a harm reduction product on the market so high as to be unfeasible and contrary to the views expressed in the IOM report, the presidential commission report and other statements from some of the public health community. It may also have the unintended consequence of perpetuating the use of higher toxic products. We also think that the Secretary should have the authority to establish labeling and marketing standards based upon the risks, relative risk, and intended uses between product categories.

We propose that in consideration of the IOM report, several statements of the public health community, and recommendations of the presidential tobacco commission that the current sections (g) and (h) be deleted and the following new (g) and (h) be substituted:

(g) APPROVAL. ---

(1) MODIFIED RISK PRODUCTS.—

The Secretary shall approve an application for a modified risk tobacco product if the Secretary finds that that the applicant has demonstrated that, as intended to be used by consumers ---

(A) The product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects to an individual as compared with whatever benchmark product or products the Secretary may establish*

(B) The product substantially reduces the exposure to one or more tobacco toxicants based upon whatever benchmark product or products the Secretary may establish.*

(C) The product has the reasonable expectation based upon a consensus of the available scientific evidence (both evidence submitted by the applicant and evidence available through other sources) to benefit the individual and the population as a whole, taking into account:

- **i) the risks and relative risk to individuals of the tobacco product that is the subject of the application especially when compared to other categories and products on the market.**
- **ii) the increased or decreased likelihood that existing users of tobacco products who might otherwise quit might switch to the tobacco product which is the subject of the application.**
- **iii) the increased or decreased likelihood that persons who do not use tobacco might start using the tobacco product that is the subject of the application.**

iv) the risks and benefits to persons from the use of the tobacco product that is the subject of the application compared to the use of other higher toxic tobacco products.

v) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation to treat nicotine dependence.

(D) That the product as intended to be used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product meets the other requirements required as part of the application.

(E) That the labeling and advertising for the modified risk products will enable the user of such products, as well as the public, to comprehend information concerning the modified risk and to understand the risks and relative risks and significance of such information in the context of total health.

* This language is derived from the Regulatory Principles (regulatory Principle # 4) contained in the IOM Report, Clearing the Smoke.

(h) ADDITIONAL AUTHORIES AND CONDITIONS.—

(1)The Secretary may require that a product that is the subject of the Application also:

(A) Disclose on the label or through other means such as package inserts, other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health related conditions associated with the use of the tobacco product.

(B) Disclose on the label or through other means such as package inserts other information that will ensure that consumers are fully and accurately informed of the known, likely, and potential consequences of using the tobacco product.**

(C) Label the product detailing the conditions of use of the tobacco product if the tobacco product may affect the risk of the product to human health.

(D) Meet protocols and specified criteria for the allowance or disallowance of comparative claims of the product, taking into

consideration how such comparative claims will be understood by the users of the tobacco product in comparison with other products on the market.

(2) Absent the submission of an application for a specific modified risk product, the Secretary may also establish generic labeling and marketing standards for product categories that will allow users of tobacco products to understand the risks, relative risks and intended uses of and between such categories. Such generic labeling and marketing standards shall compare the risks, relative risks and intended use between:

(A) combustible tobacco products with noncombustible tobacco products and nicotine replacement therapies;
(B) noncombustible tobacco products with combustible tobacco products and nicotine replacement therapies;
(C)nicotine replacement therapies with noncombustible and combustible tobacco products.

In developing such generic labeling and marketing standards for product categories the Secretary shall consider the effects of such regulations on the individual and the population as a whole taking into consideration:

(A) the increased or decreased likelihood that a tobacco user who might otherwise quit using tobacco might continue to use a tobacco product;
(B) the increased or decreased likelihood that a user of a higher risk tobacco product will switch to a lower risk tobacco and or nicotine product;
(C) the increase or decreased likelihood that nonuser of a tobacco product will start using a product within one of the tobacco and nicotine categories;
(D) the critical first amendment requirement that the public is entitled to truthful, accurate, non- misleading information about the products they choose to use.

In developing such generic labeling and marketing standards for product categories, the Secretary shall not be precluded from permitting truthful, non-misleading statements to be made about a particular category even if different products within such category have, as among themselves, different degrees of relative risk, so long as such statement accurately apply to the category as a whole and are based on sound science.

<u>Subsection 911(i) Postmarket Surveillance Studies</u>

We suggest revising 911(i)1 concerning post market surveillance and studies to include provisions ensuring authorities of the Secretary to conduct survey and studies and to read as follows:

(i) POST MARKET SURVEILLANCE AND STUDIES.-

(1) IN GENERAL.- Applications approved by the Secretary under (g) (1) shall require the applicant's agreement to conduct post-market surveillance and studies for the tobacco product and to submit to the Secretary the results of such surveillance and studies to enable the Secretary to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product.
(B) The results of such post-market surveillance and studies required under paragraph (A) shall be submitted annually.
(C) Nothing in this section shall limit the authority of the Secretary to conduct independent studies and surveys of consumer perception, and behavior relating to reduced risk products or the tobacco product which is the subject of the application..**

** This language is derived from the IOM report **Clearing the Smoke**, Regulatory Principle 5.

Section 911(l) Implementing regulation or guidance.—(Pages 99(lines 13-24)-100 (lines 1-25)

We suggest revising (l)(1) and (2) as follows:

(l)IMPLMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.--- Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall ---

(A) establish criteria for scientific studies needed prior to approval to show that there is a reasonable expectation that the product will reduce the risk of one or more specific diseases or other adverse health effects , as compared with whatever bench mark product the Secretary requires;***

(B) establish criteria for scientific studies needed prior to approval to show that the product substantially reduces exposure to one or more tobacco toxicant;***

(C) establish appropriate guidance and standards on the use of biomarkers, intermediate clinical endpoints, and other feasible outcome measures;

(D) provide guidance and standards for post market surveillance related to consumer perceptions, behavior and health outcomes;

(2) CONSULTATION.- The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance. The Secretary shall as appropriate and necessary also consult with tobacco manufacturers to ensure that the necessary data and information is made available that will allow the Secretary to develop the appropriate standards and guidance. ****

*** These are (again) based on the language contained in the IOM report, **Clearing the Smoke**, Regulatory Principle # 4.

**** The provision allowing the Secretary to consult with tobacco manufacturers is consistent not only with other requirements of the legislation (submission of data) but also with the recommendations of the IOM report and the presidential commission report.

We also suggest deleting subparagraph (E) (page 100 of S.625, lines 16-19) as the legislation already requires that the applicant submit the results of post-market surveillance and studies on an annual basis.

Section 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE Pages 109-110)

Comment:

It would seem that given that the Scientific Advisory Committee is charged with a number of functions under the legislation including reviewing such things as applications for modified risk products, setting performance standards etc. that its composition should

include several members who have other critical expertise and training. We suggest the following additional voting members:

(iii) 1 individual who is an expert in agronomy and tobacco plant technologies;
(iv) 1 individual who is an expert in labeling, marketing, and consumer affairs;
(v) 1 individual who is an expert in harm reduction

(Note: re-designate the current subparagraphs (iii), (iv), and (v) accordingly)

Respectfully Submitted on Behalf of AHEAD,

Scott D. Ballin
Steering Committee Member
AHEAD (Alliance for Health Economic and Agriculture Development
202 686-8898

Mr. WAXMAN. Thank you very much, Mr. Ballin. I appreciate your testimony.

Mr. Winkler, I am looking forward to hearing from you.

STATEMENT OF JAMES WINKLER, GENERAL SECRETARY, GENERAL BOARD OF CHURCH AND SOCIETY, UNITED METHODIST CHURCH

Mr. WINKLER. Thank you, Mr. Chairman. I am Jim Winkler, general secretary of the United Methodist General Board of Church and Society of the United Methodist Church. As you may know, our denomination is the third largest in the United States with more than 8 million members in nearly 35,000 local congregations.

I am also chair of Faith United Against Tobacco, a broad-based coalition of faith leaders. Since it was founded in 2002, Faith United Against Tobacco has grown to include over 20 national faith denominations and organizations. In addition to our agency, the coalition includes the Ethics and Religious Liberty Commission of the Southern Baptist Convention, the National Council of Churches, the Presbyterian Church USA, the Commission on Social Action of Reformed 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.

I appreciate this opportunity to testify in favor of H.R. 1108, Family Smoking Prevention and Tobacco Control Act, lifesaving legislation to authorize the Food and Drug Administration to regulate tobacco products. We have made enactment of the tobacco legislation introduced by yourself and Mr. Davis one of our top legislative priorities for this Congress. The legislation is long overdue, and on behalf of the many members of our faith groups united in our coalition, I strongly urge Congress to take action now and enact this critically important legislation with all due speed.

In addition to our national effort to convince Congress to enact FDA regulation of tobacco, 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 Methodist, Southern Baptist 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.

Our focus on the Federal level has always been on enacting legislation to give FDA authority over tobacco products. Recently, 24 national faith leaders from our coalition sent a letter to every Member of the Senate and the House urging support for the FDA legislation. The signers of this letter represent very diverse groups including Christian, Jewish, Muslim and Sikh denominations

whose members include 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 hold widely diverse positions on other important social and political issues but we are and we will remain united in our desire to reduce smoking, especially among children and in our commitment to the enactment of this legislation authorizing the FDA to regulate tobacco products.

Our faith traditions teach us it is morally wrong to know the good that should be done and not do it. It is also morally wrong to leave the most impressionable and vulnerable among us, our children, unprotected from tobacco enticements that confront them and so we in the faith community believe that those who are called to positions of leadership and power have a moral imperative to exercise their power to safeguard the men, women and children of our country from falling into the pitfalls of tobacco abuse.

All members of Faith United Against Tobacco believe that 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 an obligation both morally and as guardians of our citizens 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.

Mr. Chairman, I want to thank you especially for your leadership in this effort. We are happy to work alongside you. Thank you.

[The prepared statement of Mr. Winkler follows:]

STATEMENT OF JAMES WINKLER

Good morning, Chairman Pallone, Representative Deal and Members of the Subcommittee. I am James Winkler, General Secretary of the General Board of Church and Society of The United Methodist Church. As you may know, The United Methodist Church is the third largest religious denomination in the United States, with more than 8 million members worshipping in nearly 35,000 local congregations in the United States.

I am also the Chair of Faith United Against Tobacco, a broad-based coalition of faith leaders. 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 General Board of Church and Society of The United Methodist Church, our coalition includes the Ethics & Religious Liberty Commission of the Southern Baptist Convention, 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.

I appreciate this opportunity to testify in favor of H.R. 1108, 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 Representatives Henry Waxman and Tom Davis one of our top legislative priorities for the 110th Congress. This legislation is long, long overdue, and, on behalf of United Methodists and the many members of the other faith groups united in our coalition, I strongly urge you to take action now and to enact this critically important legislation with all due speed.

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.

Our focus at the Federal level has always been on enacting legislation to give the FDA authority over tobacco products. Recently, twenty-four 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. The signers of this letter represent very diverse groups, including Christian, Jewish, Muslim, and Sikh faith denominations, whose members include 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 widely diverse positions on other important social and political issues. But we are, and we will remain, united in our desire to reduce smoking, especially among children, and in our commitment to the enactment of this legislation authorizing the FDA to regulate tobacco products.

Many Americans now know the terrible statistics about the toll of tobacco on our families—over 1200 Americans die each day, every day from tobacco use. Another 1200 will die tomorrow; and the day after that; and every single day of the year. In all, 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, there are tragic faces attached to these frightening statistics. Every day clergy in our faith groups assist families in burying mothers and fathers, sisters and brothers who die absolutely preventable and premature deaths caused by tobacco addiction. And, more often than not, these addictions began at a young age. We, then, are left with the difficult task of trying to comfort their grieving survivors. Every one of these people who dies of tobacco use leaves behind families and friends who miss them very much and suffer their untimely and tragic loss.

I speak this morning from personal experience. My father, uncle, and brother are United Methodist clergy. All of them have dealt with church members over the years who have become addicted to tobacco and each of them have dealt directly with the negative effects of cancer on their congregations and the families who have suffered from this product.

Literally, millions of Americans have died 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 a future that is cut short due to lack of knowledge about the ingredients and addictive nature of tobacco. 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 faith groups in our 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; 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, dog food and nicotine cessation products, but has no authority over tobacco, a product that causes more preventable deaths than any other.

The United Methodist Church is unwavering in its declaration to ensure protection for all of God's children especially from harmful and addictive products. Our Faith Coalition is simply asking that tobacco products be subject to the same common sense consumer protections that apply to other products. Why should manufacturers of nicotine 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 excessive 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 and spiritual reasons. Our faith traditions inform us that our bodies are gifts from God and, therefore, should be treasured and treated with dignity. This means, among other things, that tobacco companies should not be allowed to entice our children to pollute their bodies. While each adult 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, to end the marketing of these products to children and to significantly reduce the illness and death that these practices can produce.

Our faith traditions teach us that it is morally wrong to know the good that should be done and not do it. It is also morally wrong to leave the most impressionable and vulnerable among us, our children, unprotected from the tobacco enticements that confront them. And so, we in the faith community believe that those who are called to positions of leadership and power have a moral imperative to exercise their power 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 and without the full knowledge of the dangers of tobacco 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 the bill before you, but it was killed in a conference committee. And on August 1, the Senate Committee on Health, Education, Labor and Pensions passed this bill. 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.

All members of Faith United Against Tobacco believe that the United States 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 an obligation, both morally and as guardians of our citizens 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 H.R. 1108, bipartisan legislation to provide the Food and Drug Administration authority to regulate tobacco products.

Chairman Pallone, Representative Deal, and other Members of the Committee, I thank you for permitting me to testify this morning. I will be happy to entertain any questions.

Mr. WAXMAN. Thank you very much, Mr. Winkler. I appreciate your testimony.

Mr. Armour.

STATEMENT OF HENRY ARMOUR, PRESIDENT AND CEO, NATIONAL ASSOCIATION OF CONVENIENCE STORES

Mr. ARMOUR. Thank you, Mr. Chairman, for giving me the opportunity to testify before you today. My name is Henry Armour. I am the president and CEO of the National Association of Convenience Stores. Founded in 1961, NACS is a not-for-profit trade association representing more than 2,200 retail member companies in the United States and abroad. NACS is the preeminent representative of interests of the convenience store operators. The convenience store industry in the United States, with over 145,000 stores, posted $569 billion in total sales in 2006. More than 70 percent of NACS members are small family businesses owning and operating 10 or fewer stores.

I appreciate this opportunity to share the convenience store industry's views regarding H.R. 1108. Tobacco sales are a highly important component of our members' businesses. Convenience stores sell more than 60 percent of the cigarettes sold in the United States in more than 20 million transactions per day.

I want to make clear that NACS takes no position with respect to the manufacturing provisions in H.R. 1108. That is not our issue. Our industry simply wants to sell legal products responsibly

under regulatory regimes that are fair and effective. With respect to retail sales, the overall approach taken in this bill has not changed much from previous legislative proposals that Congress has considered over the past decade. The facts on the ground, however, have changed dramatically.

During the past 10 years, the rates of retail noncompliance nationwide fell from 40.1 percent in 1997 to 10.9 percent in 2006. You can see a chart over here to my left showing that decline. Virtually every State has shown consistent improvement, and in 2006 for the very first time every single State in the Nation reduced its rate of sales to minors below the threshold set by Congress. Our goal is to completely eliminate illegal tobacco sales and clearly the regulatory scheme in place has been and continues to be very effective in making progress towards achieving this goal. In our view, some of the specific provisions and omissions in the bill are less effective than they might be.

H.R. 1108 puts at risk a retailer's license to sell tobacco even if that retailer has an excellent compliance program. I disagree with this approach. While there may be fines imposed for any violation, losing the ability to sell tobacco often means that a convenience store goes out of business and is sold. Forcing a store transfer is too harsh a sanction if a business owner has done everything in his or her power to prevent a violation and may likely result in less diligent owners operating the store.

Another problem with this legislation is that it makes the FDA responsible for duplicating the regulation of retailers when States are already doing this well. We all know and have heard this morning that the FDA has its hands full trying to keep our food supply and pharmaceutical products safe and adding responsibility to regulate over 300,00 retail establishments that are not currently under its jurisdiction will undoubtedly put even greater strains on the agency.

This legislation also does not adequately cover sales made through the Internet or on Native American lands. A cigarette purchased over the Internet or an Indian reservation is no less harmful to the youths of America and should be regulated in the same manner as all other cigarette sales.

There are other concerns with this legislation but there is one particular issue that I would like to call to your attention. In 1997 the FDA prohibited the sale of over-the-counter smoking cessation products like Nicorette gum in convenience stores. I must say that the reasoning behind this decision baffles me. If we are serious about wanting people to stop smoking, we should want them to be able to get products that help them quit in convenient settings and in those places where they would purchase cigarettes. This legislation ought to fix this mistaken policy.

If the committee is going to legislate with respect to retail sales, then it should with the current effective system, not against it. Setting standards for State regulation, closing loopholes for Internet and Native American sellers, providing incentives for retailers to have good compliance programs and allowing convenience stores to sell smoking cessation products are critical elements to sound regulation of tobacco sales.

We would welcome the opportunity to work with you to address these concerns. I thank you for your time and the opportunity to share NACS's view with you. Thank you very much.

[The prepared statement of Mr. Armour follows:]

TESTIMONY OF HENRY ARMOUR

My name is Henry Armour and I am President and CEO of the National Association of Convenience Stores (NACS). Founded in 1961, NACS is a non-profit trade association representing more than 2,200 retail and 1,800 supplier company members in the United States and abroad. NACS is the pre-eminent representative of the interests of convenience store operators. The convenience store industry in the United States, with over 145,000 stores across the country, posted $569.4 billion in total sales in 2006. More than 70 percent of NACS members are small family businesses owning and operating 10 stores or less.

I appreciate this opportunity to share the convenience store industry's views regarding H.R. 1108, the Family Smoking Prevention and Tobacco Control Act. Tobacco sales are a highly important component of NACS member's businesses. Convenience stores sell more than 60 percent of the cigarettes sold in the United States in more than 20 million transactions per day. Such sales, on average, constituted nearly thirty four percent of the in-store sales at NACS members' retail locations in 2006. Tobacco is a legal product that is important to the economic viability of the convenience store industry. I have firsthand experience with the everyday realities of operating a business and selling tobacco products. Before coming to NACS, I owned and operated a chain of more than 50 retail outlets in the states of Washington, Oregon, and California.

I want to make clear that NACS takes no position with respect to the manufacturing provisions in H.R. 1108—that is not our issue. Our industry simply wants to sell legal products responsibly under regulatory regimes that are fair. And we do have quite a bit of experience with the retail sale of tobacco products. In our view, H.R. 1108 should take a different approach to the regulation of retail tobacco sales. My testimony will explain why we believe a system of state regulation with Federal goals—like the current system—is the right one and why the approach taken in H.R. 1108 should be changed to reflect the lessons we have learned.

THE CURRENT SYSTEM FOR REGULATING TOBACCO RETAILING IS WORKING

Underage Sales Are Falling. H.R. 1108's overall approach to retail sales has not changed much from previous legislative proposals that Congress has considered and failed to enact for the past decade. While the overall approach has been largely stagnant, however, the facts on the ground have changed dramatically.

The Department of Health and Human Services recently released the latest numbers regarding state efforts to enforce laws against tobacco sales to minors. Since the mid–1990s, states have faced the possibility of losing some of their substance abuse and mental health services grant funds if they have not reduced the rate of violations of these laws to below 20 percent. This Federal standard, known as the Synar Amendment, has produced consistently improving results.

During the past 10 years, the violation rates nationwide have fallen every single year. In fact, the percentage of retail violations found nationally fell from 40.1 percent in 1997 to 10.9 percent in 2006. Virtually every state has shown consistent improvement. And in 2006, for the first time, every single state in the Nation reduced its rate of sales to minors below the threshold set by the Congress. I have included a copy of this latest report as exhibit A to my testimony. There does not appear to be any other way to read this report than to conclude that our current system of regulating retail sales of tobacco is making progress. In light of these clear findings, Congress should not impose costly regulations that are unnecessary and counterproductive. Instead, Congress should continue its successful policy of working with states to ensure that they diligently regulate tobacco sales.

Retailers Are Taking Action to Reduce Underage Sales. Part of the reason for the success of the Synar Amendment is the effort put forward by retailers. Convenience store operators and other retailers have dedicated considerable resources and money trying to prevent tobacco sales to minors by investing in employee training, signage, company-operated stings, incentives for employees, and enforcement of company policies. Some retailers have even installed electronic age verification (EAV) devices to help eliminate these sales.

In order to assist in the elimination of tobacco sales to minors, retailers, wholesalers and manufacturers have formed the Coalition for Responsible Tobacco Retail-

ing. This Coalition developed the "We Card" training program, which provides education and training to help retailers prevent underage tobacco sales. The program includes development and dissemination of retailer best practices to tobacco retailers across the country. The "We Card" training materials include signage, training videos, training guides, posters, interactive on-line training, and daily reminder calendars. To date, over one million "We Card" kits have been distributed to retailers nationwide. "We Card" offers hundreds of classroom training sessions that train almost 10,000 retailers annually. Indeed, since its inception, "We Card" has held over 2,070 classroom training sessions in all 50 states in the U.S. and U.S. territories. In the past decade, over 100,000 owners, managers and frontline employees have been trained by "We Card."

In addition to NACS, "We Card" has been endorsed by the National Grocers Association, the National Retail Federation and the National Association of Police Organizations. Forty-four state coalitions have been assembled to support state level training and education and 236 regional, state and local trade associations support the "We Card" initiative. Several governors, mayors, state attorneys general, and tobacco control boards throughout the United States have also endorsed this program.

Many retailers have strengthened their efforts to reduce the sales of tobacco products to minors by incorporating "We Card" into a multi-pronged approach to combat this problem. In addition to the training and signage included in the "We Card" program, many companies have set stringent company policies. Retailers across the United States understand that solely training employees and setting a "No ID-No Sale" policy is not enough to eliminate these sales. Without enforcement of their policy, the inclusion of incentives and/or use of additional tools retailers would not be able to be successful. For example, many companies conduct mystery shopper programs. Through these programs, companies hire teenagers to conduct company operated stings in order to obtain an accurate account of their compliance rate, and continually remind their employees of the company's tobacco retailing policy. These mystery shopper programs are becoming more prevalent throughout the industry. Additionally, many retailers have instituted incentive programs for their employees. Many employers are providing incentives, either through bonuses or other benefits, for those employees who pass a company operated sting. Some retailers also have adopted zero tolerance policies. For those companies, if an employee is caught even once selling to a minor that person is terminated on the spot. Retailers are also looking at other, non-traditional, avenues to assist in this effort. Many companies are purchasing EAV devices to help eliminate calculation errors. An EAV will electronically read birth date information stored on state driver's licenses to determine whether a consumer can purchase an age-restricted product, thus removing an element of human error.

