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POTENTIAL REDUCED EXPOSURE/REDUCED RISK TOBACCO PRODUCTS: AN EXAMINATION OF THE POSSIBLE PUBLIC HEALTH IMPACT AND REGULATORY CHALLENGES

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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POTENTIAL REDUCED EXPOSURE/REDUCED RISK TOBACCO PRODUCTS: AN EXAMINATION OF THE POSSIBLE PUBLIC HEALTH IMPACT AND REGULATORY CHALLENGES

TUESDAY, JUNE 3, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 2:01, in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.

Present: Representatives Tom Davis of Virginia, Shays, McHugh, Ose, Lewis, Platts, Putnam, Schrock, Duncan, Sullivan, Carter, Janklow, Blackburn, Waxman, Towns, Maloney, Cummings, Kucinich, Tierney, Clay, Watson, Van Hollen, Ruppersberger, Norton, and Bell.

Staff present: Peter Sirh, staff director; Melissa Wojciak, deputy staff director; Bill Womack, legislative director, Keith Ausbrook, chief counsel; Jim Moore, counsel; David Marin, director of communications; Scott Kopple, deputy director of communications; Teresa Austin, chief clerk; Joshua E. Gillespie, deputy clerk; Susie Schulte, legislative assistant, Corinne Zaccagnini, chief information officer; Phil Barnett, minority chief counsel; Kristin Amerling, minority deputy chief counsel; Althea Gregory, minority counsel; Karen Lightfoot, minority communications director/senior policy advisor; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; Jean Gosa, minority assistant clerk; and Cecelia Morton, minority office manager.

Chairman TOM DAVIS. The committee will come to order. Tobacco smoke is the cause of a great many illnesses, among them, cancer, cardiovascular disease and stroke. Indeed, over 400,000 Americans die every year from tobacco-related illness, the leading preventable cause of death. Imagine if this same number of people died from a communicable disease such as SARS or smallpox. The mere threat of such illnesses has been sufficient to garner far greater public attention and response.

We are left with the question of how best to respond to this situation. While smoking rates steadily declined from the 1960's to the end of the 1980's, we have reached something of a plateau since the early 1990's. According to the most recent figures, approximately one quarter of the adult population smokes, 47 million people. Of this number, 70 percent express a desire to quit. While 34 percent of this number will make an attempt to do so annually, less than

3 percent will succeed. These numbers beg the question of whether current approaches to controlling tobacco-related morbidity and mortality are sufficient.

In recent years, we have seen pharmaceutical products such as the patch and nicotine gum emerge as cessation aids. We are also seeing the emergence of the harm-reduction tobacco market. That is, products that aim to decrease harm to health from tobacco use without completely eliminating it. This latter form of product is largely unregulated, and there are questions whether these products, which give the impression of being a safer alternative to conventional cigarettes, are in the public interest.

In 1999, the Food and Drug Administration requested the Institute of Medicine [IOM], to conduct a thorough study into tobacco harm reduction products. In 2001, IOM published the seminal work on the subject entitled, "Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction." It is this study and its recommendations that serves as the basis for today's hearing.

Clearing the Smoke makes a number of recommendations and sets out a number of principles for the ideal regulatory scheme to oversee harm reduction products, referred to as potential reduced risk products [PREPs], in tobacco in general. However, as I read the study, the take-away messages are these.

First, it is feasible but not easy to produce tobacco products that could expose a consumer to lower level of toxins than conventional cigarettes. Second, it is possible that reduced exposure to these toxins could reduce the risk of tobacco-related disease and death. Third, great care must be taken to ensure these products don't result in increased harm to individuals and to the public's health in general.

Said another way, harm reduction presents both promise and uncertainty. There is still much that we don't know about tobacco-related illness, nor do we fully understand why people smoke cigarettes in the first place. Finding the answer to these questions is a critical component in harm reduction efforts.

Tobacco harm reduction is not without its critics. As I mentioned earlier, the core concern with these products is that while they may be able to remove a degree of the risk from the individual user, the notion of a safe product could prove damaging to the population as a whole. Smokers who might otherwise quit altogether could instead opt to use the safer products. In addition, those who have already quit smoking could be enticed to start anew.

Finally, children, a group already convinced of their own invincibility, could be drawn to a life of tobacco dependency by the lure of safe tobacco.

History bears out these concerns. Earlier attempts at harm reduction, most notably the advent of the filtered cigarette later followed by low yield cigarettes, were heralded by the public health community. However, time has shown that these were false hopes. All the vast majority of cigarettes today are filtered. There has been no discernible decrease in morbidity or mortality. Similarly, while low tar cigarettes may have produced lower toxins as measured by an automated device, human consumers changed their smoking behavior by inhaling more deeply, for example, to leach out the same nicotine and tar levels found in other cigarettes.

In the wake of these products, smoking rates increased and public health suffered. To this day, most smokers use light or low-tar products despite the information available that they offer little if any improvement over other products. The perception of safety is hard to break.

These concerns are well taken and must be given due consideration as we move forward. However, given the fact that a significant number of people will continue to use tobacco for the foreseeable future, I am not of the opinion that these concerns merit abandoning tobacco harm reduction in favor of an abstinence-only approach. That said, development of this marketplace must take place in the proper regulatory environment. A scientific agency, in my opinion, Food and Drug Administration, should oversee all tobacco products, but especially products intended to be sold for harm reduction purposes.

Currently, our regulatory structure has been turned on its ear. Based on the IOM study as well as works from a great many experts, including some of those in our panel today, it seems obvious that pharmaceutical nicotine therapies present the least amount of risk of any potential reduced exposure product, but they are subjected to the most stringent regulatory examination. Perhaps as a result they are quite expensive and there are few options available to the consumer. Ironically, potential reduced-exposure products made from tobacco, which are regarded as the most risky form of these products, are subjected to little if any regulation at present. I think we should not only look for ways to increase regulation of tobacco products, but also ways in which the FDA can facilitate a vibrant medicinal nicotine market.

Finally, I believe it is important to achieve balance in our efforts at tobacco harm reduction. As the IOM states, manufacturers must be given the 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. This incentive comes in the form of being able to communicate the message that a given product does just that. These claims must be based on good science, but if the science is there, undue skepticism of regulators should not discourage development.

The facts are these: Many experts believe harm reduction could play an important role in decreasing tobacco-related disease and death. If this is to work and the American people are to benefit, two parties with little regard for each other are going to have to learn to co-exist.

Future regulators and public health officials need the ingenuity and resources the industry can bring to bear to create palatable, acceptable, and less risky products that current smokers use. The industry needs independent government regulators to validate its science and confirm the value of the products they wish to market to the public. Anything less will surely return us to the days of snake oil. We must be prepared to work past old notions regarding tobacco products. In this vein, we will consider today the role smokeless tobacco plays in this debate. Some believe there is scientific evidence that smokeless does in fact represent a significant decrease in risk compared to conventional cigarettes. If this is so, what do we do with this information?

In closing, there are a great many questions to be answered regarding potential reduced exposure products. We have constructed two panels today that I believe will help us understand many of the relevant issues, and I very much look forward to today's hearing. I welcome all the witnesses to today's hearing, and I look forward to hearing their testimony.

[The prepared statement of Chairman Tom Davis follows:]

Opening Statement of Chairman Tom Davis
Government Reform Committee Hearing
Potential Reduced-Risk Products: An examination of the Regulatory Challenges and Public Health Implications

June 3, 2003

Tobacco smoke is the cause of a great many illnesses, among them cancer, cardiovascular disease and stroke. Indeed, over 400,000 Americans die every year from tobacco-related illness – the leading preventable cause of death. Imagine if this same number died from a communicable disease such as SARS or smallpox. The mere threat of such illnesses has been sufficient to garner far greater public attention and response.

We are left with the question of how best to respond to this situation. While smoking rates steadily declined from the 1960's to the end of the 1980's, we have reached something of a plateau since the early 1990's. According to the most recent figures, approximately one quarter of the adult population smokes – 47 million people. Of this number, 70 percent express a desire to quit. While 34 percent of this number will make an attempt to do so annually, less than 3 percent will succeed. These numbers beg the question of whether current approaches to controlling tobacco-related morbidity and mortality are sufficient.