Independent studies have shown that retail education and training as well as asking for proper identification can help prevent underage tobacco sales. A University of Idaho study conducted for the Idaho Department of Health compared retailers using the "We Card" program to retailers using other materials or no materials at all. The study found:

- The violation rate among retailers using "We Card" materials was 7.22 percent, while the rate for other retailers was 16.96 percent.
- Retailers displaying "We Card" materials were 12.9 times more likely to ask for identification than not to ask for identification, while other retailers were 4.9 times more likely to ask for identification than not to ask for identification.

SHORTCOMINGS OF THE RETAIL PROVISIONS OF H.R. 1108

Not only does NACS differ with the overall approach to tobacco retailing taken by H.R. 1108, some of the specific provisions and omissions in the bill are less effective than they should be and/or are unfair.

Retailers Should be Encouraged to Sell Responsibly. The first thing to note is that in most areas of regulation we do not hold people liable for things over which they do not have control. Penalizing activity that we have no ability to control loses does not deter illegal conduct—it is simply punitive. That is important to note when legislating on this subject. When I ran a chain of convenience stores, I had compliance plans in place to try to ensure that we followed the laws with respect to selling age-restricted products like tobacco. For example, we conducted comprehensive training for all employees to ensure that they were trained on their responsibilities for checking ID cards and we had a zero tolerance policy if they failed to follow the rules, including immediate termination if tobacco was sold to a minor. We also conducted sting operations on our own stores to try to detect problems and correct them. But I could not guarantee that an employee would never make a mistake or intentionally violate my company policies. Unfortunately, H.R. 1108 puts at risk a retail-

er's license to sell tobacco even if that retailer has an excellent compliance program but has one or two bad employees who unintentionally (or intentionally) sell to minors. I believe that is the wrong approach. While there may be fines imposed for any violation, losing the ability to sell tobacco often means that a convenience store goes out of business. That is just an economic reality given the very thin margins in the industry and the number of adults who frequent convenience stores in order to buy tobacco. Closing the store is too harsh a sanction if a business owner has done everything in his or her power to prevent a violation. And such a harsh sanction against companies with quality compliance programs may have the unintended consequence of stores being sold to individuals with no such training programs. In addition, having a provision requiring an adequate compliance program as a condition to avoid the loss of a license to sell tobacco can be a powerful incentive for retailers to do the right thing. In our view it would help us make real progress on this issue if retailers had this incentive for implementing strong compliance programs.

The States, not FDA, Should Have Primary Enforcement Responsibility. Another problem with this legislation is that it makes the Food and Drug Administration responsible for duplicating the regulation of retailers when states are already doing a good job in this area. We now have a decade of experience with the Synar amendment in place and retailer noncompliance rates have gone down every single year. As I said earlier, the national weighted average noncompliance rate in 1997 was 40.1 percent and last year that number fell to 10.9 percent. While our goal is to completely eliminate tobacco sales to minors, the current system is a real success story and is certainly making progress toward achieving our goal.

Rather than creating a new Federal bureaucracy for retail sales, Congress should be looking at ways to improve upon the successes we have gained through the Synar Amendment's incentive to states. We are willing to work with the Committee in setting standards that state regulations must meet, making Synar's requirements tougher, or otherwise, but it is difficult to see why adding an already overtaxed FDA on top of the current system of state regulation will improve the system. We all know that the FDA has its hands full just trying to keep our food supply safe and adding the responsibility to regulate 300,000 retail establishments that are not currently under its jurisdiction will undoubtedly put even greater strains on the agency.

Innovative legislative activity relating to the retailing of tobacco is occurring in the States. Pennsylvania, Texas, Idaho, Colorado, Michigan, Florida, Ohio and others have laws that offer an affirmative defense for retailers who take necessary compliance measures to avoid underage sales. These laws incentivize retailers to take appropriate measures to ensure their businesses comply with the law and the approach has been quite successful. H.R. 1108 would remove some of these incentives and make retailers subject to a loss of their license to sell tobacco even if they do everything right. That change threatens to undo some of the progress made by these states.

Pennsylvania, Missouri and Iowa have enacted laws that place the shared responsibility upon retailers, minors and clerks. In Missouri, the law allows for the assessment of a fine upon clerks as well as retailers. The person making the underage sale is then subject to a fine of $25 for the first offense, $100 for the second offense and $250 for subsequent offenses. In Pennsylvania, minors purchasing or attempting to purchase tobacco products are required to participate in tobacco education programs, lose their driving privileges, or be fined. In fact, many states have passed laws creating penalties for minors who purchase or possess tobacco and have been successful in curtailing underage smoking.

Vermont law provides that people under age 18 who possess tobacco will be fined $25 and, if the fine is not paid within 60 days, will lose their driver's license for up to 90 days or their initial eligibility for a driver's license will be delayed by up to 1 year. If a person under age 18 misrepresents his or her age to buy tobacco, then that individual will be subject to a $50 fine or 10 hours of community service or both. Vermont's approach is working. Vermont's 2005 Youth Risk Behavior Survey showed that smoking rates among eighth graders in the State have steadily fallen from 26 percent in 1997 to 22 percent in 1999 to 13 percent in 2001 to 8 percent in 2005. For all Vermont students surveyed (including students in grades 8 through 12), smoking rates fell from 36 percent in 1997 to 31 percent in 1999 to 22 percent in 2001 to 16 percent in 2005. In all, Vermont experienced a drop of more than 50 percent in youth smoking over a 4-year period. In fact, the Campaign for Tobacco-Free Kids called Vermont's results "among the most impressive in the Nation." The Centers for Disease Control and Prevention (CDC) has noted that the number of states and localities imposing such penalties is increasing.

H.R. 1108 fails to include any penalties for minors who attempt to purchase tobacco. That means they have absolutely no deterrent and the same 17-year old can attempt to buy cigarettes at a store over and over again and get tobacco from older friends, family members, the Internet or elsewhere without threat of sanction. This is a major flaw in the legislation. We have penalties when minors possess age-restricted products like alcohol because we understand that taking action on both the supply and the demand side of the equation is more comprehensive and produces better results.

Some States have used incentives based on new technology to try to get better results. New York and Connecticut, for example, have passed state legislation giving retailers an affirmative defense if they purchase and use EAV (electronic age verification) devices solely for the purpose of age verification on sales of age-restricted products.

All of these state activities have affected where minors get tobacco products. According to the most recent Youth Risk Behavior Surveillance study conducted by the CDC, the percentage of students who said they purchased their cigarettes from a store or gas station fell from 38.7 percent in 1995 to 15.2 percent in 2005. Minors now report that friends and family members are more frequent sources of tobacco products than convenience stores. This demonstrates that we need to adjust our thinking to address all of the ways that minors get tobacco. It also shows that States, localities, and private efforts are having an effect and should be given the opportunity to make further improvements.

THE RETAIL PROVISIONS OF H.R. 1108 CAN AND SHOULD BE IMPROVED

If the committee moves forward with H.R. 1108, it must address some of the most difficult—and growing—problems in tobacco retailing.

Internet and Native American Sales. The improving compliance rates I noted earlier do not cover sales made through the Internet or on Native American lands. We do not know how often these retailers check IDs to make sure their customers are old enough to purchase tobacco. What we do know is that what you typically see when you attempt to purchase tobacco on the Internet is woefully inadequate. In many cases, when a customer clicks on a pack of cigarettes on a website to try to purchase tobacco, a box appears. The wording can vary slightly but often says that by clicking "OK" the purchaser verifies that he or she is 18 years old. As if this "honor system" approach were not inadequate enough, many of these sites only have one box—the one that says "OK." A minor could not respond that he was underage even if he wanted to do so. H.R. 1108, however, revives 10-year old FDA regulations that exempt Internet and mail order purchases from the requirement for checking IDs. This makes no sense. Internet cigarette sales are now about 14 percent of the national market. That is big business. IDs can be checked at the point of delivery—and often are when alcohol is shipped—so there is no reason to exempt these sales from regulation.

Any legislation also should address tobacco sales on Native American reservations. Without explicit provisions making clear that the law should be enforced on reservations, the history on these issues shows that such sales will be ignored. Yet, Native American tobacco retailers have increased their share of the retail tobacco market over the past several years and there is no reason why they should not abide by the same rules, and deal with similarly effective enforcement mechanisms, as their off-reservation competitors. This can be done without violating tribal sovereignty and is essential if Congress's goal is to have a fair and comprehensive bill. A cigarette purchased over the Internet or on an Indian reservation is no less harmful to the youths of America and should be regulated in the same manner as all other cigarette sales.

Sales of Smoking Cessation Products. A number of other problems exist in this legislation, including placing responsibility in the wrong place for labels and setting unrealistic penalties, but there is one issue in particular that I would like to call to your attention. Several years ago, FDA entered into a consent decree preventing convenience stores from selling over-the-counter a popular smoking cessation product, Nicorette gum. This was done when the product first became available over-the-counter so there was no evidence of any kind that there were issues with sales of these products in convenience stores. Indeed, products like Nicorette are sold over the counter today at drug stores from a shelf right above cartons of cigarettes. Why drug stores can offer these products and the local convenience store cannot baffles me. If Congress is serious about wanting people to stop smoking, it should enable people to get products that help them quit in convenient settings and in those places where they would purchase cigarettes. Prohibiting such sales is counter-productive.

CONCLUSIONS

As noted, the current system of state regulation to try to meet Federal goals is making measurable progress. This approach should be preserved. If the Committee is going to legislate with respect to retail sales, then it should work with the current system—not against it. Four elements are critical.

First, the legislation should preserve the role of states as the regulators of retail tobacco sales but could set additional Federal goals that states must meet. Such legislation could range from compliance targets like those set in the Synar Amendment to detailed model legislation that states must adopt and enforce. NACS has advocated for this type of approach in the past and experience has shown that it is the right way to address retail sales. The bottom line is that states have the experience and resources to regulate retail sales—the FDA does not. States have a record of a decade of solid progress in reducing tobacco sales to minors—the FDA does not. States have the enforcement and judicial personnel to enforce the law and provide due process to retailers—FDA does not. In fact, just a cursory glance at the newspapers demonstrates that the FDA is an agency that is already stretched incredibly thin. It is being asked to address more issues—including new questions about the safety of imported food and drugs—without enough resources. Adding the responsibility of policing more than 300,000 retailers of tobacco products across the Nation is a prescription for disaster for the FDA and will not improve efforts to curb youth smoking. Instead, it may make things significantly worse. State regulation to meet Federal standards is an approach that works in this area. Let's do what works.

Second, any new legislation should explicitly address tobacco sales over the internet and on Indian reservations and require all tobacco retailers to obey the same rules.

Third, Congress should adopt appropriate incentives for companies to implement effective compliance programs by protecting them from losing their license to sell tobacco products.

Finally, Congress should lift the ban on the sale of smoking cessation products in convenience stores.

I thank you for your time and for the opportunity to share NACS' views with you. I welcome any questions you may have.

Mr. WAXMAN. Thank you very much, Mr. Armour.

Dr. Henningfield.

STATEMENT OF JACK E. HENNINGFIELD, VICE PRESIDENT, RESEARCH AND HEALTH POLICY, PINEY ASSOCIATES, BETHESDA, MD

Mr. HENNINGFIELD. Mr. Chairman and members of the committee, thank you for the opportunity to testify and 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. H.R. 1108 is vital to get FDA off the bench and onto the field to help address a category of product that kills more than 400,000 Americans every year.

Many people do not understand how FDA could help prevent tobacco use, addiction and related diseases. Let me help you to understand. Many people think of tobacco products as relatively simple concoctions of tobacco and flavorings that people smoke for simple pleasure, with full awareness of the dangers, and that smoking is a completely free choice. But 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 regulatory oversight to draw the line on practices that unnecessarily increase harmful and addictive effects. Over time, FDA authority could lead to less addictive and less harmful products and regulation of marketing to reduce deception.

Existing and future tobacco products need to be regulated. Existing products are used by more than 50 million Americans, killing more than 1,000 every day. Setting standards for chemicals that can heighten addictiveness such as ammonia and acetaldehyde and flavorings such as menthol, chocolate, cherry, honey and others could be steps towards less addictive and less attractive tobacco products. Developing performance standards for toxicants such as heavy metals, arsenic, tobacco-specific nitrosamines, carbon monoxide, formaldehyde could reduce toxin exposure to 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 they left my throat raw compared to lights. Let me tell you a few things she didn't know. She assumed there were Government standards. She thought they were regulated. She thought there were standards for light cigarettes. She thought 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 a 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 have really good eyes. If you tear the paper from a cigarette filter and hold it to a light, you can see bands of tiny holes about three-eighths to one-half inch from the end. This is right where they can be easily covered by fingertips or lips and unbeknownst to most smokers, blocking some of the holes can easily double or triple delivered tar and nicotine. I did a demonstration on this a few years ago for my son's third grade class, and his classmates reacted with clarity and passion. Their comments included "that is cheating. They can't do that." That is cheating and there is a means of stopping it and preventing such deception for food products, for dog food, and for drugs but not for tobacco, not until tobacco is regulated by FDA.

New generations of products appear to be following the same commercially effective model of light cigarettes. Lights are just the tip of the iceberg, and new products and new marketing campaigns are used to assuage fears about tobacco so as to hook more people and to keep those who are using to keep using. These products will need their own standards and they will need standards that are studied and developed before the products are allowed to be marketed so that marketing does not inappropriately promote use. FDA is the right agency and the only agency with appropriate experience to develop and enforce product performance standards. FDA was designed to assess safety in ingredients and resultant toxicant exposures for a broad range of products. Furthermore, tobacco products are drug delivery systems at heart. Even the tobacco industry admits this in their own documents. Moreover, tobacco products are designed to heighten and deceive and heighten addiction risk.

Finally, let me emphasize that FDA authority will not make tobacco products safe, is not the answer to American's tobacco problem in its own right. It should not be seen as a substitute for com-

prehensive tobacco control efforts. In fact, FDA regulation should be viewed as a partner in tobacco. The bill will bring the most sophisticated health regulatory body in the world to the table finally in partnership with tobacco control experts seeking to reduce tobacco use and prevent it in children. FDA will then be positioned to serve these efforts because it will restrict the ability of the industry to modify their products, use descriptors and marketing that undermine prevention and cessation. I therefore urge expeditious passage and implementation of the Family Smoking Prevention and Control Act. Thank you very much.

[The prepared statement of Mr. Henningfield follows:]

STATEMENT OF JACK E. HENNINGFIELD

Thank you for the opportunity to testify on H.R. 1108, 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 tobacco 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 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 US 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 one thousand 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 1700-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 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.

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 H.R. 1108. 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 weakened. 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 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 AmericansToday, 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 3/8 to 1/2 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 that are intended to hide them. When the cigarettes are smoked according to the FTC method, the holes leak anywhere from about 20–90% 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.

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 manufactures 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 with 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 H.R. 1108.. I therefore urge its most expeditious passage and implementation.

Mr. WAXMAN. Thank you very much, Dr. Henningfield.

Mr. Corr, I think the last time I chaired a hearing on tobacco, you were on this side, not that side. We are pleased to welcome you.

STATEMENT OF WILLIAM V. CORR, EXECUTIVE DIRECTOR, CAMPAIGN FOR TOBACCO-FREE KIDS.

Mr. CORR. Thank you, Mr. Chairman, very much for those remarks, and Mr. Sullivan, thank you both for your patience. We know this has been a long day and we appreciate you giving us the opportunity to testify.

This legislation, Mr. Chairman, as you know, and its predecessor bills have been under consideration and evaluation in multiple Congresses. In this Congress, this legislation has 200 cosponsors. The public overwhelmingly supports this bill. Five hundred and nineteen public health medical and faith organizations support it. As you heard this morning, the Institute of Medicine has recommended it, and the President's cancer panel in August recommended that FDA be given the authority to regulate tobacco products.

You have heard from other witnesses about the tobacco company's behavior. I would like to take just a moment to show you what it looks like. Tobacco companies design and market products to influence and addict our children. The company's business model in fact, depends upon the addiction of children to replace the lifetime customers who die each year. Please look at these couple of ads and consider who they are designed to attract. This first one, it is hard to see possibly but it is "back to school special." If you look in the lower right-hand corner, you will see a hand with chalk writing on the board. The key question is this designed for adults who want to switch brands or is this designed for our children? Here are some ads that as you will see are on a Good Humor ice cream

freezer, and here is an ad that appeared in Sports Illustrated in 2006.

Consider also flavored products. Who are these ads for? It may be hard to see but the ad is Camel, pleasure to burn. And this is Liquid Zoo coming in any number of flavors—coconut, chocolate, strawberry, mint. Again, who are these products designed for, switching adults or for children? And as just was pointed out, the companies are still marketing light and low-tar products with their implied health benefits, even though the companies know well that there are no health benefits.

Beyond these marketing abuses, tobacco companies manipulate nicotine and other ingredients to assure addiction. They add and delete additives without oversight, even though some of them are addicting or deadly. These slides, if I may, involve the companies' claims of reduced-risk products to show you how they have designed deceptive marketing that misleads adult users in order to keep them as customers. This first ad compares the carcinogen levels and the claim is made that with Eclipse there is an 80 percent reduction in carcinogens. There is no evidence to back this up. There is no regulatory agency with objective scientific credentials to evaluate these claims. In the next ad for Omni, you will see reduced carcinogens, premium taste, and the company claims they are introducing the first cigarette to significantly reduce the major causes of lung cancer in smokers. These kinds of claims are going totally unregulated. And last, beyond these marketing abuses, companies are manipulating the ingredients.

This is a list of possible, probable and known cancer-causing chemicals in cigarette smoke. There are over 60 known carcinogens in cigarette smoke. Some of these can be easily removed in the manufacturing process but have not been because it is entirely at the discretion of the companies.

Regulating tobacco company marketing and advertising and regulating the content of tobacco products are two of the key authorities that are contained in this legislation that are urgently needed. Mr. Chairman, FDA is the only agency that can carry out the responsibilities of this legislation. It is the only Federal agency that combines scientific expertise, regulatory expertise and a public health mandate. No other Federal agency combines these three essential capabilities.

In light of this kind of industry behavior and recognizing that only FDA has the ability to implement this legislation, I would like to comment very quickly on something Commissioner von Eschenbach said in his written testimony. He said, "We are concerned that the public will believe that products approved by the agency are safe and that this will actually encourage individuals to smoke more rather than less." As was pointed out earlier, the current status quo allows the public to be mislead repeatedly by the companies with misleading ads like "light and low tar." But more importantly, what I want to bring to the committee's attention is that there are provisions in H.R. 1108 that address this very issue. The bill authorizes FDA to stop any statement by the companies that would mislead the public like being "FDA approved." The bill mandates new warnings covering the top 30 percent of the front and back of the pack. This is a mockup of what Camel No. 9 would

look like with such a written warning, and FDA has the authority under the bill to expand this to 50 percent of the top, front and back of the product and to use graphic pictures. So imagine a consumer picking up a pack of cigarettes with half of the pack a diseased lung, and the question is, is this a Government stamp of approval?

Just to point out to you as well, the Senate HELP Committee added additional provisions because they also addressed this issue as it came up in their markup. They have added a congressional finding and they added an explicit prohibition on company statements implying that FDA has regulated their products.

Mr. Chairman, I realize that my time is expired. I wanted to make some other remarks about the testimony of the retailers but we will add those for the record.

[The prepared statement of Mr. Corr follows:]

TESTIMONY OF WILLIAM V. CORR

Chairman Pallone, Ranking Member Deal, and members of the Health Subcommittee, thank you for this opportunity to testify in support of H.R. 1108, 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 Bill Corr, and I am the Executive Director of the Campaign for Tobacco-Free Kids, the Nation's largest non-profit, advocacy organization solely devoted to reducing the harm caused by tobacco use and exposure to secondhand smoke.

H.R. 1108 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. Far from being the excessive regulation that some have claimed, this carefully crafted, thoughtfully balanced legislation would correct the glaring absence of regulation of tobacco products 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, H.R. 1108 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 H.R. 1108 has been before the Congress for close to a decade. A bill virtually identical to H.R. 1108 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 two-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. The Court commented that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States."

In May of this year the Institute of Medicine issued a report, "Ending the Tobacco Problem—a Blueprint for the Nation," in which it strongly recommends that Congress enact the pending legislation granting FDA broad regulatory authority over the manufacture, distribution, marketing and use of tobacco products. In addition, the President's Cancer Panel issued a new report in August with a call to action on how to significantly reduce tobacco use and its devastating toll in the United States and around the world. The report of this prestigious panel of national experts appointed by the President, including Dr. LaSalle Leffall of the Howard University College of Medicine, Lance Armstrong and Dr. Margaret Kripke of The University of Texas M.D. Anderson Cancer Center, concluded: "The Panel recommends foremost that the influence of the tobacco industry—particularly on America's children—be weakened through strict Federal regulation of tobacco products sales and marketing."

Thus, it is no surprise that H.R. 1108 has broad bipartisan support including liberals and conservatives and Representatives from every geographic region of the country. It has been endorsed by every major national public health organization, many organizations representing health care providers (see attached letter), 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 from 70 percent of voters in a national poll. State surveys from around the country have consistently found similar 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 whether tobacco companies should be required to take measures to make cigarettes less harmful; whether tobacco companies should be prevented from making claims that some products are less harmful than others unless FDA determines those claims are true; or whether 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

H.R. 1108 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 1200 people every day. The critical word is "prematurely." Fifty percent of the people who die from tobacco die in middle age.

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. The fact is that almost 80 percent of the adults who smoke began their deadly habit before age 18.

While some hoped that the 1998 Master Settlement Agreement (MSA) would end tobacco marketing to children, in August 2006, Federal District Court Judge Gladys Kessler found tobacco companies liable for engaging in a 50-year conspiracy to defraud the American public—which included continuing to market in ways that appeal to young people and continuing 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 2005, the latest year for which data are available, the major cigarette companies almost doubled their marketing and promotional expenditures from $6.73 billion to a staggering $13.1 billion—more than $35 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 twenty-one, as well as those under eighteen. 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 that 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 its 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 influences 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 towards 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 doubled its marketing expenditures with knowledge of the impact of its marketing on children; continued marketing "light" and "low tar" cigarettes despite clear 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 two-year investigation, impact tobacco use by children. It also 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 drugs and medical devices 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.