In recent years, we have seen pharmaceutical products such as the patch and nicotine gum emerge as cessation aids. We are also seeing the emergence of the "harm-reduction" tobacco market -- that is, products that aim to decrease harm to health from tobacco use without completely eliminating it. This latter form of product is largely unregulated, and there are questions whether these products, which give the impression of being a safer alternative to conventional cigarettes, are in the public interest.

In 1999, the Food and Drug Administration (FDA), requested that the Institute of Medicine (IOM) conduct a thorough study into tobacco harm reduction products. In 2001, IOM published the seminal work on the subject, entitled *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.* It is this study and its recommendations that serve as the basis for our hearing today.

Clearing the Smoke makes a number of recommendations and sets out a number of principles for the ideal regulatory scheme to oversee harm reduction products (referred to as Potential Reduced Risk Products, or PREPs, in the study) and tobacco in general. However, as I read the study, the take-away messages are these:

1. It is feasible, but not easy, to produce tobacco products that could expose the consumer to lower levels of toxins than conventional cigarettes.

2. It is possible that reduced exposure to these toxins could reduce the risk of tobacco-related disease and death.

3. Great care must be taken to ensure these products do not result in increased harm to individuals and to the public's health in general.

Said another way, harm reduction presents both promise and uncertainty. There is still much that we do not know about tobacco-related illness, nor do we fully understand why people smoke cigarettes in the first place. Finding the answers to these questions is a critical component in harm-reduction efforts.

Tobacco harm reduction is not without its critics. As I mentioned earlier, a core concern with these products is that while they may be able to remove a degree of the risk from the individual user, the notion of a "safer" product could prove damaging to the population as a whole. Smokers who might otherwise quit tobacco use altogether could instead opt to use the "safer" products. In addition, those who had already quit smoking could be enticed to start anew. Finally, children, a group already convinced of their own invincibility, could be drawn to a life of tobacco-dependency by the lure of "safe" tobacco.

History bears out these concerns. Earlier attempts at harm reduction, most notably the advent of the filtered cigarette, later followed by low-yield cigarettes, were heralded by the public health community. However, time has shown these were false hopes. While the vast majority of cigarettes today are filtered, there has been no discernable decrease in morbidity or mortality. Similarly, while low-tar cigarettes may have produced lower toxins as measured by an automated device, human consumers changed their smoking behavior (by inhaling more deeply, for example) to leach out the same nicotine and tar levels found in other cigarettes. In the wake of these products, smoking rates increased and the public health suffered. To this day, most smokers use light or low-tar products, despite the information available that they offer little, if any, improvement over other products. The perception of safety is hard to break.

These concerns are well taken and must be given due consideration as we move forward. However, given the fact that a significant number of people will continue to use tobacco for the foreseeable future, I am not of the opinion that these concerns merit abandoning tobacco harm reduction in favor of an abstinence-only approach. That said, development of this marketplace must take place in the proper regulatory environment. A scientific agency, in my opinion the Food and Drug Administration, should oversee all tobacco products, but especially products intended to be sold for harm-reduction purposes.

Currently, our regulatory structure has been turned on its ear. Based on the IOM study, as well as works from a great many experts, including some of those on our panel today, it seems obvious that pharmaceutical nicotine therapies present the least amount of risk of any potential reduced-exposure product. Yet they are subjected to the most stringent regulatory examination. Perhaps as a result, they are quite expensive, and there are few options available to the consumer. Ironically, potential reduced-exposure products made from tobacco, which are regarded as the most-risky form of these products, are subjected to little, if any regulation at present. I believe we should not only look for ways to

increase regulation of tobacco products, but also at ways in which FDA can facilitate a vibrant medicinal nicotine market.

Finally, I believe it is important to achieve balance in our efforts at tobacco harm reduction. As the IOM states, manufacturers must be given the 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. This incentive comes in the form of being able to communicate the message that a given product does just that. These claims must be based on good science, but if the science is there, undue skepticism of regulators should not discourage development.

The facts are these: Many experts believe harm-reduction could play an important role in decreasing tobacco-related disease and death. If this is to work, and if the American people are to benefit, two parties with little regard for each other are going to have to learn to coexist.

Future regulators and public health officials need the ingenuity and resources the industry can bring to bear to create palatable, acceptable, and less-risky products that current smokers will use. The industry needs independent government regulators to validate its science and confirm the value of the products they wish to market to the public. Anything less will surely return us to the days of snake oil.

We must be prepared to work past old notions regarding tobacco products. In this vein, we will consider today the role smokeless tobacco plays in this debate. Some believe there is scientific evidence that smokeless does, in fact, represent a significant decrease in risk compared to conventional cigarettes. If this is so, what do we do with this information?

In closing, there are a great many questions to be answered regarding potential reduced-exposure products. We have constructed two panels that I believe will help us understand many of the relevant issues, and I very much look forward to today's hearing.

Chairman TOM DAVIS. I now recognize any other Members who wish to make any opening statements. Any Members wish to make statements? Mr. Ruppersberger.

Mr. RUPPERSBERGER. Thank you, Mr. Chairman.

Today we are here to discuss the health implications and public policy issues that surround the use and marketing of reduced risk tobacco products. Reduce risk tobacco products are cigarettes with lower carcinogens and less nicotine, products that burn only when inhaled, producing less secondhand smoke, and, finally, smokeless tobacco. Hopefully, in this hearing we will get some insight as to whether these products are safer than traditional cigarettes, and if the marketing of these products is truthful and accurate. Ultimately, what we are seeking are ways to help people to quit smoking. The questions before the committee today are, No. 1, are reduced-risk tobacco products a step in assisting smokers to quit, or are they just a modified form of addiction with no real benefits? No. 2, if we have evidence that a reduced-risk product can help a smoker to quit even in stages, shouldn't we look at providing that information? Congress needs to ensure that marketing of these reduced risk products is accurate. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you. Any other Members wish to make statements? The gentleman from South Dakota. Let me note, Members have will have five legislative days to insert opening statements into the record.

Mr. JANKLOW. Thank you, Mr. Chairman. I am going to be extremely brief in my comments.

I am an individual who never smoked a cigarette in his life until I went in the U.S. Marine Corps and was given free cigarettes in my C rations and my K rations, and that is how I started smoking. I currently have 105 pack years behind me during the period of time when I did smoke. And only because of serious medical problems that I had at one time was I able to quit. The hardest thing I have ever done in my life was to quit smoking. The addiction was the most difficult thing that I ever dealt with. When I was another public life, I smoked every single place where it was illegal. I smoked in meeting halls, in my office, and other people's meeting halls, in the hallways, every place I could to get a cigarette.

400,000 people a year die as a result of smoking in this country. How much smaller would the group have to be before we would put an all-out crime activity program together to deal with individuals who brought about the death of hundreds of thousands of Americans a year? There is no such thing as reduced-risk smoking. You either smoke or you don't smoke. You are either at risk or you are not at risk. And so, Mr. Chairman, this is a terribly timely group that you have convened as a panel, and it is the most appropriate subject matter. Thank you for doing it.

Chairman TOM DAVIS. Thank you very much.

I recognize our ranking member, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to acknowledge the statement just made by our colleague, Mr. Janklow. I thought that was a very wise statement. I, too, have been down that road. I was a smoker and gave it up, and I have spent a great deal of my congressional career trying to bring to people's attention the dangers of cigarette smoking. It is really

shocking, and people get numb to it, but it is really shocking the number of deaths and amount of disease related to cigarette smoking still in this country, even though many people have given up cigarette smoking. Now we are holding a hearing, and I appreciate the chairman calling this hearing, to look at whether a reduced-risk tobacco product might be a useful way for us to look to helping people in the future. These kinds of products are already starting to appear on the market. They have the potential to effect for good or ill the health of millions of smokers. So it is important we look at this carefully.

I am not opposed to any product that will reduce the risk of heart disease, cancer, and other diseases caused by smoking. If new technology can help, if it is not just another clever marketing gimmick by the tobacco industry, I will bring an open mind to this debate. But I have been down this road before, and I know what the risks are. The claims that we are hearing today about this new generation of safer cigarettes are strikingly similar to claims I heard from the companies 30 years ago when they started to market light and low tar cigarettes. And we know how the experiment turned out.