A perfect example is the marketing of smokeless tobacco products to children. Smokeless tobacco companies in the United States have a long history of creating new products that appeal to kids and marketing them aggressively to children, including adding candy flavors. Even after the Smokeless Tobacco Master Settlement

Agreement, smokeless tobacco companies continued to advertise heavily in magazines with high youth readership and to market to youth through a number of channels, including sports events like auto racing and rodeos that are widely attended by children. Since 1970, smokeless tobacco has gone from a product used primarily by older men to one used predominantly by young boys. In 2005, the most recent year for which FTC data is available, the total marketing expenditures of the top five smokeless tobacco companies in the U.S. were more than $250 million.

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 H.R. 1108 are consistent with the Supreme Court's analysis in Lorillard 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; 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. H.R. 1108 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. H.R. 1108 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 non-users" 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. [2]

The standard in H.R. 1108 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 non-smokers to start. The goal is protecting the pubic and saving lives, and the standard set forth in H.R. 1108 is right on the mark.

---

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.

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 towards 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 non-tobacco users to start or discourage 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.

This bill does hold store owners responsible for illegal tobacco sales to children, a policy supported by 87 percent of voters, but 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.

During consideration of this legislation by the Senate HELP Committee, additional provisions were added by the Committee to accommodate the concerns of retailers. Those provisions include: clarifying that retailers receive formal notice of violations; establishing a graduated system of fines for violations that eliminates uncertainty for retailers; mandating the provision of a hearing by phone or at a nearby facility; and a number of other procedural protections. The public health community has not opposed any of these accommodations.

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 bill responds to these concerns by providing new resources for FDA to create a new office and hire new, 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 sup-

port 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.

Recognizing that the tobacco responsibilities should be implemented by new staff, the Senate HELP Committee, during its consideration of the legislation, created a new center for tobacco products to carry out the purposes of this legislation. This provision was designed to clarify the intent of the bill's authors that FDA authority over tobacco products will not interfere with other FDA activities.

FDA IS THE RIGHT AGENCY TO REGULATE TOBACCO PRODUCTS

Some have argued that the FDA is not the right agency to regulate tobacco products, but that is essentially an argument for no regulation of tobacco products at all. It is an argument for the continuation of the unacceptable status quo in which tobacco products kill more than 400,000 people in the United States each year. This is because FDA is the only agency with the scientific expertise and regulatory experience to effectively regulate tobacco products to reduce the death and disease they cause.

There is no question that tobacco products are uniquely lethal and different from any other product on the market. In fact, if tobacco products were introduced for the first time today, they wouldn't be allowed on the market at all. But the reality is there are nearly 50 million addicted tobacco users in the United States and public health experts recognize it is not feasible to ban tobacco products. The question then is this: What government agency is best qualified to regulate this dangerous product to reduce the death and disease it causes? The FDA is the only agency that can do the job well.

Some have argued that other Federal agencies, such as the Federal Trade Commission (FTC), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), or even the Agriculture or Treasury Departments (USDA/DOT) would be more appropriate to handle the job of tobacco product regulation. But the FDA is a public health regulatory agency, and the others are not. The FTC's primary orientation is law enforcement and broad consumer protection; the NIH's is research; the CDC is primarily focused on preventing disease outbreaks, injury and disability. EPA works to develop and enforce regulations that implement environmental laws enacted by Congress; the Alcohol and Tobacco Tax and Trade Bureau at the Treasury Department describes its mission as "to collect taxes owed;" and USDA is primarily involved with the business of farming, not in overseeing non-food manufactured products such as cigarettes.

These other agencies do not have the requisite expertise to regulate the design and content of tobacco products or to know about the accuracy of health claims about these products. The FTC, for example is, by its own admission, an "agency of lawyers and economists" and is not a science-based agency. The FDA is the only agency with the scientific expertise, regulatory experience and skills, and public health mission to effectively regulate tobacco products and the health claims about them.

Impact on Tobacco Companies: Some tobacco companies have argued that this bill will give an advantage to one tobacco manufacturer over others, that some tobacco companies cannot comply with stringent FDA regulations and that industry leaders will benefit by the bill's restriction of tobacco marketing. None of these arguments have 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.

That said, it should be noted that H.R. 1108 contains several provisions that consider small manufacturers" resources and take into account that they may need more time and technical assistance to comply, including making clear that FDA should take into account the financial resources of the different manufacturers in setting effective dates for good manufacturing standards, and that FDA should minimize, consistent with the public health, economic loss to domestic and international trade.

In addition, the Senate HELP Committee went even further during its consideration of the legislation, creating a special office within FDA tasked with providing assistance to small tobacco product manufacturers. The Senate Committee also

added a representative of small manufacturers to the Tobacco Products Advisory Committee as a non-voting member.

The bill's marketing restrictions are also fair and balanced. Today, close to 90 percent of all new long term smokers began as 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 and promotion. 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 forty 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.

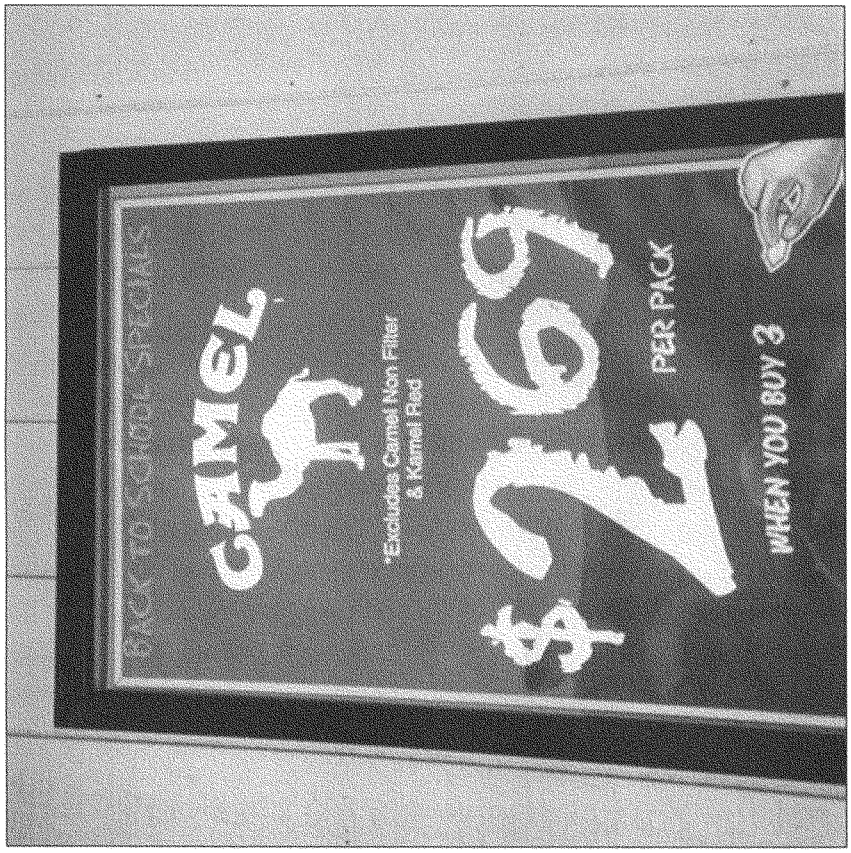
The bill does give the FDA exclusive authority in such areas as tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products. States could not establish requirements in these areas. This approach is consistent 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

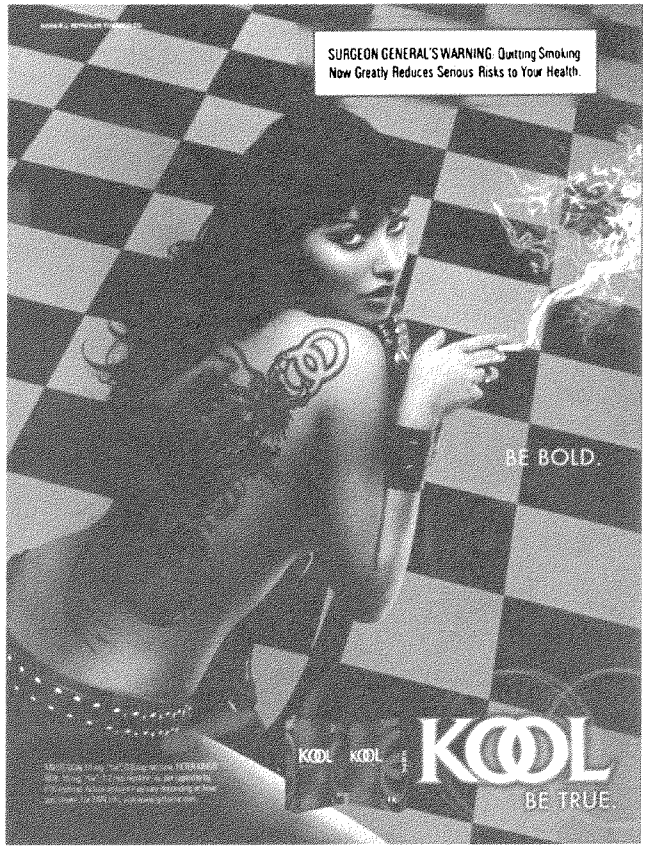
tobacco farms. The bill establishes FDA authority over tobacco manufacturers and their products and prohibits FDA from regulating leaf tobacco. Even FDA's standard-setting authority is limited to standards for manufactured tobacco products. Many tobacco growers believe American producers, much more easily 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.

Mr. Chairman, in summary, the Campaign strongly supports 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.



Camden, DE
2006

Washington DC, April 2006



GQ, August and April 2006; *Sports Illustrated*, February 17, 2006.
Courtesy of trinketsandtrash.org

Marie Claire (8/03, 8/04)

Time (6/28/04)

Vanity Fair (8/04)

Sporting News (7/12/04)

Rolling Stone (7/8/04)

Entertainment Weekly (7/30/04)

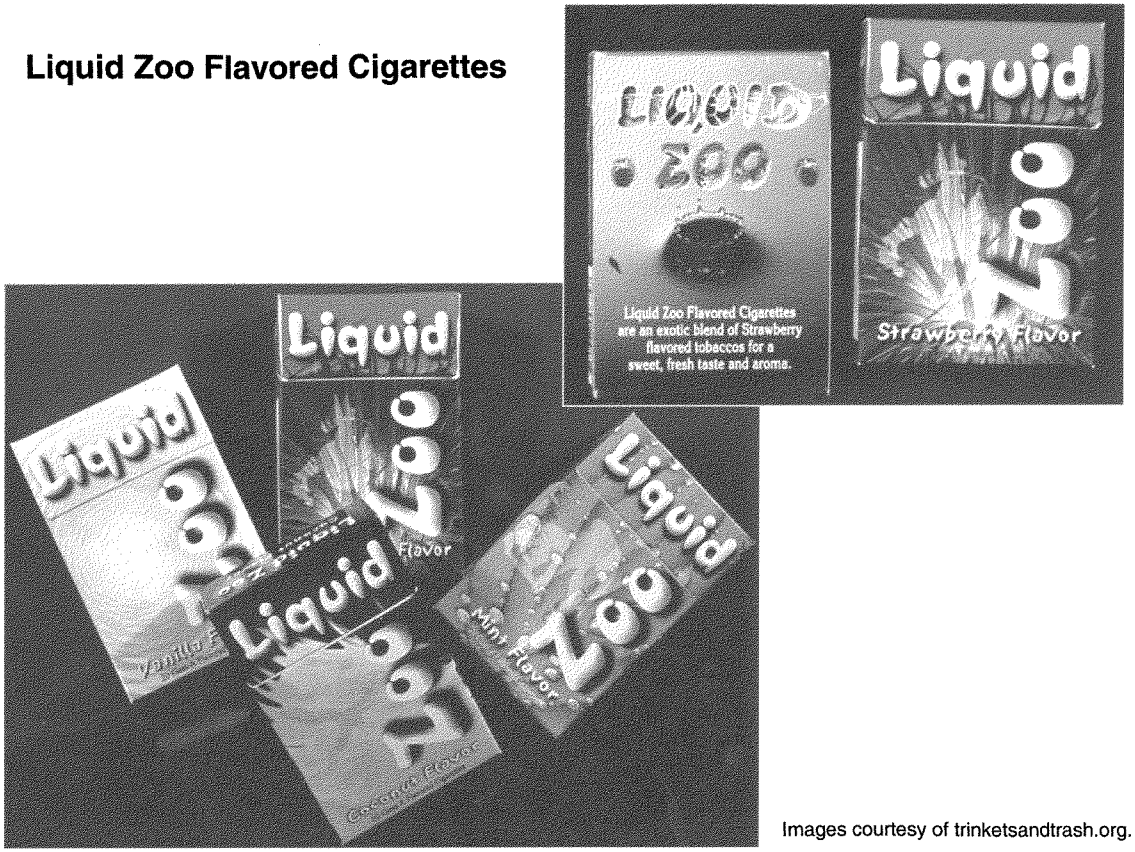
Vogue (8/04)

Glamour (8/04)

Elle (8/04)

Sports Illustrated (6/28/04, 7/26/04)

Liquid Zoo Flavored Cigarettes



Images courtesy of trinketsandtrash.org.

Advertisement for Eclipse Cigarettes

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.**

WHY THERE'S NO CIGARETTE LIKE ECLIPSE.

	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	0.8 mg 3.3 mg	83% less 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
Ashes	Yes	No	

Carcinogens** 0.68 mg 0.13 mg 80% less

A Marlboro Ultralight was tested as the typical ultralight and a Marlboro Light as the typical light.

*FTC "tar" minus glycerin. **Under FTC conditions, NIH 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

Family Circle, March 12, 2002
Courtesy of trinketsandtrash.org

LIST OF KNOWN, PROBABLE, AND POSSIBLE CANCER CAUSING CHEMICALS IN CIGARETTE SMOKE

Polycyclic Aromatic Hydrocarbons Benz(a)anthracene Benzo(b)fluoranthene Benzo(j)fluoranthene Benzo(k)fluoranthene Benzo(a)pyrene Dibenz(a,h)anthracene Dibenzo(a,l)pyrene Dibenzo(a,e)pyrene Indeno(1,2,3-cd)pyrene 5-Methylchrysene	Miscellaneous Organic Compounds Acetamide, Acrylamide Acrylonitrile, Vinyl chloride DDT, DDE Catechol, Caffeic acid 1,1-Dimethylhydrazine, Nitromethane 2-Nitropropane, Nitrobenzene Ethyl carbamate Ethylene oxide Propylene oxide Methyleugenol MeAaC (2-amino-3-methyl-9-H-pyrido[2,3-b]indole
N-Nitrosamines N-Nitrosodimethylamine N-Nitrosoethylmethylamine N-Nitrosodiethylamine N-Nitrosodi-n-propylamine N-Nitroso-di-n-butylamine N-Nitrosopyrrolidine N-Nitrosopiperidine N-Nitrosodiethanolamine N-Nitrosonornicotine 4-(Methylnitrosamino)-1-(3pyridyl)-1-butanone	Inorganic Compounds Hydrazine Arsenic Beryllium Nickel Chromium (only hexavalent) Cadmium Cobalt Lead Polonium-210
N-Heterocyblic Amines AaC, IQ Trp-P-1, Trp-P-2 Glu-P-1, Glu-P-2 PhIP	Aldehydes Formaldehyde Acetaldehyde
Volatile Hyrocarbons 1,3-Butadeine Isoprene Benzene Styrene	Heterocyclic Compounds Quinoline, Dibenz(a,h)acridine Dibenz(a,j)acridine, Dibenzo(c,g)carbazole Benzo(b)furan, Furan
Aromatic Amines 2-Toluidine, 2,6-Dimethylaniline 2-Naphthylamine, 4-Aminobiphenyl	

FDA is the only agency that combines

- Scientific expertise
- Regulatory expertise
- Public health mandate

Mr. WAXMAN. Thank you very much. We will be pleased to add any further comments you have for the record.

Before we start questioning, let me indicate that two of our witnesses had to leave to do another engagement so members of the committee will be afforded the opportunity to submit questions in writing to any of our witnesses after the hearing and of course for those of you here, we would welcome you to respond to those questions.

Let me start off with Dr. Henningfield. Dr. Blum and others have raised concerns about the authority given to FDA under the bill to regulate the design and contents of cigarettes. Some have suggested that tinkering with the ingredients in a cigarette in the hopes of making it less dangerous is a fool's errand and that it amounts to conducting R&D for the tobacco industry while misleading consumers into thinking that cigarettes are safe. Do you agree with that assessment?

Mr. HENNINGFIELD. No, I don't. Currently, we know that even an old-fashioned simple cigarette is deadly and addictive just like an old-fashioned muzzle-loading rifle is deadly. Modern cigarettes are more like armor-piercing bullets with laser guidance and rapid fire. That is the difference and that is part of the reason, for example, why police departments often oppose armor-piercing bullets: they kill more people more rapidly. Modern cigarettes are designed with a lot of different kinds of innovations, chemical and physical, to increase their ability to pierce the armor. Last night I looked at a Camel snus Web site where it explained that the pleasure occurs about 5 minutes after you put the snus in your mouth. Snus is a type of oral smokeless tobacco product. Now, the flavor, which I thought they used to say is where the pleasure was, occurs as soon as you put it in the mouth. They have obviously designed it to deliver the nicotine to the brain in about 5 minutes. That is by design, and in my experience, that was designed to be very effective at hooking people.

Mr. WAXMAN. Well, what would you think about the idea of lowering or even eliminating the nicotine in cigarettes completely? Would it reduce or—I know the bill wouldn't allow nicotine to be completely eliminated, but with respect to reducing the nicotine to extremely low levels, is there any scientific evidence that there is a level of nicotine below which it is no longer addictive?

Mr. HENNINGFIELD. We know that there is a threshold and people that have looked at this agree. Whether or not lowering nicotine over time is something that could or should be done is another question. I believe that FDA needs to have the authority to do that but I myself who have argued how that could work have argued in my writings with others that before you would implement such a policy, we need a lot of things in its place including treatment, including more research as to how to do it. So I think the agency should have the authority. The tobacco industry itself has argued that that would be tantamount to prohibition. They understand the power of nicotine to addict. So I don't think it is something FDA should launch as a first effort. I concur with the FDA's own conclusion in the 1990s on this matter.

Mr. WAXMAN. Mr. Corr, let me follow up that question with you. I am interested in how well you think the bill would address a com-

plex scientific issue like regulating nicotine levels. I know that some have raised concerns that if FDA lowered the amount of nicotine in cigarettes, consumers would simply smoke more or inhale more deeply, possibly endangering their health more than if the levels had remained the same. Is this really a danger, and under this bill, would FDA be required to order a change in nicotine levels if there was evidence that it would cause people to smoke more or inhale more deeply to get the nicotine they need out of the cigarette?

Mr. CORR. Mr. Chairman, this legislation gives FDA the authority it needs to make science-based public health decisions. The standard for many of its decisions will be appropriate for the protection of public health. In the instance you are talking about, FDA would have to make a decision based on the science as to what level of—what the consequences might be, as Dr. Henningfield just said, of reducing nicotine. There are no mandates with regard to nicotine levels in this bill. There is simply authority for the agency to act consistent with public health.

Mr. WAXMAN. And you would disagree with Dr. von Eschenbach when he says that there is little science available to FDA on which to base decisions on tobacco product standards. He doesn't think for that reason that FDA ought to have jurisdiction. You made it very clear in your presentation that you thought FDA was the place to have this regulatory agency. I guess he is fearful that they don't have the science at that agency. How would you respond?

Mr. CORR. This legislation would anticipate that FDA would act based upon sound science. They would have the regulatory authority and the mandate to protect public health. Dr. Henningfield can speak to the state of current science but the agency's responsibility would be to compile the science and to make sound public health decisions. Once again, the bill does not mandate any particular action with regard to product standards. It simply gives the agency the authority to protect public health.

Mr. WAXMAN. Thank you very much.

I want to yield to my colleague.

Mr. SULLIVAN. Thank you, Mr. Chairman, and I want to thank the witnesses for being here today and we all I think can agree that we don't want kids smoking and we want to do all we can to make sure they don't. I think everyone wants that. We don't want kids buying cigarettes. We hope they don't even start. We don't want any kid to start down that path but this is a big issue about the regulatory efforts of the agency to regulate this product, and I have a question for Mr. Ballin. Mr. Ballin, you have written extensively about the difference between combustible tobacco products, non-combustible tobacco products and alternative nicotine products. Does the legislation before us today adequately reflect those differences, and if not, how could it be improved to do so?

Mr. BALLIN. Well, in the testimony I have submitted, we have suggested that it might be more appropriate for all nicotine and tobacco products to be brought under one umbrella and that we address the overlapping regulatory issues for combustible products, non-combustible products and also the therapeutic products so that we can label things according to risk and relative risk, restrict advertising and marketing of those products based on risks and rel-

ative risks so that the consumer for the first time when they go into the CVS and look at that wall of all those various products will understand what those products do and do not do. We are far from that because there have been certain scientific research studies that when people are asked what is more dangerous, they get it all wrong. A lot of people think smokeless products are a lot more dangerous than cigarettes. They also think that some of the nicotine replacement therapies are more dangerous than cigarettes. We have got a lot of sorting out to do with respect to making sure that consumers are fully educated, understand the risks and relative risks of the products available to them.

Mr. SULLIVAN. And also in your view, does this bill provide adequate incentives for the industry to develop reduced-risk products like smokeless tobacco?

Mr. BALLIN. Well, I think one of the things that we have suggested but it is not our suggestion, it was the Institute of Medicine as well as others, that there have to be incentives for industry, and I am not just talking about the tobacco industry. I am also talking about giving incentives to pharmaceutical companies and other biotech companies who are working in these areas to develop these products. I didn't see much in the bill that does that. I think there needs to be greater encouragement with regulatory oversight. You have to have the oversight in order to be able to do it effectively. You just can't say go do this because we are going to end up along the same lines that Dr. Henningfield has mentioned, going down the low-tar, low-nicotine road. You have got to have regulation but we also have to give incentives for companies to change their behaviors.

Mr. SULLIVAN. Thank you.

And Mr. Armour, in your opinion, does H.R. 1108 give massive new authority to the FDA to regulate the retailing of tobacco products? I know that socially responsible retailers go to great lengths to assure their employees do not make illegal sales. States already regulate retail outlets so they can be given standards to follow without adding huge costs. Is this not the case if FDA regulates retail sales correctly?

Mr. ARMOUR. Congressman, the short answer is yes. As you saw from the chart, the States have done an excellent job in reducing non-compliance since 1997 and I think in the testimony this morning, it was pointed out that there were State by State interesting ways to reduce youth access to tobacco and our concern is by creating an entirely new bureaucracy at FDA duplicating State efforts that we are going to replace or put a whole other system there that interferes with what has been an effective system. I think it is important, as I said in my testimony, we don't oppose it at all. We take no position on FDA regulation of the manufacturing process of cigarettes. We do have problems with H.R. 1108 with respect to retailing because we think at State level it has been done effectively. We think that the Federal Government can set standards as it did in the Synar amendment to further reduce youth access to tobacco.

Mr. SULLIVAN. Thank you very much. I appreciate that. I think that was a good answer. I appreciate it. Thank you.

I yield back.

Mr. WAXMAN. Thank you very much.

Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman, and Mr. Corr, thank you, each of you. This has been a long day for you and some of us have had to come and go, but I believe the topic is of such importance that I am glad you stayed and thank you very much for the testimony each of you have given.

Mr. Corr, I am interested in learning a little bit more from you how this legislation would impact the labeling for a product like Camel No. 9 which clearly targets young women and girls. You referred to it in your testimony, and I don't know if you remember way back to the opening statements but we will get the charts up again, and I am co-chair now of the Congressional Caucus for Women's Issues and several of us, and not just us, have made it a point to become involved in this issue that does directly relate to, we feel, enticing new consumers of tobacco. It is my understanding that the legislation before us would require the removal of terms such as "light" and "low" and "mild" which have misled smokers into believing that these products might be less risky or less harmful than other regular cigarettes. Is that correct?

Mr. CORR. That is correct, Congresswoman Capps.

Mrs. CAPPS. And there seems to be a lot of bright pink in the advertising on the packaging for Camel No. 9. I would think that the use of pink coloring and terms such as "luscious" would be directed toward attracting young girls to this product. I wonder if you have, because your organization does target young children and teenagers and hoping that they don't smoke and working toward that goal, would this legislation do anything about the colors? Could it be useful to structure the advertising such as is used now in the magazines that young women are attracted to for Camel No. 9 as one example of the kind of packaging and promotional materials? Would it do anything about the use of terms such as "luscious"?

Mr. CORR. Congresswoman, the legislation as you pointed out does ban terms like "light," "low" and "mild." It also gives FDA the authority to consider other aspects of advertising and marketing and its impact on young people. For example, based on evidence that terms like "luscious," colors, imagery were being used in a way that influenced and attracted young people, the agency would have the authority to prohibit that.

Mrs. CAPPS. And in your work with young children, have you determined that they are vulnerable to, they are easily persuaded by such colors and use of such language?

Mr. CORR. There is a well-established record to that effect. It is why the FDA in its 1996 rule requires that all advertising and promotion in publications, at point of sale, and on outdoor billboards would be black-and-white text only; removes the imagery and colors that are so attractive to young people. It still allows, as Mr. Bonnie pointed out this morning, the companies to continue to communicate other information to adults consistent with the first amendment.

Mrs. CAPPS. Well, I took it upon myself to, as I was waiting in line at the grocery store to pick up a magazine like this one and thumbing through it like we are inclined to and I have seen a lot of young kids doing the same kind of mimicking their parents or

the older adults that they are with but when you turn to a page like this, and you see it blown up there, but this is what it looks like in this month's issue of Glamour magazine, and I don't mean to pick on them particularly but they are one of several women's magazines that run these very ads and have been doing so now for several months right around back-to-school time. This ad over here is the one that is very deceptive because it is called Dress to the Nines. You notice this fashionable shoe is replicated in the word "stiletto" over here and if you look down here to see where you can get some of this free stuff, you are directed to *camelsmokes.com*. There are two pages worth of tobacco advertising right here and if you thumb through, this page looks like several other pages of fashion layouts in a magazine that is known for this. Young kids are thinking about what to buy. When they go back to school, they want to look like the big girls and this is what they pick up.

Mr. CORR. In the absence of FDA regulation, you and others have raised this to the attention, the consciousness of the American people and to these magazines. Possibly they will stop it. It is just a matter of time before you see another kind of advertising like this that they will come up with. It is why it is imperative that the FDA have the authority on an ongoing basis to evaluate and regulate advertising and promotion to protect public health.

Mrs. CAPPS. Thank you. I understand that when Camel No. 9 was launched, promotional events were planned in several States to generate interest in the new cigarette. At these events, women were given pink-colored goody bags with promotional items, many with the Camel logo on them, including makeup, hand lotion and even cell phone jewelry, which is typically used not by career women but by teenagers, teenage girls. It is my understanding that under this legislation, FDA would be allowed to restrict these types of giveaways. Is this true?

Mr. CORR. Yes, it is, Congresswoman. Any kind of brand name on these products, recognizable patterns of color, those types of things would be prohibited.

Mrs. CAPPS. There is a history with this with Joe Camel, right?

Mr. CORR. There is a long history with this.

Mrs. CAPPS. Thank you very much all of you.

I yield back.

Mr. WAXMAN. Thank you, Mrs. Capps.

Mr. Deal.

Mr. DEAL. Thank you, Mr. Waxman.

I apologize to the panel members for not having been here for hearing all of your testimony. We had an important bill on the floor of the House that we have been debating and that is where I was. And I will not bore you with further questions because I don't know what you have already answered and I would certainly not want to be duplicative of questions you have already entertained.

Mr. Chairman, I would ask unanimous consent that the written testimony from the chairman of Phillip Morris USA be included in the record.

Mr. WAXMAN. Without objection.

Mr. DEAL. Let me just say though to all of you that obviously there are some different points of view that have been expressed both by others as they looked at the legislation. I do think it is

helpful for us to hear those concerns, if possible to have the legislation address those concerns, and I thank Mr. Waxman for his willingness to listen to concerns and make concessions even prior to this hearing here today as this legislation was being crafted. I do thank all of you for taking your time and we regret that we prolonged your day with votes but that is just the nature of the beast here, and with that, I would yield back my time.

Mr. WAXMAN. Thank you, Mr. Deal.

I too want to join in thanking each of you for your presentation and willingness to wait this long day for this hearing and I want to continue to work with all of you on this legislation. We want to get the very best product because I think we all share the same goals.

That concludes the hearing and we stand adjourned.

[Whereupon, at 3:30 p.m., the subcommittee was adjourned.]

[Material submitted for the record follows:]

SUBMISSION OF U.S. SMOKELESS TOBACCO COMPANY

TO THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

WITH RESPECT TO

H.R. 1108: FAMILY SMOKING PREVENTION

AND TOBACCO CONTROL ACT

OCTOBER 3, 2007

Table of Contents

Page

I. Introduction 1

II. USSTC's History, Business Focus and the Importance of Adult Sampling 2

A. USSTC and its History 2

B. USSTC's Business Focus on Converting Adult Smokers 3

C. Current Marketplace Dynamics of the Smokeless Tobacco Segment 4

D. The Importance of Adult Sampling and How it Has Changed in the Last Ten Years as a Result of the STMSA 5

III. H.R. 1108 Creates an Unfair Competitive Advantage for Major Cigarette Companies 6

A. The Sampling Prohibition Unfairly Favors Cigarette Manufacturers 6

B. The Labeling Requirements Unfairly Favor Cigarette Manufacturers 8

C. The "Modified Risk" Provisions Do not Provide an Appropriate Mechanism to Consider the Distinct Differences Between Cigarettes and Smokeless Tobacco 8

IV. USSTC's Efforts to Convert Adult Smokers to Smokeless Tobacco Are Consistent With Tobacco Harm Reduction 9

V. Conclusion 11

ATTACHMENT A
USSTC's Commitment to Dark Tobacco Growers 12

ATTACHMENT B
Tobacco Harm Reduction 13

ATTACHMENT C
The Smokeless Tobacco Master Settlement Agreement (STMSA) 21

ATTACHMENT D
Underage Usage of Smokeless Tobacco is Low and Has Decreased Substantially 27

ATTACHMENT E
Photos of Cigarette Packages with Free Smokeless Tobacco Products and/or Coupons for Free Products Attached 29

I. Introduction

On behalf of U.S. Smokeless Tobacco Company ("USSTC"), I make this submission to the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, in connection with its consideration of H.R. 1108, the Family Smoking Prevention and Tobacco Control Act, to explain why the Company cannot support H.R. 1108 in its current form. USSTC is the leading U.S. producer of moist smokeless tobacco or moist snuff; it does not manufacture cigarettes. Copenhagen and Skoal – two of USSTC's brands – are America's best-selling moist snuff products. USSTC places a high value on corporate responsibility – it is committed to being a responsible manufacturer and marketer of quality, 100% American-made smokeless tobacco products for adult tobacco consumers.

USSTC is not opposed to additional federal regulation of tobacco products, and appreciates this opportunity to participate in the process regarding this important public health issue. Its senior management has extensive experience in the food industry and is accustomed to managing a consumer product manufacturer in a regulated environment. USSTC's position has been and continues to be that it would not oppose this FDA regulation if it were consistent with the following principles:

- First, the legislation should take into account the distinct differences between smokeless tobacco products and cigarettes.
- Second, the legislation should allow companies to responsibly manufacture, market, and sell high-quality, American-made smokeless tobacco products to tobacco-interested adults and should not stifle competition.
- Third, the legislation should allow tobacco-interested adults to obtain accurate and relevant information regarding all tobacco products.

However, USSTC does not believe that H.R. 1108, in its current form, is consistent with these principles. For example, as discussed more fully below, one of USSTC's principal concerns about H.R. 1108 is that its passage would put large cigarette companies at a significant competitive advantage over smokeless tobacco companies in a number of ways. For example, H.R. 1108 would prohibit USSTC's responsible adult sampling of smokeless tobacco products in age-restricted adult only facilities. Communicating with adult cigarette smokers in such facilities has been an essential component of USSTC's efforts to compete with cigarette companies by

converting adult cigarette smokers to smokeless tobacco – which, according to some in the public health community, is consistent with public health goals. USSTC is hopeful that, with several important changes to H.R. 1108 that are consistent with the principles listed above, USSTC could support this significant public health initiative.

II. USSTC's History, Business Focus and the Importance of Adult Sampling

A. USSTC and its History

USSTC's history extends back nearly 200 years to 1822, when George Weyman created Copenhagen – one of the nation's oldest trademarks – and began selling it in his tobacco shop in Pennsylvania. A century later, in 1934, United States Tobacco Company introduced its Skoal brand, now the second leading smokeless tobacco brand in the U.S. Over its nearly 200 year history, USSTC has been committed to the American farmers in Kentucky, Tennessee and Virginia, who grow the dark tobacco that is essential to achieve the distinctive taste and other signature characteristics of its moist smokeless tobacco products. The Company is proud to use 100% American-grown tobacco.[1] USSTC does not manufacture cigarettes.

USSTC's consumers represent a wide range of adults, including farmers, office workers, financial professionals and blue-collar workers throughout the United States. Its consumers are characteristically avid participants in outdoor activities and recreation, such as hunting and fishing, as well as sporting events, such as rodeo and NASCAR.

USSTC's smokeless tobacco products are distinctly different from cigarettes in a number of ways: They are made from a different type of tobacco; they look, feel and are used differently; their packaging is different; they are marketed with a different emphasis on adult sampling; they comprise a relatively small percentage of the tobacco market; their consumers are different; underage use has been and continues to be substantially lower than underage cigarette smoking; they do not produce smoke; and there is a general acceptance in the scientific and public health communities that cigarettes are considered to be substantially more dangerous than smokeless tobacco. As discussed below, USSTC does not believe that H.R. 1108 takes into account these

[1] For more information on USSTC's commitment to American dark tobacco growers, *see* Attachment A.

distinct differences between smokeless tobacco and cigarettes, but rather is one-size-fits-all legislation that was drafted with cigarettes in mind.

B. USSTC's Business Focus on Converting Adult Smokers

In 2000, the Company experienced a change in senior management, resulting in a change in its business focus. The Company's focus became converting adult cigarette smokers to smokeless tobacco consumers, and having the Company's smoke-free products be "recognized by adults as the preferred way to experience tobacco satisfaction." In 2001, consistent with this shift in focus, the Company changed its name to U.S. Smokeless Tobacco Company to highlight the fact that it makes only smokeless tobacco, not cigarettes; that smokeless tobacco is distinctly different from cigarettes; and that the Company has a distinct position in the tobacco industry. These changes coincided with the expanding debate in the public health community regarding whether smokeless tobacco should be recommended as a reduced risk alternative to smokers who do not quit or use medicinal nicotine products.[2]

The basis for this shift in business focus was that the smokeless tobacco segment represents only approximately 3% of the U.S. tobacco industry, whereas cigarettes represent approximately 90% of the U.S. tobacco industry, and that even a switch of a small percentage of the roughly 45 million American cigarette smokers to smokeless tobacco would have a large impact on the smokeless tobacco segment and USSTC's business operations. Not surprisingly, USSTC's shift in its business focus was met with initial skepticism. The presumption was that cigarette smokers would not be interested in smokeless tobacco. However, USSTC's consumer research indicates otherwise. Survey data show that at least 50% of cigarette smokers were and are looking for an alternative. Now, as suggested by the data below, USSTC's focus on converting cigarette smokers is working. In recent years, the smokeless tobacco segment has been increasing while the cigarette segment has been decreasing.

Of note, USSTC's primary vehicle for accomplishing its goal of converting adult cigarette smokers to smokeless tobacco consumers has been responsible one-on-one communications in

---

[2] For a discussion of tobacco harm reduction and the possible role of smokeless tobacco as a reduced risk alternative to cigarettes, *see* Section IV and Attachment B.

adult only facilities. However, in its present form, H.R. 1108 would severely limit this important means of communication and place cigarette companies at an unfair competitive advantage over smokeless tobacco companies.

C. Current Marketplace Dynamics of the Smokeless Tobacco Segment

In recent years, the use of moist smokeless tobacco in the United States has continued to increase, whether measured by the number of adult moist smokeless tobacco consumers, the percentage of adults who use moist smokeless tobacco, or the amount of moist smokeless tobacco manufactured. Indeed, the number of adult males who use moist smokeless tobacco is estimated to have risen from 4.7 million in 2001 to 6.1 million in 2006. In addition, the percentage of adult males who use moist smokeless tobacco is estimated to have risen from 4.6% in 2001 to 5.5% in 2006.[3]

During roughly this same period of time, cigarette smoking in the United States has continued to decline, whether measured by the number of adult cigarette smokers, the percentage of adult cigarette smokers or the number of cigarettes sold. For example, the number of adult cigarette smokers has declined from approximately 50 million[4] in 2000 to approximately 45 million[5] in 2006.

These changes in tobacco consumption trends in part are presumably due to cigarette smokers switching to moist smokeless tobacco. Survey data suggests that for the majority of new moist smokeless tobacco consumers, their first tobacco experience was cigarettes. For example, over ten years ago, approximately two out of ten new smokeless tobacco consumers first smoked cigarettes; today, approximately six out of every ten new smokeless tobacco consumers first smoked cigarettes. Survey data also suggest that for the majority of the approximately

---

[3] The amount of moist smokeless tobacco manufactured has increased from 67.6 million pounds in 2001 to 83.9 million pounds in 2006. Capehart T. Tobacco Outlook. Economic Research Service, United States Department of Agriculture, April 24, 2007 at p.11.

[4] *Treating Tobacco Use and Dependence*, U.S. Public Health Service, Fact Sheet (June 2000).

[5] Pleis JR, Lethbridge-Çejku M. Summary health statistics for U.S. adults: National health interview survey, 2006. National Center for Health Statistics. Vital Health Stat 10(235). 2006 provisional data table 24.

one million new moist smokeless tobacco consumers who have entered the category over the past several years, their first tobacco experience was cigarettes.

The interest of cigarette smokers in smokeless tobacco is a reality that is validated by the entry into the smokeless tobacco segment by the market leaders of the U.S. cigarette industry. In 2006, Reynolds American Inc., the second-largest cigarette maker, purchased Conwood Company, L.P., the second-largest U.S. manufacturer of smokeless tobacco for $3.5 billion. In addition, in 2006 Reynolds introduced Camel brand smokeless tobacco products. 2006 also saw the entry of Philip Morris USA, the nation's largest cigarette manufacturer, into the smokeless tobacco business with a new brand of smokeless tobacco products. In 2007, Philip Morris introduced several varieties of Marlboro brand smokeless tobacco products. Philip Morris and Reynolds can be expected to utilize adult smokers' brand recognition of Marlboro and Camel to create a strong position in the smokeless category in the environment contemplated under H.R. 1108.

D. The Importance of Adult Sampling and How it Has Changed in the Last Ten Years as a Result of the STMSA

A major component of USSTC's efforts to convert adult smokers to smokeless tobacco is one-on-one interactions and sampling at adult only facilities ("AOF") that conform to the strictures set forth in the 1998 Smokeless Tobacco Master Settlement Agreement and additional restrictions (collectively, the "STMSA"). As will be discussed in Section III, H.R. 1108 would severely restrict USSTC's ability to communicate with adult cigarette smokers by prohibiting this vital tool of one-on-one adult sampling through AOFs and thereby severely hamper USSTC's ability to compete with cigarette manufacturers in reaching adult cigarette smokers.

Survey data have shown that one of the reasons that smokers were not switching to smokeless tobacco is that they were unaware of smokeless tobacco products; smokeless tobacco was not even part of their consideration as an alternative to cigarette smoking. Furthermore, when the vast majority of adult cigarette smokers first become acquainted with smokeless tobacco, the look and taste of the product is unfamiliar. Many lack an understanding of how to use the product. Communicating with adult smokers in a one-on-one exchange to acquaint them with the product, demonstrate its use and provide a free sample are, therefore, vital components of converting adult smokers to smokeless tobacco.

Furthermore, AOFs already address the concerns giving rise to the marketing restrictions set forth in H.R. 1108 – underage access to tobacco products. AOFs are not a broad-based marketing campaign directed to the public at large. Rather, they are venues that are narrowly directed exclusively to tobacco-interested adults, especially smokers. As discussed more fully in Attachment C, AOFs are venues that are enclosed on all sides by opaque barriers that are at least six feet high to avoid the sampling and various activities being conducted inside from being viewed from the outside. AOFs are strictly limited to age-verified adults, who must present valid age identification at the entrance to personnel who are trained about USSTC's policies relating to AOFs. AOFs are also restricted as to what signage may be displayed on the exterior of the facility.

As the only signatory to the STMSA, USSTC takes its responsibility to abide by the sampling restrictions of the STMSA extremely seriously. Provisions pertaining to the STMSA are set forth in the Company's corporate code of responsibility, which must be reviewed and signed by every employee. Failure to abide by its provisions is grounds for termination from the Company. USSTC's responsibility in sampling its products to adults only is evidenced by the fact that, in the nearly ten years it has been governed by the sampling restrictions of the STMSA, it has never been found to have violated any requirement relating to its AOFs, notwithstanding that USSTC's sampling activities are monitored regularly and continuously by the State Attorneys General and others. In addition, national government and academic studies reflect that there has been a substantial decrease in underage usage of smokeless tobacco during the last ten years.[6]

III. H.R. 1108 Creates an Unfair Competitive Advantage for Major Cigarette Companies

A. The Sampling Prohibition Unfairly Favors Cigarette Manufacturers

Quite simply, one-on-one communication with cigarette smokers provides an essential way for USSTC to compete with cigarette manufacturers in reaching adult cigarette smokers. H.R. 1108 would severely restrict USSTC's ability to communicate with adult cigarette smokers by prohibiting the vital tool of one-on-one adult sampling through AOFs and thereby severely

[6] For more information on the decrease in underage usage of smokeless tobacco, *see* Attachment D.

hamper USSTC's ability to compete with cigarette manufacturers in reaching adult cigarette smokers.

First, the sampling prohibition in H.R. 1108 would not impact the cigarette companies to the same degree it would impact smokeless tobacco companies. Virtually every adult in the United States is familiar with cigarettes and how to use them. Therefore, introducing consumers to cigarettes and demonstrating their use through one-on-one sampling is not a vital tool in the cigarette industry. It has therefore not been used by cigarette manufacturers in recent years to the same degree as it has been used by smokeless tobacco manufacturers.

Second, given the entry of the two largest U.S. cigarette companies into the smokeless tobacco business, cigarette companies will have a dramatic advantage over smokeless tobacco manufacturers in communicating with adult smokers about their smokeless tobacco products. In fact, they already provide their smokeless tobacco products for free to cigarette smokers by attaching their smokeless tobacco products to their cigarette packages, or attaching coupons for their smokeless tobacco products at no cost. (Copies of some recent examples are attached at Attachment E). Such practices permit cigarette manufacturers to provide free product to every cigarette smoker, every day, with every cigarette purchase. This practice would appear to be permitted under H.R. 1108, thus providing large cigarette manufacturers an extreme and unfair competitive advantage over USSTC.

From a public policy standpoint, H.R. 1108 should codify at least the adult sampling provisions of the STMSA. The restrictions set forth in the STMSA, including, but not limited to those pertaining to AOFs, are a model of up-to-date, proven methods of combating youth access. Moreover, they accomplish that important objective without providing cigarette companies a distinct competitive advantage over smokeless tobacco companies. By contrast, the prohibition of adult sampling in H.R. 1108 eliminates an important means of communicating with adult cigarette smokers and has the counterproductive effect of providing cigarette companies with a distinct competitive advantage in the marketplace. Furthermore, codifying provisions of the STMSA would ensure that all manufacturers of smokeless tobacco are bound by the same restrictions and are competing on a fair and level playing field.

B. The Labeling Requirements Unfairly Favor Cigarette Manufacturers

H.R. 1108 contains labeling requirements that are a one-size-fits-all approach to different tobacco products and do not account for the different sizes and types of smokeless tobacco product packages. Most smokeless tobacco packages have fewer and smaller surface areas than cigarette packages. In addition, unlike cigarettes, which generally come in uniform packaging styles and sizes, smokeless tobacco products come in a wide variety of shapes and sizes. By way of example, some smokeless tobacco products come in small round cans, some come in foil pouches, some come in cylindrical tins, some come in cardboard boxes, and some come in rounded plastic boxes.

The result of these requirements is that warning statements would occupy a smaller proportion of the available package space on cigarette packages than they would on smokeless tobacco packages, such as moist snuff round cans. The consequence is that H.R. 1108 provides cigarette companies with the unfair advantage of having a greater amount of remaining surface space than smokeless tobacco packages for product information and marketing messages.

H.R. 1108 should take into account that smokeless tobacco packaging is different from traditional cigarette packaging in terms of size, shape and display area.

C. The "Modified Risk" Provisions Do not Provide an Appropriate Mechanism to Consider the Distinct Differences Between Cigarettes and Smokeless Tobacco

Although one of the objectives of H.R. 1108 is to better inform consumers, H.R. 1108 contains an entire section (section 911 - "Modified Risk Tobacco Product") that has been widely noted by independent observers to have the unintended consequence of actually inhibiting efforts to provide consumers with truthful, non-misleading information about the comparative risks of cigarettes and smokeless tobacco products. The regulatory "test" prescribed in section 911 for a "reduced risk" or "reduced exposure" claim to be approved includes nearly insurmountable hurdles and is inconsistent with the type of standards discussed in the landmark 2001 report issued by the Institute of Medicine ("IOM") on Tobacco Harm Reduction entitled, *Clearing the*

smoke. Assessing the science base for tobacco harm reduction.[7] In that report, the IOM proposed that risk-reduction claims be permitted for tobacco products if, among other things, they are neither false nor misleading, and if the issue of overall population effects are addressed through post-marketing surveillance.[8]

The nearly insurmountable hurdles and other provisions of section 911 of H.R. 1108 also raise significant First Amendment issues that could be addressed, at least in part, with the adoption of standards consistent with those discussed in the IOM Report.

IV. USSTC's Efforts to Convert Adult Smokers to Smokeless Tobacco Are Consistent With Tobacco Harm Reduction

As discussed in Section II. B., USSTC's efforts to convert adult cigarette smokers to smokeless tobacco are consistent with the role of smokeless tobacco in a tobacco harm reduction strategy according to some in the public health community. As discussed below, by banning one-on-one adult sampling, H.R. 1108 would severely hamper the type of narrowly tailored one-on-one communications used by USSTC to convert adult smokers to its smoke-free products.

As mentioned above, the debate about tobacco harm reduction came to the fore in 2001 when the IOM issued its landmark report, *Clearing the smoke*, which assessed the science base for tobacco harm reduction. The report explained the idea of a tobacco harm reduction strategy and suggested that smokeless tobacco products could be part of such a strategy because cigarettes are considered more dangerous than smokeless tobacco. The following year, the UK's Royal College of Physicians issued a landmark report recognizing that smokeless tobacco could be part of a tobacco harm reduction strategy since the report estimated that smokeless tobacco is up to 1,000 times less hazardous than cigarettes.

Since those seminal reports, the debate on smokeless tobacco as part of a tobacco harm reduction strategy has flourished in the scientific and public health communities, and much has been

---

[7] Stratton K, Shetty P, Wallace R, Bondurant S (eds.) Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine. National Academy Press, Washington, D.C., 2001. For a more complete discussion of *Clearing the smoke* and the role of smokeless tobacco as a reduced risk alternative to cigarettes, *see* Section IV and Attachment B.

[8] *Id.*

published in the scientific literature. However, the focus of the debate has changed. The issue is no longer whether smokeless tobacco is a reduced-risk product as compared to cigarettes. Smokeless tobacco is generally accepted in the scientific and public health communities as involving significantly less risk of adverse health effects than cigarettes. In fact, many public health advocates believe that smokers who do not quit and do not use medicinal nicotine products should switch completely to smokeless tobacco.

Consequently, the issue being debated is whether cigarette smokers, who do not quit and do not use medicinal nicotine products, should be encouraged to switch completely to smokeless tobacco. Simply put, the issue is now one of communication. In fact, some in the scientific and public health communities believe that smokers have an ethical "right to know" this comparative health risk information in order to make informed decisions on tobacco use. Moreover, the need to communicate the comparative health risks of smokeless tobacco and cigarettes is highlighted by survey data indicating that adult cigarette smokers are seriously misinformed about the comparative risks of tobacco products and believe that smokeless tobacco products are just as dangerous as cigarettes. Many in the scientific and public health communities believe that communicating comparative risk information and encouraging smokers to switch completely to smokeless tobacco should result in both an individual and public health benefit.[9]

The issue of whether comparative risk information should be communicated will ultimately be determined by FDA in a regulatory context if H.R. 1108 becomes law. However, during the period that FDA considers the issue, H.R. 1108 should not hamper the type of narrowly-tailored one-on-one communications used by USSTC to introduce adult smokers to smokeless tobacco, demonstrate its use, and provide a free sample in the Company's efforts to convert adult smokers to its smoke-free products, which many believe would achieve a significant public health benefit.

---

[9] For a more detailed discussion of tobacco harm reduction and the possible role of smokeless tobacco as a reduced risk alternative to cigarettes, *see* Attachment B

V. Conclusion

USSTC is not opposed to additional federal regulation of tobacco products that takes into account the distinct differences between smokeless tobacco products and cigarettes; allows companies to responsibly manufacture, market, and sell high-quality, American-made smokeless tobacco products to tobacco-interested adults; does not stifle competition; and allows tobacco-interested adults to obtain accurate and relevant information regarding all tobacco products. In its present form, however, USSTC believes that H.R. 1108 is inconsistent with these principles. USSTC appreciates the opportunity to be part of this important process regarding H.R. 1108. USSTC hopes that the Subcommittee will consider the types of changes discussed in this submission in the constructive manner in which they were offered, and that the Subcommittee will make the types of changes discussed. Indeed, if such changes are incorporated into H.R. 1108, USSTC will support this significant public health initiative.

Respectfully submitted,

Daniel W. Butler
President, U.S. Smokeless Tobacco Company

ATTACHMENT A

USSTC'S COMMITMENT TO DARK TOBACCO GROWERS

USSTC is committed to the American farmers who grow the dark tobacco that is used to make its smokeless tobacco products. Unlike cigarettes, which consist mainly of bright, burley and oriental tobaccos that are sourced from all over the world, smokeless tobacco products are made primarily from American-grown dark tobacco. Historically, it is difficult to determine which came first – the class or type of tobacco known as dark tobacco or moist snuff products themselves. Most likely, oral use of tobacco preceded the development of a distinct plant type for that use. Today, smokeless tobacco products in the United States are primarily manufactured using a type of dark tobacco that is either air-cured or fire-cured to produce a leaf that gives U.S. products the unique taste that American consumers prefer. The fundamental distinctiveness of dark tobacco that is seen today was begun by the early, dedicated tobacco farmers who each year selected seeds for the next year's crop from plants that appeared to have improved yield or better quality traits.

While the tobacco industry has seen considerable change and consumer preferences have evolved over the years, the one thing that has not changed is the dedication that enables American farmers to produce the highest quality tobacco in the world. USSTC believes that no tobacco is of higher quality than the dark tobacco grown in the states of Kentucky, Tennessee and Virginia, and USSTC is committed to these growers. The Company uses only 100% American-grown tobacco in its products, and it pays growers fair and reasonable prices for their leaf so they are able to remain in the business and maintain their quality of life. USSTC's commitment is further demonstrated by various technical and educational support that it provides to this community of growers, and its financial support for research related to dark tobacco varieties.

USSTC is committed to continuing to support the American farmers who grow the dark tobacco used to make USSTC's quality smokeless tobacco products for adult consumers. USSTC hopes that Congress, through its consideration of H.R. 1108, will not impact USSTC's ability to continue to purchase 100% American-grown tobacco.

ATTACHMENT B

TOBACCO HARM REDUCTION

This Attachment examines support in the scientific and public health communities for the proposition that cigarette smoking is substantially more dangerous than smokeless tobacco use. It also examines concerns expressed by some in the public health community of the possible unintended consequences of encouraging cigarette smokers to switch to smokeless tobacco.

A. Scientific Support for the Proposition that Cigarette Smoking is Substantially More Dangerous than Smokeless Tobacco Use

USSTC has identified over 100 publications in the scientific literature, most of which were peer-reviewed, which assert or support the proposition that cigarettes are substantially more dangerous than smokeless tobacco use. Several examples are discussed below.

In December 2002, the UK's Royal College of Physicians ("RCP") issued a landmark report entitled *Protecting smokers, saving lives. The case for a tobacco and nicotine regulatory authority*,[1] which assessed various issues relating to future tobacco regulation in the UK (the "2002 RCP Report"). The RCP is England's oldest medical institution; among its main functions is to advise the government, the public and the medical profession on health care issues. For example, in 1962, the RCP was the first major medical institution to issue a report concluding that cigarette smoking caused lung cancer. The 2002 RCP Report recognized that smokeless tobacco would be a key component of any tobacco harm reduction strategy since the Report estimated that smokeless tobacco "is of the order of 10-1,000 times less hazardous than smoking, depending on the product."[2]

In December 2006, Dr. Brad Rodu, Professor of Medicine at the University of Louisville School of Medicine, and a co-author, published a review paper entitled *Tobacco harm reduction: an*

---

[1] Tobacco Advisory Group of the Royal College of Physicians. *Protecting smokers, saving lives. The case for a tobacco and nicotine regulatory authority.* Royal College of Physicians of London, 2002.

[2] *Id.* at p.5.

alternative cessation strategy for inveterate smokers, which summarizes its analysis of smokeless tobacco in the context of tobacco harm reduction as follows:

> "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."[3]

A recently published editorial paper entitled *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic* contains the following analysis of the "continuum of risk" for various tobacco products:

> "Current cigarettes and cigarette-like products are at the high end of a continuum of risk. Moving down the continuum, but still very likely to be high risk are alternative 'cigarette' designs that primarily heat rather than burn tobacco. These products are undoubtedly more hazardous than non-combustion-based delivery, but very likely less hazardous than smoking. Even tinkering with the toxicity levels of cigarettes, through such things as lowering nitrosamine levels in the tobacco leaf, has potential to reduce mortality. Non-combustion products, and particularly low nitrosamine smokeless tobacco and medicinal nicotine products are at the least hazardous end of this risk continuum."[4]

Based on the published literature, there appears to be a general acceptance in the scientific and public health communities that the use of certain smokeless tobacco products involves significantly less risk of adverse health effects than cigarette smoking.

---

[3] Rodu B, Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm Reduct J;* **3:** 37, at p.1. USSTC has provided financial support for research conducted by Dr. Rodu.

[4] Sweanor D, Alcabes P, Drucker E. Tobacco harm reduction: how rational public policy could transform a pandemic. *Int J Drug Policy* 2007; **18:** 70-4, at p. 71.

B. Support for the Proposition that Possible Unintended Population Effects Are Unlikely to Occur

Those in the scientific and public health communities who express the opinion that there is insufficient evidence that a significant public health benefit should be achieved if cigarette smokers are encouraged to switch completely to smokeless tobacco, frequently point to the possibility that such a strategy could have an adverse impact on public health at the population level. That is, while often agreeing that smokeless tobacco use involves significantly less risk of adverse health effects than cigarette smoking, the concern is expressed that if cigarette smokers are encouraged to switch to smokeless tobacco, total tobacco use in the US population as a whole may be increased, without a significant decrease in tobacco-related morbidity and mortality[5] because:

(i) some smokers who might otherwise quit tobacco use completely will switch to smokeless tobacco;[6]

(ii) some cigarette smokers may start using smokeless tobacco while continuing to smoke cigarettes (sometimes referred to as "dual use");[7] and

(iii) some who might never have started to use tobacco, will start to use smokeless tobacco, especially young people.[8]

One response to the concerns raised about the possibility of increased use of smokeless tobacco as a result of its inclusion as one component of a tobacco harm reduction strategy, is provided by Professor Lynn T. Kozlowski, professor and chair, Department of Health Behavior, University at Buffalo School of Public Health and Health Professions. To assess the issue of individual risk reduction versus aggregate population impact, Professor Kozlowski has utilized an analytical tool to test whether a particular product is likely to contribute to overall risk. This test is

---

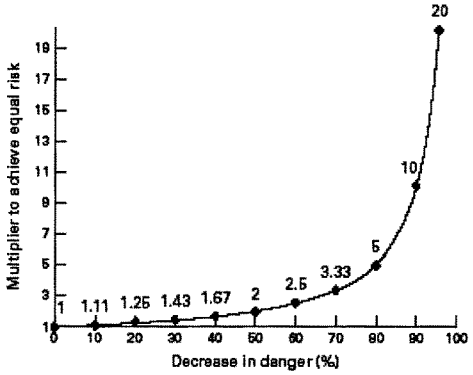
[5] Hatsukami DK, Zeller M. Tobacco harm reduction: The need for research to inform policy. APA Online, Volume 18: No. 4, April 2004 (http://www.apa.org/science/psa/sb-hatsukami.html.).

[6] WHO Scientific Advisory Committee on Tobacco Product Regulation. SACTob Recommendation on Smokeless Tobacco Products. World Health Organization, Geneva, Switzerland, 2003, at pp. 2 – 3.

[7] Burton SL. Prepared Statement. *Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction.* Hearing before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, House of Representatives, 108th Cong. 1st Sess. (June 3, 2003), at p. 101.

[8] WHO Scientific Advisory Committee on Tobacco Product Regulation, at pp. 2-3.

reflected in a "risk/use equilibrium" chart that compares the "decrease in danger (%)" displayed on the horizontal axis to the "multiplier to achieve equal risk" on the vertical axis.[9]



According to Professor Kozlowski's analysis, a tobacco product that reduces risk by only 10% raises a difficult public health issue because an 11% increase in use of the product would offset the risk reduction in the population as a whole, and an increase in excess of 11% would result in a negative public health impact on the population as a whole. On the other hand, a tobacco product which results in a reduced risk in excess of 90%, as many believe smokeless tobacco does, presents a relatively easy public health decision since the increase in usage necessary to offset the reduction in risk to the population as a whole is so substantial that it is highly unlikely to occur. Thus, Professor Kozlowski and other researchers believe it is highly unlikely the public health benefit of communicating comparative risk information to cigarette smokers and encouraging them to switch to smokeless tobacco would ever be offset by increased usage of smokeless tobacco.

---

[9] Kozlowski, L., Strasser, AA, Giobino, GA., Erickson, PA, Terza, JV. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction (Editorial). *Tob Control* 2001; **10**: 201-203.

C. Adult Cigarette Smokers' Knowledge Regarding the Comparative Health Risks of Tobacco Products

Also relevant to a consideration of concerns about possible negative population effects are surveys indicating that the majority of adult cigarette smokers believe that the use of smokeless tobacco is just as dangerous to their health as cigarette smoking. There is opinion in the scientific community that some of the potential negative population effects that might result from implementing a tobacco harm reduction strategy could be mitigated if adult cigarette smokers were educated about the comparative health risks of tobacco products. Indeed, there is also opinion in the scientific and public health communities that unless adult cigarette smokers are provided with accurate information on the comparative health risks of tobacco products, the status quo will remain with respect to tobacco-related morbidity and mortality.

(i) Surveys Indicate Adult Cigarette Smokers Are Seriously Misinformed About the Comparative Health Risks of Cigarette Smoking and Smokeless Tobacco Use

Although there is general acceptance in the scientific and public health communities that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking, recent surveys indicate that the majority of adult cigarette smokers are misinformed on the comparative risk issue. For example, at the May 2004 conference "40 Years of Tobacco or Health. How Can We Do Better," sponsored by the University of Medicine & Dentistry of New Jersey, Dr. K. Michael Cummings of New York's Roswell Park Cancer Institute, presented data from a nationally representative sample of over 1000 US adult smokers during a presentation entitled *Harm Reduction for Tobacco Control.* Among the survey findings presented by Dr. Cummings was that 82% of smokers believed that "chewing tobacco is just as likely to cause cancer as smoking cigarettes."[10]

Similar findings were presented by Haddock, et al. in a 2004 paper entitled *Modified tobacco use and lifestyle change in risk-reducing beliefs about smoking.*[11] The purpose of this study was to

[10] Cummings KM. Harm reduction for tobacco control. 40 Years of Tobacco or Health. How Can We Do Better. University of Medicine & Dentistry of New Jersey, May 28, 2004.

[11] Haddock CK, Lando H, Klesges RC, Peterson AL, Scarinci IC. Modified tobacco use and lifestyle change in risk-reducing beliefs about smoking. *Am J Prev Med* 2004; **27**: 35-41.

examine beliefs about potential risk-reduction strategies for tobacco users among a large group of young adults. The study population consisted of approximately 36,000 US Air Force recruits who entered the service between October 1999 and September 2000. Approximately 32% of the recruits were current smokers. One of the questions used to assess risk-reduction beliefs was "if a smoker switched from cigarettes to chewing tobacco/snuff, how much would they reduce their health risks associated with using tobacco products?"[12] Each question was rated on a 5-point scale ranging from "no reduction in risk" to "they would no longer be at risk."[13] Haddock, et al. reported that 75.5% of current male smokers believed that switching to smokeless tobacco would result in "no risk reduction."[14] Among current female smokers, 82.1% believed that switching to smokeless tobacco would result in "no risk reduction."[15]

(ii) Opinion that Adult Cigarette Smokers Should Be Provided Accurate Information Regarding the Comparative Health Risks of Tobacco Products

There is significant support in the scientific and public health communities for providing adult cigarette smokers with truthful and nonmisleading information regarding the options that are available to reduce the potential risks to their health. For example, Professor Lynn T. Kozlowski, in a commentary entitled *Harm reduction, public health and human rights: smokers have a right to be informed of significant harm reduction options*,[16] argues that cigarette smokers have a right to relevant health information:

> "Cigarettes kill about half of those who smoke them (English et al. 1995; Peto et al., 1994; U.S. Department of Health and Human Services., 1989). It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete

---

[12] *Id.* at p.36.

[13] *Id.* at pp. 36 - 37.

[14] *Id.* at p. 38.

[15] *Id.* at p. 39. Another interesting finding of the study was that "[s]mokers who believed that switching to smokeless tobacco would lower the health risks associated with smoking were more likely, while smokers reporting switching to low-yield cigarettes were significant [sic] less likely, to quit during a 1-year follow-up period." *Id.* at p. 35.

[16] Kozlowski LT. Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine Tob Res* 2002; **4 Suppl 2**: S55-60.

> quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information."[17]

In an analysis focused on marketplace forces, Dr. K. Michael Cummings, in a commentary entitled *Can capitalism advance the goals of tobacco control?*[18] offers a similar rationale for providing cigarette smokers accurate information regarding comparative health risks:

> "Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products (Stratton et al. 2001). *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 governmental regulation, has the greatest potential to alter the world-wide epidemic of tobacco-related disease." [19] (Emphasis added).

In sum, surveys indicate that the majority of adult cigarette smokers are misinformed regarding the generally accepted view in the scientific and public health communities concerning the comparative health risks of cigarette smoking and smokeless tobacco use. There is significant public health support for providing adult cigarette smokers accurate information on this subject,

---

[17] *Id.* at p.S59.

[18] Cummings KM. Can capitalism advance the goals of tobacco control? *Addiction* 2002; **97**: 957-958.

[19] *Id.* at p. 957.

and there is significant public health opinion that unless such information is provided to adult cigarette smokers, the status quo with respect to tobacco-related morbidity and mortality will remain.

ATTACHMENT C

THE SMOKELESS TOBACCO MASTER SETTLEMENT AGREEMENT (STMSA)

In November 1998, USSTC became the only smokeless tobacco manufacturer to reach an agreement with 45 state attorneys general. Pursuant to the STMSA, USSTC has adopted a comprehensive array of provisions containing restrictions, prohibitions, and other measures relating to the advertising, marketing, and promotion of its smokeless tobacco products and agreed to contribute to a national fund, the primary purpose of which is to fund programs to reduce underage usage of tobacco products. USSTC today remains the only smokeless tobacco company in the country participating in this agreement, even though it has put USSTC at a competitive disadvantage with other smokeless tobacco manufacturers. USSTC believes that its decision to enter into the STMSA, along with its adoption over the years of the additional measures described below, demonstrate its corporate responsibility and its commitment to its firm and longstanding policy that its smokeless tobacco products are for adults only.

Although the STMSA is a highly detailed agreement that should be reviewed for its precise terms, the extensive provisions contained in the STMSA regarding advertising, marketing, and promotions are generally summarized in part below.

- No direct or indirect targeting of youth (persons less than 18 years old).
- No distribution of free samples, except in an Adult-Only Facility.[1]
- No cartoons.[2]
- No billboards advertising tobacco products.
- No signs advertising tobacco products in arenas, stadiums, shopping malls, or video arcades.

---

[1] *See* § i. for a more complete description of the sampling restrictions with which USSTC abides. Pursuant to the STMSA, sampling does not include, among other things, adult consumer testing or evaluation and products provided in conjunction with a purchase at retail.

[2] This restriction does not apply to any cartoons appearing on product packaging or corporate logos as of July 1, 1998.

- No transit advertising of tobacco products.
- No more than one brand name sponsorship per year.
- No brand name sponsorships of:
  - concerts;
  - events in which youth comprise a significant portion of the intended audience;
  - events in which youth are paid participants or contestants; or
  - events between football, baseball, soccer, basketball or hockey teams.
- No distribution of non-tobacco merchandise or apparel bearing the brand name, logo, or trademark of a tobacco product other than to adult employees for their personal use.
- No tobacco product brand placement in media directed at the general public, such as motion pictures, television shows, theatrical productions, music performances, or video games.
- No gifts to underage persons based on proofs-of-purchase.
- No use of non-tobacco brand names.
- No providing of product to sports teams or entertainment groups at less than fair market value or in consideration for services.
- No agreements inhibiting anti-tobacco advertising.
- No agreements allowing third parties to advertise USSTC's brands in a manner that is otherwise prohibited by the STMSA.
- Corporate culture commitments:
  - Reaffirm commitment to the STMSA and to reducing youth usage.
  - Designate executive level manager, and encourage employees, to identify methods to reduce youth access and usage.

Notwithstanding that USSTC is the only smokeless tobacco manufacturer to have agreed to the STMSA, USSTC remains committed to complying with the STMSA:

- Relevant provisions are incorporated into the Company's corporate code of responsibility, which must be reviewed and signed by every employee.

- Company sales personnel are provided ongoing and extensive training regarding STMSA compliance, including by way of state-of-the-art, computer-based technologies.

ADDITIONAL MEASURES ADOPTED BY USSTC BEYOND THE STMSA

In addition to the comprehensive restrictions contained in the STMSA, USSTC has adopted a number of other measures to combat underage access to smokeless tobacco products. USSTC believes that taken together the additional measures that it has adopted are unique among smokeless tobacco manufacturers and further demonstrate its corporate responsibility and commitment to its longstanding policy that its smokeless tobacco products are for adults only.

(i) Additional Restrictions Regarding Providing Free Product

USSTC operates its Adult-Only Facilities ("AOFs") in a manner that goes above and beyond the requirements of the STMSA. Under the STMSA, USSTC generally may distribute its smokeless tobacco products for free to adult consumers only as follows:

- in an AOF, which generally means an area where the operator ensures that no underage person is present; or
- in conjunction with the purchase of a tobacco product at retail, but only after the purchase transaction has been completed (so as to allow the retailer to fulfill his obligation to verify age).

In addition to the foregoing restrictions, USSTC has adopted the following additional measures with respect to its AOFs at considerable effort and expense even though USSTC believes that the STMSA does not require it to do so:

- to enclose all of its AOFs with opaque barriers in an effort to restrict further the ability of individuals outside of its AOFs from seeing certain activities inside of it, such as sampling;
- to limit the words that it places on the outside of its AOFs to identify the AOFs;
- to post a sign no smaller than 28 inches by 22 inches at the entrances of AOFs which read: "WELCOME - MUST BE 18 YEARS OR OLDER TO ENTER. THANK YOU FOR YOUR COOPERATION";[3]

[3] To the extent minimum age of purchase laws are higher, all signs are adjusted accordingly.

- to post a sign at the table or other structure in the AOF from which smokeless tobacco samples are distributed which reads: "NO SAMPLES GIVEN TO ANYONE UNDER THE AGE OF 18"; and
- to require personnel at the AOF to wear in a visible location on his/her clothing a button which states: "NO SAMPLES GIVEN TO ANYONE UNDER THE AGE OF 18".

In addition, as described in Section iii. below, USSTC has had a longstanding advertising and sampling code pursuant to which it has not conducted sampling within two blocks of any premises identified as being used primarily for underage activities, such as schools or organized youth centers, at times when such premises are being used for such purposes.

(ii) Additional Magazine Advertising Restrictions

USSTC has also gone above and beyond the STMSA by adopting advertising restrictions regarding underage readership that are consistent with those contained in H.R. 1108, whereby USSTC only advertises in publications that have more than 85% adult readership and fewer than two million readers under 18 years of age. In addition, USSTC goes even further than this voluntary standard by reviewing not only subscriptions and readership data but also the content of the publication, including:

- the general age of persons depicted in the other advertisements in the magazine;
- other product advertising in the magazine;
- the subject matter and complexity of the photography in the magazine; and
- the language, character, tone and overall message.

(iii) Advertising and Sampling Code

Long before USSTC entered into the STMSA in 1998, in the early 1980s, USSTC agreed to an Advertising and Sampling Code for Smokeless Tobacco Products ("Code"). USSTC continues to adhere to the standards set out in the Code that have not been superseded by the STMSA. Some of these standards are as follows:

- Models who appear in smokeless tobacco advertising shall be at least 25 years of age;

- No athlete actively competing in professional sports shall be used to present any smokeless tobacco product in any advertisement by way of oral or written endorsement or by depiction of use of any such product.

- No professional entertainer who appeals primarily to persons under the age of 18 shall be used to present any smokeless tobacco product in any advertisement by way of oral or written endorsement or by depiction of use of any such product.

- Promotional offers of smokeless tobacco products and of premium items shall carry the designation "Offer not available to minors" and, on the coupon for mail-in offers, a statement by which the person requesting the offer certifies that he or she is 18 years of age or older.

(iv) Adoption of Age of Purchase Icon

USSTC created and is the first smokeless tobacco manufacturer to utilize an Age of Purchase Icon proclaiming its long-standing policy. The Icon reads: "U.S. Smokeless Tobacco Co. Reminds You – NOT FOR SALE TO MINORS". USSTC voluntarily places this icon on:

- print and point of sale advertisements for its traditional moist smokeless tobacco products;

- its millions of pieces of direct mail to adult consumers; and

- a lapel pin worn by Company sales representatives and marketing promotions personnel while working at retail stores or events in AOFs.

In 1999, USSTC began an advertising campaign directed at tobacco retailers featuring the Age of Purchase Icon, telling advertisers exactly where USSTC stands – our products are intended for adults only. "We say it, we print it, we mean it, and it's not open for interpretation."

(v) Participation in the "We Card" Coalition

USSTC has for many years been part of the "We Card" Coalition, helping retailers enforce minimum age laws for the purchase of tobacco products. The Coalition encourages retailers to train sales clerks to abide by their state's minimum age laws and to display "We Card" signage on doors, windows, and at sales counters. In the 12 years since the coalition was founded in 1995, more than one million "We Card" kits have been distributed to retailers nationwide. Over the same time, more than 2,000 classroom training sessions have been held in all 50 states and U.S. territories. Online training has also been made available for those unable to attend classroom sessions. Through this process, nearly 100,000 retail employees have been trained to learn

responsible retailing practices. The Coalition encourages retailers to require that customers under age 27 provide a photo ID for tobacco purchases.

(vi) Support of Electronic Age Verification Legislation

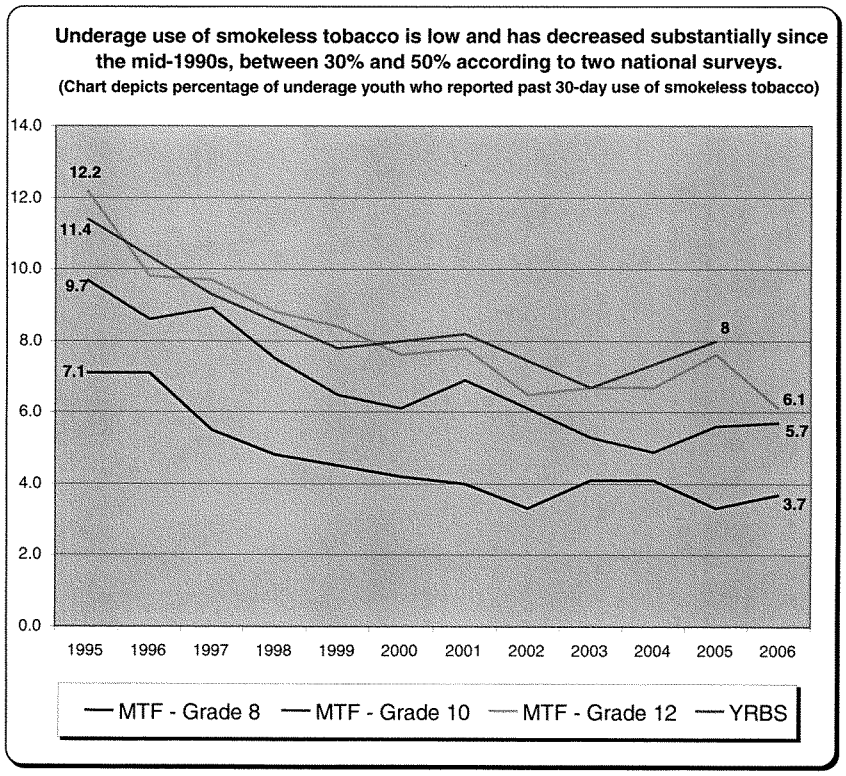
USSTC supports legislation that encourages retailers to use electronic age verification devices. These devices read the bar code or magnetic strip on drivers' licenses, enabling retailers of tobacco products to determine whether the printed information on the front has been falsified. Several states have already enacted legislation encouraging the use of these electronic-scanning devices.

ATTACHMENT D

UNDERAGE USAGE OF SMOKELESS TOBACCO IS LOW AND HAS DECREASED SUBSTANTIALLY

National government and academic studies reflect that over approximately the last decade there has been a substantial decrease in underage usage of smokeless tobacco. According to the Monitoring the Future Study ("MTF") and the Youth Risk Behavior Surveillance Survey ("YRBS") – the only two national surveys of smokeless tobacco products that have reported data since the mid-1990s using consistent methodologies from year to year – underage use of smokeless tobacco (as measured by past 30-day use) has dropped between 30% and 50% since 1995. The following graph demonstrates not only the substantial reduction, but the low percentage of underage consumers who were reported to use smokeless tobacco last year.[1]

[1] The MTF is conducted annually by the University of Michigan's Institute for Social Research and reported by the National Institute on Drug Abuse. The MTF is a national survey that covers segments of the population to age 32. The YRBS is conducted biennially by the Centers for Disease Control of the U.S. Department of Health and Human Services. It is a national, school-based survey of high school students in grades 9-12. None of the recently reported changes in underage use in either the MTF or the YRBS is statistically significant compared to the prior year.



These data are supported by two other national surveys of underage use of smokeless tobacco, the National Survey on Drug Use & Health ("NSDUH") and the National Youth Tobacco Survey ("NYTS"). While these studies do not provide comparable data from year to year for the past ten years due to changed methodologies or sporadic reporting, they support the conclusion that such usage is low: 2.4% for 12-17 year olds in 2006 (NSDUH); 2.9% (middle school) and 6% (high school) in 2004 (NYTS).

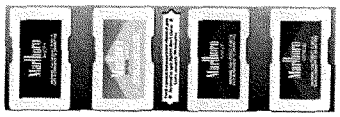
ATTACHMENT E

PHOTOS OF CIGARETTE PACKAGES
WITH FREE SMOKELESS TOBACCO PRODUCTS
AND/OR COUPONS FOR FREE PRODUCTS ATTACHED

Philip Morris USA
New Marlboro Snus Retail Brochure Pg 6 Excerpt

Marlboro Snus Variety Pack Promotion

A unique Buy 1 Pack of Marlboro Cigarettes Get 1 Marlboro Snus Variety Pack Free product promotion.



Marlboro Snus Free Pack Coupon Promotion

PM USA will offer a Marlboro Snus Free Pack coupon promotion to increase Adult Smoker awareness and tria of Marlboro Snus.

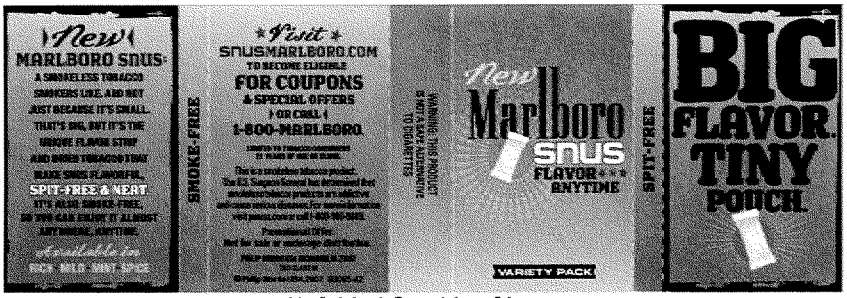
These coupons will be offered with select Marlboro cigarette packings.

Philip Morris USA
On-Pack Free Promotional Package
with Free Product

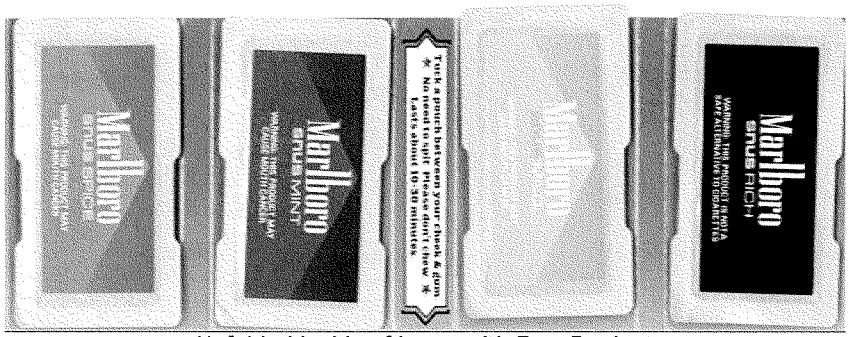
Front of Package

Back of Package

Philip Morris USA On-Pack with Free Product Promotional Insert

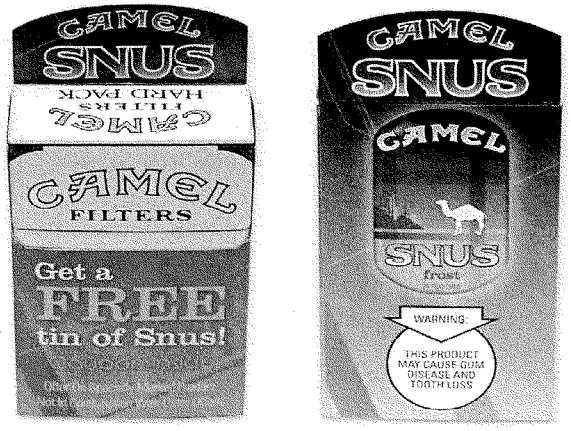


Unfolded Outside of Insert



Unfolded Inside of Insert with Free Product

R.J. Reynolds Tobacco Company
Snus Promotional Package



Camel Cigarette Package with Promotional Coupon for Free Camel Snus

In-package Coupon, Front and Back, for Free Camel Snus

January 25, 2008

Richard J. Bonnie, L.L.B.
John S. Battle Professor of Law and Director
Institute of Law, Psychiatry, and Public Policy
University of Virginia
580 Massie Road
Charlottesville, VA 22903-1789

Dear Mr. Bonnie:

Thank you for appearing before the Subcommittee on Health on Wednesday, October 3, 2007, at the hearing entitled "H.R. 1108, Family Smoking Prevention and Tobacco Control Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your responses to the Member who has submitted the questions and include the text of the Member's questions along with your responses. As you have been asked questions from more than one Member of the Committee, please begin your responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Monday, February 11, 2008**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. We also request that you send by e-mail an electronic version of your responses in a single Word formatted document to Ms. Sidman at **melissa.sidman@mail.house.gov**.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Ms. Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachments

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Steve Buyer, Member
Subcommittee on Health

The Honorable Marsha Blackburn, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

Answers to Additional Questions for the Record from

Dr. Richard J. Bonnie
Chair, Committee on Reducing Tobacco Use: Strategies, Barriers, and Consequences
Institute of Medicine
The National Academies

to the

Subcommittee on Health
House Committee on Energy and Commerce
For the Hearing on H.R. 1108, Family Smoking Prevention and Tobacco Control Act

Held on October 3, 2007

******

The Honorable Steve Buyer

1. **Looking at tobacco regulation in Europe, they regulate cigarettes by setting maximum levels for tar, nicotine, and carbon monoxide in the smoke. Is that a rational form of regulation? The Europeans don't attempt to set thousands of different "performance standards" for compounds found in the smoke. This bill sets up a new bureaucracy to regulate 4,000 different compounds in tobacco smoke at a cost of hundreds of millions of dollars per year. Isn't this a huge waste of money and wouldn't this type of regulation place such a burden on smaller manufacturers that they wouldn't be able to meet, therefore solidifying the market share for the larger companies?**

The 2007 IOM Report, *Ending the Tobacco Problem: Blueprint for the Nation*, authored by the Committee on Reducing Tobacco Use, focused on reducing prevalence of tobacco use and, on page 32, disclaimed any effort to duplicate the work on harm reduction undertaken only a few years ago by the IOM Committee to Assess the Science Base for Tobacco Harm Reduction and reported in its important report, *Clearing the Smoke* (2001). Instead, the 2007 report generally embraced the recommendations pertaining to so-called reduced exposure or reduced-risk products appearing in *Clearing the Smoke* (see Chapter 7 of that report, pages 210-230). Specifically, the 2007 report's brief discussion of performance standards (pages 288-89) refers to, and should be read together with, the passage on the same subject in *Clearing the Smoke* (pages 225-26).

Read together, *Ending the Tobacco Problem* and *Clearing the Smoke* reflect the view that FDA should be empowered to prescribe performance standards if and only if the agency concludes that doing so would "be appropriate for protection of the public health." Both IOM

reports repeatedly emphasize that regulating tobacco products poses unique challenges for many reasons, including lack of adequate information about the risks associated with particular constituents and about consumer preferences. For this reason, it is clear that both IOM committees anticipated careful science-based regulation and not the reflexive, unthinking approach you describe in your question. Let me refer specifically to the following passage from *Clearing the Smoke:*

> [A]s scientific knowledge evolves regarding product risks and consumer preferences, the regulatory authority should be empowered to require product modifications to eliminate unreasonable risks. ... Performance standards might take the form of limits on the concentrations of toxic ingredients in the product or the smoke; sets of limits that taken together would qualify a smoked product to be labeled as high, average or low on a risk scale; or a list of reviewed constituents that could be used without challenging the no increased risk standard. A performance standard cannot be adopted without good scientific data, deliberate planning, and careful monitoring to assure that it is achieving the desired goal. As the FTC test for tar and nicotine illustrates, even well-intended performance standards can sometimes be subverted, with perverse and unintended health consequences. Performance standards aimed at setting definitions for terms must therefore be thought through with great care and be subject to change as experience is gained. Such standards will undoubtedly require a public rule-making process, meaning considerable time for their adoption.

I might add that the WHO and many tobacco scientists think that regulating maximum levels of tar, nicotine and CO based on ISO (FTC) testing is meaningless because these test yields do not correspond to human exposures.

Neither IOM committee report addressed the possible economic effects of setting performance standards on competitiveness within the tobacco industry or the possible effect of market concentration on public health.

2. Do you believe sampling of smokeless tobacco should be permissible as part of a harm reduction strategy?

As noted above, harm reduction was ancillary to the charge of the Committee on Reducing Tobacco Use, and *Ending the Tobacco Problem* is accordingly silent on the role of smokeless products in harm reduction strategies which, as Congressman Buyer knows, is very controversial and would require careful consideration by the regulatory agency.

In the section of the report dealing with youth access (page 206), "[t]he committee reaffirms all of the specific recommendations pertaining to youth access recommended by the IOM in 1994, including requiring sale units to contain at least 20 cigarettes (thereby banning so-called 'kiddie packs' or 'loosies' and making it an offense for an adult to purchase tobacco products for a minor." One could infer that the committee would be opposed to the distribution of samples of

smokeless products in any context where they would be accessible to minors. It should also be noted that there is evidence that adolescents who become regulator users of smokeless tobacco are more likely than those who do not use any tobacco product to become addicted cigarette smokers as young adults.

The Honorable Marsha Blackburn

1. **I would like to delve into the constitutionality of the bill before us. In *Central Hudson*, 447 U.S. at 569, the Supreme Court requires "a reasonable fit between the means and ends of the regulatory scheme," *Lorillard Tobacco Corp.*, 533 U.S. at 561 (quotation omitted). As explained by Justice Stevens: Any "interest" in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment; more speech and a better-informed citizenry are among the central goals of the Free Speech Clause. Accordingly, the Constitution is most skeptical of supposed State interests that seek to keep people in the dark for what the Government believes to be their own good. In *Central Hudson,* the Supreme Court declared that laws restricting advertising by casinos, billboards advertising tobacco products, and alcohol content on beer labels as unconstitutional. Aren't the provisions within H.R. 1108 unconstitutional when you apply the *Central Hudson* test?**

As will be more fully explained in the answer to your next question, a black-and-white text only restriction, which preserves the free flow of information about the products and its price would meet the *Central Husdon* test. It substantially furthers the government's compelling interest in reducing initiation of tobacco use by minors and in helping adult smokers quit, and does so in a manner that is properly tailored to allow truthful non-misleading product information while restricting only the typically misleading non-informational images that have the purpose or effect of promoting and encouraging smoking and other forms of tobacco use. No one is kept "in the dark" by such a restriction.

2. **In response to a question from Ms. Capps, you indicated that the advertising restrictions in H.R. 1108 would survive a Supreme Court challenge under First Amendment scrutiny, an assertion contested by the advertising community.**

   a) **Please describe in detail the First Amendment implications of <u>tobacco advertising restrictions</u>, such as black and white text only advertising as otherwise set forth in H.R. 1108.**

   b) **Please provide all records related to the panel's analysis of this issue.**

Ending the Tobacco Problem recommended that tobacco advertising be limited to black-and-white-text. Recommendation 35 states: **Congress and state legislatures should enact legislation limiting visually displayed tobacco advertising in all venues, including mass media and at the point-of-sale, to a text-only, black-and-white format.** The committee explained (on pages 323-24):

> [This] approach, recommended by the IOM in 1994, is suitably tailored to promote the government's interests in reducing the initiation of smoking by youth, and in reducing the level of smoking in general while respecting the industry's interests in communicating product and price information. The government's compelling interest in preventing the initiation of smoking by youth justifies constraints on the use of promotional messages and images that have a unique appeal to youth (such as cartoon characters) and the placement of commercial messages depicting smoking in a positive light in venues attracting substantial numbers of youth. Under the FDA's 1996 Tobacco Rule, the ban applied to magazines with a youth readerships of greater than 15 percent. However, in light of the overt purpose of all non-informational tobacco advertising to make smoking appear to be attractive to smokers and nonsmokers alike, including youngsters and former smokers, the committee believes that all commercial messages promoting smoking should be limited to a black-and-white–text only format, even if the level of youth exposure is less than 15 percent.
>
> The committee's proposed restriction on advertising in mass media would apply to magazines and broadcast media (if the current ban were invalidated) and to advertising over the Internet through third parties. However, the committee recognizes that direct communication with customers through the Internet cannot feasibly be restricted.

In light of Congresswoman Blackburn's request for an analysis of the validity of such a restriction under the First Amendment, I am setting forth the Committee's discussion of the recommendation in *Ending the Tobacco Problem*, and will then present my own analysis of the case law, as the Congresswoman requested.

Excerpts from Committee Report

On pages 324-327, the Committee discussed the First Amendment implications of its proposal as follows:

> It is by no means clear that restrictions on tobacco advertising of the kind recommended above would survive a constitutional challenge.1 However, the committee believes that the proposed restriction on non-informational advertising is justified not only by the government's powerful interest in suppressing the use of tobacco, an unreasonably dangerous product, but also by the unique history of deception and manipulation by the tobacco industry. Furthermore, allowing informational advertising in a black-and-white–text only format fully respects the genuine constitutional interests of tobacco companies and consumers. Accordingly, the committee believes that there is a reasonable prospect that the U.S. Supreme Court can be persuaded to uphold restrictions for tobacco advertising that would not be constitutionally permissible in other contexts.

1 Professor Cass Sunstein from the University of Chicago Law School, a member of the committee, expressed doubt about the constitutionality of this recommendation. However, as indicated below, I believe that the recommended approach would survive a First Amendment challenge.

The committee acknowledges that smokers have a legitimate interest in receiving accurate information from the manufacturers regarding the characteristics of their product and from the retailers regarding the prices of those products. In addition, the tobacco companies have a correlative interest in supplying such information, subject to appropriate regulation to prevent deception and unfair competition. Indeed, truthful, non-misleading information about tobacco products, including products that reduce exposure to harmful toxicants and purport to reduce the risks of smoking, can promote the public health. However, in the committee's view, the tobacco industry does not have a constitutionally protected interest in encouraging or promoting smoking, recruiting new smokers, or sustaining the demand of existing smokers. As the committee has previously noted, tobacco appears to be the only lawful consumer product for which the acknowledged governmental objective is to suppress all consumption. In this light, it would be constitutionally confusing if the tobacco companies' desire to promote smoking were held to have any constitutional value under the First Amendment in the context of a pubic policy aiming to suppress consumption.

Admittedly, individuals and companies have a First Amendment right to promote public policies that the government opposes, and to promote viewpoints that are strongly objectionable to their fellow citizens. Moreover, tobacco companies have the First Amendment right to express their opposition to laws and policies aiming to suppress tobacco use—in colorful images if they choose to do so. Spending money to promote political viewpoints on issues and candidates is constitutionally protected speech. However, in the committee's view, spending billions of dollars to promote the use of tobacco products should not be regarded as an exercise of political freedom or as its constitutional equivalent.

The federal and state governments have the constitutional authority to ban tobacco products altogether to protect the public health (see *Gonzales v. Raich*, 545 U.S. 1, 2005). However, no one believes that prohibition is a viable option in a country with 45 million addicted smokers. Under these circumstances, the federal and state governments have a compelling interest in reducing the prevalence of smoking by preventing smoking initiation and encouraging smoking cessation. The underlying issue, in a nutshell, is whether the U.S. constitutional system creates a fundamental contradiction—empowering the government to take aggressive measures to discourage smoking while simultaneously denying it the authority to restrict industry efforts to promote smoking. To put it another way, is the government barred by the First Amendment from restraining the marketing of an inherently harmful, although legal, product?

The U.S. Supreme Court has rejected the idea that the power to prohibit the sale of a product or service necessarily entails the lesser power to prohibit all commercial speech. If the product is lawful, the First Amendment provides some protection to commercial speech. The committee does not dispute that proposition. However, the question is what protection the First Amendment actually provides. On this point, the committee believes that the First Amendment protects the interests of sellers and buyers

in conveying information about the product but does not protect the interest of sellers in promoting the use of a product that the government has a compelling interest in suppressing.

The explicit goal of tobacco policy is to reduce the use of this highly hazardous product in order to reduce tobacco-related mortality and morbidity. The powerful governmental interest in suppressing tobacco use should be sufficient to override whatever economic interest the tobacco manufacturers and retailers have in encouraging people to smoke, an interest devoid of constitutional value. At the very least, the government's compelling interest in preventing youth from smoking justifies a black-and-white–text only restriction of tobacco advertising in any venue where substantial numbers of youth would be exposed to the advertising, defined quantitatively (as an absolute number such as 2 million) or as a percentage of the exposed audience.

The alternative understanding of the First Amendment would allow no distinctions to be drawn among lawful products with respect to commercial advertising by those who sell them. In effect, such a view would leave legislatures with only two choices: banning the product altogether, or allowing it to be aggressively marketed under the shield of the First Amendment. In the committee's opinion, this view is misguided, and tobacco is the test case.

In sum, the committee is drawing a crucial distinction between promoting tobacco use and informing consumers about tobacco use. Manufacturers and retailers do not have a constitutionally protected interest in promoting the use of their products, but they do have a protected interest in communicating truthful, non-misleading information about their products to consumers. Manufacturers and retailers also have a virtually absolute right to criticize the government's policies toward tobacco use. Neither of these interests is infringed by a black-and-white–text only restriction.

Admittedly, a picture can be worth a thousand words, and it is conceivable that a text-only restriction could suppress commercial expression with informational value and therefore be unconstitutional as it is applied to a specific advertisement. However, the committee regards this prospect as a marginal one. In the committee's opinion, few images in contemporary tobacco advertising convey truthful, non-misleading information about tobacco products. A good indication of the challenge that a tobacco company would have to overcome to support a claim that a visual advertisement is constitutionally protected would be to ask the company to describe the nonverbal message in words.

Diagrams depicting specific aspects of cigarette design to promote reduced-exposure products might convey important information to consumers. For example, Philip Morris and the R.J. Reynolds Company have test marketed cigarette-like products that purport to heat rather than burn tobacco. One might expect some advertisements for such products to show a diagram of the heating element, tobacco column, specialized lighter, and other aspects of design. There is a plausible claim for First Amendment pro-

tection here, but the constitutionality of the text-only restriction as applied to such an advertisement can be adjudicated on a case-by-case basis. Relevant considerations would include whether the necessary information can be conveyed effectively in words. Moreover, a regulatory agency charged with adopting rules to implement a text-only restriction might well decide to make an exception for depictions of the product design as they relate to the health effects of smoking. Such an exception would be consistent with the committee's intent and could be written into the authorizing legislation (e.g., all advertising would have to be in black-and-white text except depictions of the product itself).

Under the committee's proposal, a company would not be entitled to show a color picture of a cigarette pack on the advertisement, even for the asserted purpose of informing consumers that its particular brand can be distinguished by a specific logo or color. The reason for holding the line on logos and colors is that these logos and colors are selected not only to convey information but also to affect the attitudes and behaviors of consumers toward the product. To allow such displays would threaten to unravel the constitutionally critical distinction between informational advertising and promotional advertising.

Analysis of Case Law

In the passage quoted above, the underlying assertion is that the core First Amendment interest at stake in commercial advertising is the right of the manufacturer and seller to convey (and the corresponding right of the potential consumer to receive) truthful, non-misleading information about the product and its price. This conclusion is supported by the entire body of case law on commercial advertising, beginning with *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*, 425 U.S. 748 (1976) and culminating in the Court's most recent pronouncement on the subject in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

In *Virginia State Board of Pharmacy*, generally acknowledged to be the font of modern commercial speech jurisprudence, the Court explained why commercial speech has First Amendment value, emphasizing the importance of the free flow of commercial information:

> [T]he *particular consumer's interest in the free flow of commercial information*... may be as keen, if not keener by far, than his interest in the day's most urgent political debate. .... [S]ociety also may have a *strong interest in the free flow of commercial information.* Even an individual advertisement, though entirely "commercial," may be of general public interest. .... Advertising, however tasteless and excessive it sometimes may seem, is nonetheless *dissemination of information as to who is producing and selling what product, for what reason, and at what price*. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, *the free flow of*

> *commercial information is indispensable* [citations omitted]. And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decisionmaking in a democracy, we could not say that the free flow of information does not serve that goal.

425 U.S. 763-65 (emphasis added).

In *Central Hudson Gas v. New York Public Service Commission*, 447 U.S. 557 (1980), the Court embraced a four-part analysis regarding the constitutionality of restrictions on commercial speech: A threshold requirement for First Amendment protection is that the speech "must concern lawful activity and not be misleading." Assuming that these conditions are met, the Court gives heightened constitutional scrutiny to the legitimacy of the restrictions that have been imposed. "We ask whether the asserted governmental interest is substantial." If it is, "we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest."

Although the Court has not been of one mind about the sufficiency of the *Central Hudson* test or about the rigor with which it should be applied, a majority of the Court has been consistently unsympathetic to laws that ban businesses from conveying truthful, non-misleading information to consumers. However, the Court has never had before it a restriction analogous to the text-only restriction recommended by the IOM – one that allows truthful information regarding the price of products and services and their characteristics to be conveyed while restricting promotional images lacking any informational content.

Cases striking down advertising bans have all involved broad restrictions on all advertising, or specific bans on price advertising, about particular products or services by particular classes of businesses. See, e.g., *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*, 425 U.S. 748 (1976) (advertising of prescription drugs by pharmacies); *Carey v. Population Services International*, 431 U.S. 678 (1977) (advertising or display of non-prescription contraceptives); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977 (price advertising of routine legal services); *44 Liquormart v. Rhode Island*, 517 U.S. 484 (1996) (price advertising of alcoholic beverages); *Greater New Orleans Broadcasting Assoc. v. United States*, 527 U.S. 173 (1999) (broadcast advertising of lotteries and casino gambling); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (advertising of tobacco products within 1000 feet of a school or park). The constitutional deficiency in most of these restrictions has been that they failed to satisfy the fourth element of the *Central Hudson* test – i.e., that an otherwise justified restriction be properly tailored or "narrowed" to serve the government's important objective. See also *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) (invalidating a provision of Food and Drug Modernization Act of 1997 conditioning exemption from FDA drug approval requirements on refraining form advertising the compounding of drugs).

The most pertinent precedent is *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). In

an opinion by Justice O'Connor, the Court held that a ban on outdoor advertising of smokeless tobacco products and cigars within 1,000 feet of schools or playgrounds was unreasonably broad and did not reflect a "careful calculation of the speech interests involved." As the Court pointed out, the ban covered advertisements of any size (and even included oral statements) and constituted a "nearly complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers" within a substantial portion of the major metropolitan areas of Massachusetts. Thus, even though "the state's interest in preventing underage tobacco use is substantial, and even compelling," and even though the restriction might directly advance that interest, Massachusetts had failed to show that the regulations "are not more extensive than necessary to advance" the state's interest.

Throughout Justice O'Connor's opinion, the First Amendment interest of tobacco retailers and manufacturers is described as an "interest in conveying truthful information about their products to adults" and "a corresponding interest" of adults 'in receiving truthful information about tobacco products." Echoing *Virginia State Board of Pharmacy*, the Court observes that a "speech regulation cannot unduly impinge upon the speaker's ability to propose a commercial transaction and the adult listener's [or reader's] opportunity to obtain information about products." In a separate concurrence, Justices Kennedy and Scalia expressed reservations about whether the *Central Hudson* test was sufficiently protective of "truthful, non-misleading commercial speech," therefore emphasizing that the First Amendment value of commercial speech lies in its informational content. A dissenting opinion by Justice Stevens, joined in full by Justices Ginsburg and Breyer, and in relevant part by Justice Souter, also identifies the relevant First Amendment interest as the "ability of [tobacco] manufacturers to convey lawful information to adult consumers." (The dissenters would have remanded the case for further consideration of the state's justification for the ban.) In sum, eight of the nine Justices then on the Court characterized the relevant First Amendment interest at stake in *Lorillard* as the *right to convey and receive truthful non-misleading information about the product*. (Six of these Justices still serve on the Court.)

Central Hudson itself is consistent with the IOM's position as explicated above. The ban at issue in that case was the New York Public Services Commission order banning utilities from engaging in promotional advertising designed to stimulate the demand for electricity. The ban continued a policy that had been adopted at the time of severe fuel shortage, even though the shortage had eased. It is noteworthy that the Commission permitted "institutional and informational advertising" not intended to promote sales. The Commission thus charted a course distinguishing between promotional advertising and informational advertising. Justice Powell's opinion for the Court noted that "[i]n view of our country's dependence on energy resources beyond our control, no one can doubt the importance of energy conservation." Moreover, "the State's interest is directly advanced by the Commission order [because] there is an immediate connection between advertising and the demand for electricity." However, the Court nonetheless struck down the ban because it was much more sweeping than needed to serve the state's interest in conservation. In fact, the effect of the ban might well have been perverse because it "reaches all promotional advertising, regardless of the impact of the touted service on overall energy use." For example, the Court pointed out, the Commission's order prevents the utility companies from promoting electric services such as use of heat pumps, or use of electric heat as a back-up to solar

and other heat sources, "that would reduce energy use by diverting demand from less efficient sources or that would consume roughly the same amount of energy as do alternative sources."

As *Ending the Tobacco Problem* explains, a text-only restriction on tobacco advertising can and should be implemented so that it protects the public health. In general, it is designed to restrict only messages that promote tobacco use, while allowing the free flow of truthful, non-misleading information about the product and its price, and particularly about the health effects of using tobacco products. As envisioned by the IOM committee, the proposed restriction would be implemented in a way that would be faithful to the principles enunciated and applied in *Central Hudson*. In *Central Hudson*, the Court was concerned about the failure of the Commission's order to allow free flow of information about "the relative efficiency and expense" of the companies various electric services." In the context of tobacco products, the equivalent concern relates to the need to permit communications regarding the characteristics and possible health effects of so-called reduced risk products. The IOM proposal is explicitly designed to allow free flow of truthful, non-misleading information about these products, even if the information is conveyed with images, as long as the regulatory agency concludes that it would promote the public health to do so.

3. **In press statements and background materials accompanying the bill, Mr. Waxman has stated that certain product regulation standards must be technologically or scientifically feasible before the FDA has the authority to mandate such standards. However, I have read the bill and no such so provision exists within H.R. 1108. Do you agree with Mr. Waxman that the FDA should only have the authority to mandate standards that can be scientifically achieved? If so, do you support including such language in the bill.**

As noted above, principles, policies and practices used in other regulatory contexts do not necessarily fit the unique challenges of regulating tobacco products where "harm reduction" requires delicate empirical judgments and where the ultimate policy goal is to reduce consumption of all such products. In some regulatory contexts, Congress has favored a technology-forcing approach, while in others, Congress has stipulated that "feasibility" (both technological and economic) is a constraint on regulatory choices. *Compare,* e.g, Clean Air Act, 42 U.S.C. Sec. 7410, *Union Electric Co. v. EPA*, 427 U.S. 246 (1976) (state plans implementing Clean Air Act standards not required to consider economic or technological feasibility) *with*, e,g. Occupational Safety and Health Act, Section 6 (b), interpreted in the Cotton Dust case, American Textile Manufacturers Institute, Inc. v Donovan, 452 U.S. 490 (1981); Safe Drinking Water Act, 42 U.S.C. Sec. 300g-1(b)(4)((B) (maximum contaminant levels for contaminants in drinking water).

Neither IOM report (*Clearing the Smoke* or *Ending the Tobacco Problem*), addresses this issue. However, in my opinion, a feasibility constraint would be consistent with the overall approach of both committees. For example, in the context of discussing the goals of tobacco

regulation, *Ending the Tobacco Problem* states, on page 278, that "feasibility is a significant constraint on the regulatory measures that can sensibly be adopted" and points out that a regulatory agency will have to take into account consumer behavior, including the creation of a 'gray' market, in assessing the effects of any regulatory restriction. This implies that social and scientific feasibility should be taken into account in any regulatory decision that the agency makes. Accordingly, I believe that the additional language Mr. Waxman proposes is compatible with the committee's approach in *Ending the Tobacco Problem*, as long as the manufacturers are required to disclose pertinent scientific information needed to enable the regulatory agency to assess whether a product innovation is feasible.

The Honorable Mike Rogers

1. **In response to a question from Mr. Pallone, you indicated that the Institute of Medicine (IOM) Panel considered the impact of tobacco regulation on the mission of the FDA.**

    a) **Please provide a detailed written description and summary of the manner by which the panel considered the impact of tobacco regulation on the operations of the FDA, including the number of meetings held to discuss this issue (I bet we discussed the agency location at three meetings, maybe more, but I can't say for sure), and the criteria used to evaluate the impact.**

    b) **Please describe the impact of tobacco regulation on the mission of the FDA.**

    c) **Please provide all records related to your deliberations and the development of your position and policy statement.**

The committee was certainly aware of, and discussed many times, the concerns that have been raised about the impact of tobacco regulation on the mission and operations of FDA. See *Ending the Tobacco Problem* pages 275-77 and 285-289. Let me begin by emphasizing that this concern, even if valid, argues not against federal regulation of tobacco, but only against conferring jurisdiction on FDA. (The question of alternatives to FDA is addressed in my response to the next question.)

Regarding the impact of tobacco jurisdiction on FDA's mission, there is no doubt that tobacco regulation is compatible in principle with the agency's overall goals of "protecting the public health" and "helping the public get the accurate, science-based information they need to improve their health." Promoting the public health is the anchoring language in all of the regulatory criteria prescribed in H.R.1108. The concern about the impact on FDA's mission appears to be a more subtle one -- that the agency's overall mission of protecting the public from unsafe products could be eroded by adding the anomalous mandate of "regulating" an inherently unsafe product, and that it will be drawn into a hapless predicament of "pretending" that the public health is being served.

The committee discussed this concern, and I feel confident in repeating what I said during my testimony: First, the feared impact has been exaggerated. Second, it is associated almost entirely with the issues arising in possible approval of claims regarding PREPs and the direct regulation products regarding harm reduction; however, much of the regulatory authority conferred by H.R. 1108 aims unequivocally to reduce tobacco consumption, and on that score there is absolutely no tension between tobacco regulation and the agency's overall mission. Third, the agency can minimize any public misunderstanding about its actions regarding PREPs by using cautionary statements and disclaimers. The agency can carry out its regulatory activities in such a manner that the public is never confused that tobacco use is unsafe, that those who use it should try to stop, and no one, especially children, should start. Finally, whatever institutional discomfort may arise is far outweighed by the positive effects

that federal regulation can achieve.

The IOM committees worried more about the impact of tobacco jurisdiction on the operations of FDA, than on the mission of FDA. The main concern that has been raised – one shared by the two IOM committees – is that FDA is an over-burdened and struggling agency, incapable of absorbing such a sweeping increase in responsibility and that adding this new set of duties would drain resources from other critically important and underfunded domains of FDA activity. The Committee on Reducing Tobacco Use assumed that effective regulation will require sufficient staff, expertise, and other resources regardless of agency placement, and that Congress would not confer this responsibility on the agency without assuring that it has sufficient resources to carry it out.

2. **In response to a question from Mr. Waxman, you indicated that the IOM panel looked at and considered "other agencies" to conduct additional Federal regulation and ultimately decided that the FDA was the most appropriate agency to conduct comprehensive tobacco regulation.**

   a) **Please provide a list of the other agencies considered and a detailed summary why the IOM panel determined that these agencies were not appropriate to regulate tobacco.**

   b) **Please indicate if the IOM considered the creation of a new regulatory regime, either structured independently from other agencies or within FDA, HHS, etc.**

   c) **Please provide all records related to such discussions or considerations.**

Ending the Tobacco Problem does not explicitly recommend that FDA be given the regulatory authority over tobacco products, but says on page 277 "Overall, however, the committee reiterates the view taken by two previous IOM committees (IOM 1994; IOM 2001): broad federal regulatory authority over the manufacture, distribution, marketing, and use of tobacco products is an essential element of a comprehensive public health approach to tobacco control." This text is accompanied by a footnote stating that "[t]he committee assumes that the FDA will be the agency empowered to regulate tobacco products. If Congress decides to confer regulatory authority on another agency, recommendations addressed to FDA should be understood to refer to whatever agency has regulatory authority."

As indicated, the committee's discussions proceeded against the backdrop of earlier deliberation of two other IOM committees. Having participated on both of these previous committees, I am in a good position to reflect on their deliberations. In *Growing Up Tobacco-Free* (1994), the committee observed (page 247) that the only real choices were between FDA and a new agency established to regulate tobacco products, and urged Congress to study the matter. In *Clearing the Smoke* (2001), the committee noted on page 207 (IOM 2001) that some

of functions envisioned by its regulatory proposals "already exist for tobacco products at the Food and Drug Administration (disease claims), at the Federal Trade Commission (regulation of advertising and enforcement staff), and at the Centers for Disease Control and Prevention (analytical laboratory)." However, the committee observed that "no agency currently has the comprehensive mandate or staff necessary to fulfill the policies recommended by this committee" and concluded that "the FDA would be an appropriate site for this regulatory function, but other administrative locations are certainly possible."

When the Committee on Reducing Tobacco Use revisited this issue, it rejected CDC on the ground that CDC has no experience in product regulation, and rejected CPSC on the ground that this small agency lacks the broad expertise in health, as well as the specific expertise in nicotine, that will be needed to carry out the regulatory functions spelled out in H.R. 1105. In contrast, the committee felt that FDA has all the scientific and regulatory capacities that will be needed to carry out this mission, assuming that Congress appropriates the needed resources. It has the medical and health expertise, the analytic laboratory capacity, experience (and enforcement staff) for regulating advertising claims (so there is no need to split off this responsibility to FTC), and experience in regulating products ranging across a broad range, including food, drugs, medical devices, biologics, and cosmetics. An added virtue of giving FDA jurisdiction over tobacco products is that it would allow the agency to develop an integrated framework for regulating nicotine and other smoking cessation medications as well as tobacco products in a manner that best serves the public health.

3. **In response to a question from Mr. Engel, you indicated that the IOM panel looked at the costs of providing insurance coverage for insurance claims regarding smoking cessation products. In an earlier response to Mr. Deal, you indicated that the IOM panel did no broad cost-benefit analysis as to the FDA regulation of tobacco products.**

    a) **Please describe in detail the panel's cost-benefit analysis with respect to any aspect of FDA regulation of tobacco.**

    b) **Please provide all records related to the panel's consideration of this issue.**

The committee conducted no cost-benefit analyses regarding the FDA regulation of tobacco, believing that the costs and benefits of any particular regulation must be addressed in that specific context.

October 26, 2007

Mr. William Corr
Executive Director
Campaign for Tobacco Free Kids
Suite 1200
1400 I Street, N.W.
Washington, D.C. 20005

Dear Mr. Corr:

Thank you for appearing before the Subcommittee on Health on Wednesday, October 3, 2007, at the hearing entitled "H.R. 1108, Family Smoking Prevention and Tobacco Control Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a certain Member of the Committee. In preparing your answers to these questions, please address your responses to the Member who has submitted the questions and include the text of the Member's questions along with your responses. Please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Friday, November 9, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Marsha Blackburn, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

Responses of

William Corr, Executive Director

Campaign for Tobacco-Free Kids

to Questions Submitted by
Members of the House Subcommittee on Health

November 8, 2007

The Honorable Mike Rogers Question:

1. **Chairman Waxman explained that this bill is modeled after the medical device statute, and since a "safe and effective" standard couldn't apply to cigarettes, the bill is drafted to give FDA the authority to regulate cigarettes as "appropriate for public health." This standard is not defined anywhere in the bill. Should it be?**

ANSWER:

The safe-and-effective standard used in the drug and delivery device laws provides a broad grant of authority to FDA, not a specific, defined standard. We would also note that "safe" is not defined in the Food, Drug and Cosmetic Act in relation to human drugs and devices, so there is no clear precedent for defining such standards. Finally, "safe" in the context of drugs is understood as requiring a balancing of risks and benefits. FDA rules that certain drugs with very serious side effects (chemotherapy drugs for example) are "safe" because their benefits are greater than their risks.

Thus, the Food and Drug Administration is accustomed to weighing risks and balancing benefits in its current work with drugs and medical devices. Essentially, the same exercise is involved in determining whether an action is appropriate to the protection of the public health.

The public health standard in H.R. 1108 is intended to provide a broad grant of authority to FDA to take the necessary steps to protect the public health. H.R. 1108 provides some further guidance for the public health standard in several locations, for example, as it applies to restrictions that FDA may impose on the sale, distribution, marketing and promotion of the product in Section 906(d). That section states in part, "The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account --

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

For these reasons, we do not believe that it is necessary to define the standard in H.R. 1108 further.

Response from William Corr

The Honorable Frank Pallone, Jr. Question:

1. **Native American tobacco retailers on Tribal lands have a unique status, in that federally recognized Tribes are sovereign nations and thus not subject to certain State and local laws, absent an agreement between a State and a Tribe. Under this bill, the FDA will largely rely on contracts with State and local government agencies to ensure retailer compliance with many of the regulations, which could pose a threat to Tribal sovereignty and Tribal laws governing Native American tobacco retailers on Tribal lands. It is my understanding that under current law, the FDA does not have the authority to contract with Tribal government agencies or other appropriate agencies to perform compliance checks. Does the bill explicitly give the FDA authority to contract with Tribal government agencies for these purposes?**

ANSWER:

We do not believe that H.R. 1108 poses any threat to Tribal sovereignty or Tribal laws governing Native American tobacco retailers on Tribal lands. Indeed, Sec. 917(a)(1) of the legislation preserves the right of Indian Tribes to pass certain laws relating to tobacco products. H.R. 1108 creates only federal law enforced by the federal government. Native American tribes have no sovereignty rights or immunity against federal laws or their enforcement by the federal government. Accordingly, there is no need for the FDA legislation to pierce or weaken Tribal sovereignty rights, and it does not do so.

To implement and administer the youth-access provisions in H.R. 1108, FDA is directed to rely largely, but not exclusively, on contracts with state and local government agencies to do age-verification compliance checks of state-based retailers. In addition, H.R. 1108 allows FDA to contract with Tribal government agencies or other appropriate entities to do compliance checks on retailers based on Tribal lands. Accordingly, H.R. 1108 provides FDA with all the authority it needs to enforce its provisions with relation to Native American retailers on Tribal lands without violating Tribal sovereignty or raising any related concerns.

Response from William Corr

The Honorable Marsha Blackburn Question 1:

1. **Congress just passed a massive expansion of the State Children's Health Insurance Program (SCHIP), and paid for it with a tobacco tax increase. The Campaign for Tobacco-Free Kids supported that tax increase even though it will require an estimated 22.4 million NEW smokers by 2017 in order to pay for it. Firstly, such a tobacco tax disproportionately burdens low-income Americans. Secondly, this tax lacks long-term stability and will ultimately result in significant shifting of health care costs onto others. The FDA tobacco bill before us has been touted by supporters as the needed weapon to reduce the number of smokers. These two initiatives are in direct conflict with one another. H.R. 1108 wants to limit the number of smokers while SCHIP needs 22.4 million MORE smokers in order to pay for the expansion. How do you reconcile these two very opposing policy positions of your organization? Won't this create an unpaid burden on our economy that the Federal Government can't afford right now?**

ANSWER:

The SCHIP legislation and the FDA tobacco legislation are actually almost perfect complements. The increases in taxes on tobacco products in the former will work quickly to reduce adult and youth smoking and other tobacco use and the many related harms and costs. The latter will work more gradually to produce large additional reductions to the harms and costs caused by tobacco use, both by reducing smoking and other forms of tobacco use and by reducing the harms from using tobacco.

In addition, implementing the FDA legislation will not significantly reduce federal tobacco tax revenues during the 2008-2012 period covered by the SCHIP legislation because its primary impact in its first five years will be to prevent and reduce smoking by youth, which accounts for only a very small portion of total federal tobacco tax revenues. For example, the Congressional Budget Office estimates that implementing the FDA tobacco legislation would reduce youth smoking by approximately 12.5 percent over its first five years; total youth smoking accounts for only two to four percent of all cigarettes consumed in the United States. Accordingly, a 12.5 percent decline in youth smoking would have only a negligible effect on total federal tobacco tax revenues (reducing cigarette tax revenues by only one-quarter to one-half of one percent).

Moreover, the formal budget estimates by the Congressional Budget Office and Joint Committee on Taxation show that the proposed tobacco tax rate increases will fully fund all new spending authorized by the SCHIP legislation – despite assuming large smoking declines prompted by the increases and substantial additional smoking declines in each subsequent year during the 2008-2012 period covered by the legislation.[1] Even with an additional 12.5 percent additional youth smoking decline over that five-year period,

[1] See, e.g., Congressional Budget Office, Letter to the Honorable John D. Dingell, September 25, 2007, http://www.cbo.gov/ftpdocs/86xx/doc8655/hr976.pdf. Joint Committee on Taxation, *Modeling the Federal Revenue Effects of Proposed Changes in Cigarette Excise Taxes*, October 19, 2007.

The Honorable Marsha Blackburn Question 1 (continued)

the CBO/JT budget projections would still show adequate net new funding from the proposed tobacco tax increases to fully cover the maximum new SCHIP expenditures permitted by the legislation.

The claim that 22 million new smokers are needed to fund the proposed reauthorization of SCHIP not only contradicts the conservative findings of the CBO/JT Tax budget analysis but is seriously flawed. It is based on a comparison of expenditures and revenues over a ten-year period (2008-2017), despite the fact that the legislation authorizes CHIP only through 2012, at which point the program will terminate unless Congress reauthorizes it with adequate funding. It also assumes much larger SCHIP expenditures than are permitted under the legislation's expenditure caps; and it assumes much sharper and more sustained annual reductions to smoking (and federal cigarette tax revenues) than are likely or even possible given the addictive power of cigarettes.[2]

Implementing the FDA tobacco legislation would immediately produce significant declines to youth smoking and would open the door to much larger future reductions to the many harms and costs caused by tobacco use. But even if the FDA legislation were passed into law today it would not have any significant effect on federal tobacco tax revenues during the 2008-2012 time period covered by the separate SCHIP legislation.

The Honorable Marsha Blackburn Question 2:

2. **In press statements and background materials accompanying the bill, Mr. Waxman has stated that certain product regulation standards must be technologically or scientifically feasible before the FDA has the authority to mandate such standards. However, I have read the bill and no such so provision exists within H.R. 1108. Do you agree with Mr. Waxman that the FDA should only have the authority to mandate standards that can be scientifically achieved? If so, do you support including such language in the bill?**

ANSWER:

We agree completely with Rep. Waxman that FDA needs the authority to mandate technologically feasible, research-based tobacco product changes to protect and promote public health; and H.R. 1108 would give that authority to FDA. [See, in particular, Sec. 907.] Please note, also, that the legislation requires the "periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." [Sec. 907(a)(5)]

---

[2] For more detail, see the Campaign factsheet, *The Proposed Increases to Federal Tobacco Tax Rates Will Fully Fund the Reauthorization of SCHIP [No New Smokers Will Be Required], available on the Campaign website at http://tobaccofreekids.org/research/factsheets/index.php?CategoryID=11.*

January 25, 2008

Jack Henningfield, Ph.D.
Vice President
Research and Health Policy Pinney Associates
Suite 1400
3 Bethesda Metro Center
Bethesda, MD 20814-3472

Dear Dr. Henningfield:

Thank you for appearing before the Subcommittee on Health on Wednesday, October 3, 2007, at the hearing entitled "H.R. 1108, Family Smoking Prevention and Tobacco Control Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your responses to the Member who has submitted the questions and include the text of the Member's questions along with your responses. Since you have been asked questions from more than one Member of the Subcommittee, please begin your responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Monday, February 8, 2008**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. Please send by e-mail an electronic version of your responses in a single Word formatted document to Ms. Sidman at **melissa.sidman@mail.house.gov**.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachments

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Marsha Blackburn, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

Responses of

Jack E. Henningfield, Ph.D.
Vice President, Research and Health Policy
Pinney Associates
and
Director, Innovators Combating Substance Abuse
Awards Program
The Johns Hopkins University School of Medicine

to Questions Submitted by
Members of the House Subcommittee on Health
as follow-up to testimony given
October 3, 2007 at the Hearing Entitled:
H.R. 1108, Family Smoking Prevention
and Tobacco Control Act

February 5, 2008

The Honorable Mike Rogers:

Question 1: Chairman Waxman explained that this bill is modeled after the medical device statute, and since a "safe and effective" standard couldn't apply to cigarettes, the bill is drafted to give FDA the authority to regulate cigarettes as "appropriate for public health." This standard is not defined anywhere in the bill. Should it be?

Answer by Jack E. Henningfield:
I believe that the approach for setting standards is consistent with public health based criteria, particularly in the sections addressing product standards and claims, and is well defined. However, I do not believe that a meaningful specific standards could or should be defined in the bill. That would be like trying to legislate the specific criteria for drug safety or food purity which is not done either. The bill does require FDA to emphasize serving public health and to gives consideration to individual and population risks and benefits in the process. This includes assessing the intended impact of a product's performance standard on how it would affect initiation of use in nonusers and cessation of use in current users. There is no standard that could or should be codified to such ends because there are multiple determinants of product use, different factors may operate across existing products, new products may be developed which pose still new factors for consideration and the base of science and real world experience will evolve driving the continued evolution of performance standards. The approach of H.R. 1108 essentially, embodies FDA experience in regulating drugs for safety and foods for purity, as well as health claims and gives the agency flexibility to use regulatory tools and experience to adapt to the challenges raised by product diversity, present and future.

In fact, I note that even with respect to drugs there are no explicit standards to define safety, nor are there explicitly defined standards for food purity. Approved drugs can have dangerous side-effects (occurring even in some fraction of appropriately using patients) and these are considered from the perspective of individual users and population effects, and they are determined on a drug by drug basis. Analogously, pure foods and not truly pure nor are their legislated standards for food purity. Rather, performance standards are developed for specific foods or food categories and without necessarily demonstrating that the requirement will improve public health. For the foreseeable future, the bill concurs with FDA's own 1996 Final Rule which concluded that tobacco products should not be prohibited, though it is expected and desirable from a public health perspective that prevalence of tobacco product use would more rapidly decline under FDA regulation than not. Over time with accrual of additional scientific evidence, real world experience, and improved technological capacity to improve product, performance standards continuously evolve – generally in the direction of reduced toxicity and improved purity.

Question 2: We appreciate your attendance. For the record, have you-or anyone within your organization received any federal funding for tobacco research? Can you supply this subcommittee with a listing of all Federal research funds received by members of your organization along with an explanation and copy of the work that was produced with such funds?

Answer by Jack E. Henningfield:

I have not received Federal research funds for tobacco research since I left the National Institute on Drug Abuse in 1996 where my laboratory conducted extensive work on the addictiveness of tobacco products along with other addictive substances.

Pinney Associates does not receive any federal funding for tobacco research. I, and several other employees of Pinney Associates, have participated in meetings convened or supported by the National Cancer Institute, National Institutes of Health, and Centers for Disease Control and Prevention on tobacco products, tobacco-associated disease, and tobacco addiction. This includes my service on the Interagency Committee on Smoking or Health, my service to develop reports of the U.S. Surgeon General on Smoking and Health and Monographs by the National Cancer Institute, and my service on the World Health Organization Tobacco Research Laboratory Network (TobLabNet) and Study Group on Tobacco Product Regulation (TobLabNet) which I believe receive some U.S. funding at least indirectly. I am also listed as an advisor or consultant on various research grants but am not directly involved in the conduct of research. The Innovators Awards Program at The Johns Hopkins University School of Medicine is funded by the Robert Wood Johnson Foundation and does not conduct research.

The Honorable Marsha Blackburn:

Question 1: In press statements and background materials accompanying the bill, Mr. Waxman has stated that certain product regulation standards must be technologically or scientifically feasible before the FDA has the authority to mandate such standards. However, I have read the bill and no such so provision exists within H.R. 1108. Do you agree with Mr. Waxman that the FDA should only have the authority to mandate standards that can be scientifically achieved? If so, do you support including such language in the bill?

Answer by Jack E. Henningfield:

I agree with Representative Waxman that the FDA needs the authority to mandate technologically feasible and scientifically-based tobacco product changes to protect and promote public health. This authority is explicit in H.R. 1108, as described in Section 907, which includes the following vital requirement: "periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." [Sec. 907(a)(5)]

October 26, 2007

Fred Jacobs, M.D., J.D.
Commissioner
New Jersey Department of Health and
Senior Services
P.O. Box 360
Trenton, NJ 08625-0360

Dear Dr. Jacobs:

Thank you for appearing before the Subcommittee on Health on Wednesday, October 3, 2007, at the hearing entitled "H.R. 1108, Family Smoking Prevention and Tobacco Control Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a certain Member of the Committee. In preparing your answers to these questions, please address your responses to the Member who has submitted the questions and include the text of the Member's questions along with your responses. Please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Friday, November 9, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Marsha Blackburn, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

Fred M. Jacobs, M.D., J.D.

Commissioner

New Jersey Department of Health and Senior Services

P.O. Box 3670

Trenton, NJ 08625-0360

The Honorable Marsh Blackburn:

1. **The Synar amendment, which passed in 1992, ensured that States take the lead in reducing minor access to tobacco by conducting stings of retail establishments. According to the Substance Abuse and Mental Health Services Administration, every State has met the goal of 80 percent compliance.**

   a) **How has your State faired under the Synar amendment?**

   The Tobacco Age of Sale Enforcement Program (TASE) in the Comprehensive Tobacco Control program (CTCP) has gone from a non-compliance rate of 23.2% in FFY 2000 to achieving a non-compliance rate of 11.1% in FFY 2007.

   b) **How long did it take New Jersey to reach an 80 percent compliance rate?**

   TASE is in its' eleventh year of existence, and since FFY 2003, TASE has reached more than 80 percent compliance rate.

   c) **What has New Jersey done to go beyond the 80 percent compliance rate?**

   - Legislative Accomplishments became Law April 15, 2006.
     1. New Jersey Smoke Free Air Act.
     2. New Jersey legal age to purchase tobacco products increased from 18 to 19 years old.
   - Developed Merchant Education Package/Materials. Partially updated in 2006.
   - Developed two Media Postcards and distributed to over 13,000 tobacco retailers.

- Expanded Merchant Education to include New Jersey Retailer Association.
- Assisted Local Health Departments in developing and implementing new Merchant Education Training.
- Showcased best practices among Local Health Departments by enforcing effective Merchant Education and making progress through comprehensive collaboration.
- Expand deliverables of CTCP Community Partners grantees to include merchant education.
- Maintained close partnerships with Local Health Departments to ensure retention or encourage participation in the TASE program.
- Conduct year round tobacco inspections through participating Local Health Departments or CTCP-TASE inspectors.

The Honorable Mike Rogers

1. **Since Synar passed, nearly every State in the Nation has passed its own measures to reduce youth access to tobacco. What has New Jersey done to further reduce youth access to tobacco?**

    - On April 15, 2006 New Jersey became one of four states to legally increase the age to purchase tobacco products from 18 to 19 years of age.

Do you agree that State efforts to reduce minor access to tobacco including those in your State are effective?

While we agree that the state of New Jersey's efforts to reduce minors' access to tobacco has been effective, there are other efforts, pending implementation, which will further reduce minor access to tobacco.

Shouldn't we continue on the successful path of State's taking the lead and focus on strengthening State efforts?

Yes, we should continue taking the lead by also implementing pending initiatives and/or exploring new ones that will further reduce New Jersey violation rate.

October 26, 2007

Risa Lavizzo-Mourey, M.D., M.B.A.
President and CEO
Robert Wood Johnson Foundation
P.O. Box 2316
Princeton, NJ 08543

Dear Dr. Lavizzo-Mourey:

Thank you for appearing before the Subcommittee on Health on Wednesday, October 3, 2007, at the hearing entitled "H.R. 1108, Family Smoking Prevention and Tobacco Control Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a certain Member of the Committee. In preparing your answers to these questions, please address your responses to the Member who has submitted the questions and include the text of the Member's questions along with your responses. Please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Friday, November 9, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Marsha Blackburn, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

Route 1 & College Road East P.O. Box 2316
Princeton, New Jersey 08543-2316
Tel. 877 843 RWJF (7953)
www.rwjf.org

Robert Wood Johnson Foundation

Response from Risa Lavizzo-Mourey, M.D., M.B.A.

Follow-up to October 3, 2007, Subcommittee on Health Hearing
"H.R. 1108, Family Smoking Prevention and Tobacco Control Act"

Question from the Honorable Marsha Blackburn:
In press statements and background materials accompanying the bill, Mr. Waxman has stated that certain product regulation standards must be technologically or scientifically feasible before the FDA has the authority to mandate such standards. However, I have read the bill and no such so provision exists within H.R. 1108. Do you agree with Mr. Waxman that the FDA should only have the authority to mandate standards that can be scientifically achieved? If so, do you support including such language in the bill?

RESPONSE:
I agree with Rep. Waxman that Congress should give the Food and Drug Administration the authority to require tobacco product standards that are technologically or scientifically feasible. I would have to defer to the Committee's legal counsel as to whether such language needs to be explicitly included in the statute.

It is most important, however, that the tobacco companies are not the ones who determine what is technologically or scientifically feasible. As we have seen with fire-safe cigarette standards, some tobacco product manufacturers continue to claim the standards are not feasible even after 22 states have enacted workable regulations. FDA's scientific experts in disciplines such as chemistry, toxicology, statistics and epidemiology should make that determination with the input provided by both the Tobacco Products Scientific Advisory Committee and the comment period required in this legislation.

Question from the Honorable Mike Rogers:
Chairman Waxman explained that this bill is modeled after the medical device statute, and since a "safe and effective" standard couldn't apply to cigarettes, the bill is drafted to give FDA the authority to regulate cigarettes as "appropriate for public health." This standard is not defined anywhere in the bill. Should it be?

RESPONSE:
Although H.R. 1108 uses a different standard for the regulation of tobacco products, it seems to me that the agency will apply the same basic set of skills that it has used successfully for decades. The core competencies of the FDA can and should be applied to the regulation of tobacco products. Because of its expertise, FDA is the most qualified agency to determine what is appropriate for the protection of public health and should have the freedom and flexibility to make those decisions related to tobacco products. I do not believe that that requires further definition in the statute.

STATEMENT OF MIKE SZYMANCZYK

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, PHILIP MORRIS USA

On behalf of the nearly 11,000 employees of Philip Morris USA (PM—USA) I am very pleased to submit these remarks, and to express our strong support for H.R. 1108, legislation that would give the Food and Drug Administration (FDA) authority to regulate tobacco products. Almost five years after we announced our full support for FDA regulation, PM—USA remains committed to passage of comprehensive regulation of tobacco products. H.R. 1108 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.

H.R. 1108 is the result of many difficult choices and compromises by all those who have been involved in this process over the last several years. 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 Congressman Waxman and Congressman Davis for the leadership they have shown on this issue. Likewise, we appreciate the leadership shown by Senator Kennedy and Senator Cornyn in introducing companion legislation in the United States Senate. We look forward to working with you and your colleagues in the Senate to enact this legislation 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. H.R. 1108 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.

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, non-misleading 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 invested in extensive research programs that focus on advancing our knowledge about tobacco and tobacco smoke to support our efforts to develop and launch new product designs. We believe these product technologies and related approaches 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 and other potential harm reduction products must be acceptable to adult tobacco users. We see little benefit to consumers or society if harm reduction is not pursued in the context of tobacco products that adult consumers will enjoy using. As the 1998 Canadian Experts' Committee, which addressed potential harm reduction products for smokers, 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, H.R. 1108 grants the agency an essential role in performing its own assessment and oversight of any claims, explicit or implied, made about the product by the manufacturer regarding exposure- or risk-reduction. Crafting appropriate claims regarding these products re-

quires 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 H.R. 1108 correctly gives FDA jurisdiction over communications to consumers. Future FDA regulations should ensure that consumers are not mistakenly led to believe that the use of a particular tobacco product reduces the health risks as much as quitting. At the same time, we do not believe future regulations should be utilized as a tool to suppress information that is truthful and not misleading.

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 using tobacco products. 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. PM—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 facts of reduced exposure or reduced risk products and the potential benefits of such products. Section 911 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 in its 2001 report 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..." We believe that approach is both good policy and required by the first amendment.

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.

H.R. 1108 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.

SECTION 901—FDA AUTHORITY OVER TOBACCO PRODUCTS

H.R. 1108 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." While the bill extends the scope of FDA's authority to all manufacturers of tobacco products selling tobacco products in the United States, it also makes clear that FDA does not have the authority to regulate tobacco growers. FDA will not be on the farm.

SECTION 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.

SECTION 904—SUBMISSION OF HEALTH INFORMATION

The bill requires, within six months of passage, submission to the Secretary of documents and information concerning ingredients, compounds, paper, filter and other components of tobacco products as well as content, delivery and form of nicotine. PM USA fully supports this requirement with appropriate safeguards to pro-

tect 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.

SECTION 905—ANNUAL REGISTRATION

H.R. 1108 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 even-handed application of the legislation to these foreign manufacturers, including through appropriate inspections.

SECTION 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 three-year delay for compliance to ensure that manufacturers have ample opportunity to comply.

SECTION 907—PRODUCT STANDARDS

H.R. 1108 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 towards 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.

SECTION 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 2001 report, the Institute of Medicine 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 H.R. 1108 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 2001 Institute of Medicine Report.

SECTION 920—USER FEES

H.R. 1108 requires the Secretary to require tobacco product manufacturers and importers to pay for providing, equipping and maintaining adequate service for regulating tobacco products. PM—USA believes the collection of such user fees is reasonable, assuming appropriate oversight and strict collection and enforcement by the agency.

SECTION 102—REPROMULGATION OF FDA'S 1996 FINAL RULE

Within 30 days of enactment of H.R. 1108 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 one 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 or different restrictions on the sale, distribution, advertising and promotion of tobacco products if the Secretary determines that the regulation would protect the public health and, as the bill specifies, the marketing and advertising restrictions are 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 is important. 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.

PM—USA will also work with FDA and other interested stakeholders to make sure that any advertising or marketing restrictions comport with the first amendment.

SECTION 201—CIGARETTE LABEL AND ADVERTISING WARNINGS

This section of H.R. 1108 specifies nine new warning labels required to appear on cigarette packages and advertisements. The warnings must comprise at least the top thirty-percent of the front and rear panels of the package, and at least twenty-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. PM—USA fully supports these provisions regarding the new warning labels and their size and placement. PM—USA also supports the grant of authority to FDA to modify or enlarge these warnings in the future through a rulemaking process where the potential benefits, risks and unintended consequences of such proposed changes will be thoroughly examined.

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. We do not believe that H.R. 1108 is designed to, or would in fact, give any one tobacco company a commercial advantage over others, notwithstanding the assertions of some manufacturers. Tobacco companies know very well that the first amendment of the Constitution guarantees that the FDA could not ban tobacco product advertising. An appropriate and constitutionally sound regulation of tobacco products and advertisements would effectively ensure 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 constitutionally proper advertising or marketing restrictions will lessen competition, create a monopoly or lock in market share. Indeed, we believe that, with clear guidelines and over-

sight, 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 H.R. 1108, which represents a truly historic opportunity to establish a comprehensive and coherent national tobacco policy.

○