While promising smokers that their new brands were better for their health, the tobacco industry knew all along that light and lower tar brands were just as dangerous as regular cigarettes if not more so. In fact, companies designed the cigarettes to fool the machines that measure the nicotine and tar, because it would still then deliver a full dose of toxins to smokers. The result was a deadly fraud. The National Cancer Institute recently concluded that there is no convincing evidence that light and low tar cigarettes provide any health benefits.

It is no exaggeration to say that millions of people will die because they believed that these products were safer than conventional cigarettes. And this deception continues today. Light and low tar cigarettes dominate the market, and tobacco companies are aggressively defending their ability to use these misleading terms on their labels.

Now, the topic of today's hearing is a new generation of so-called reduced risk tobacco products. These products raise the question whether history is repeating itself. Earlier today, Representative Jan Schakowsky and I released a staff report that examines the striking parallels between the low tar experience and the new reduced-risk tobacco products on the market. And I would like to ask unanimous consent that that report be made part of the record.

Chairman TOM DAVIS. Without objection, so ordered.

[The information referred to follows:]

The Lessons of "Light" and "Low Tar" Cigarettes:

Without Effective Regulation, "Reduced Risk" Tobacco Products Threaten the Public Health

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Prepared for

Rep. Henry A. Waxman
Rep. Janice D. Schakowsky

Minority Staff Report
Special Investigations Division
Committee on Government Reform
U.S. House of Representatives
www.reform.house.gov/min

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EXECUTIVE SUMMARY

After the U.S. Surgeon General concluded in 1964 that cigarette smoking causes lung cancer, tobacco companies recognized that health issues concerned millions of Americans smokers. The companies responded by introducing "light," "filtered," "low tar," and "ultra low tar" brands and marketing them as less dangerous than regular cigarettes. Millions switched brands but experienced no health benefits as a result. The "light" and "low tar" experiment was a public health disaster.

Today, the U.S. tobacco industry is marketing a new generation of "reduced risk" tobacco products. These include "low nitrosamine" cigarettes, "heated" nicotine delivery devices, and smokeless tobacco. Companies are claiming they are "safer," have "less toxins," and deliver "reduced carcinogens." An essential question regarding these products is whether history is repeating itself.

At the request of Reps. Henry A. Waxman and Janice D. Schakowsky, this report compares the history of "light" and "low tar" cigarettes to available evidence about the new "reduced risk" tobacco products, including previously undisclosed internal company documents. The report finds striking parallels between current "reduced risk" products and past experience with "light" and "low tar" cigarettes.

- **Marketing to Counter Health Fears**

Starting in the late 1960s, tobacco companies sold "light" and "low tar" brands as important scientific advances that addressed the growing anxiety smokers felt about their health. The companies' claims could be explicit, as when Brown & Williamson marketed Fact, "the low gas, low 'tar'" cigarette that should appeal to "critics of smoking." More frequently, cigarette manufacturers exploited the widespread belief that since nicotine and tar were harmful, cigarettes offering less of these toxins had to be safer. As a result, when Philip Morris relied on machine-based testing of nicotine and tar to declare "Merit Science Works" or Brown & Williamson stated "Latest U.S. Gov't Laboratory test confirms . . . Carlton is lowest," smokers heard a clear message about health. The tobacco industry also sought to enlist health officials in their campaign to promote these products, with one company hoping "to generate statements by public health opinion leaders which will indicate tolerance for smoking and improve the consumer's perception of ultra low 'tar' cigarettes."

The tobacco industry is making strikingly similar claims for its "reduced risk" products today. For example, Brown & Williamson markets its Advance Lights brand as a "revolutionary breakthrough in cigarette technology" that provides "All of the taste . . . less of the toxins." Vector Tobacco has promoted Omni as offering: "Reduced carcinogens. Premium taste." In marketing Eclipse, R.J. Reynolds proclaims that "the toxicity of [Eclipse's] smoke is dramatically reduced compared to other cigarettes." According to internal company documents, Brown & Williamson's parent company has developed a public relations campaign for "lower risk products" based on partnerships with the public health community.

- **Deceiving Consumers**

Even as their advertisements promoted "light" and "low tar" cigarettes as better for health, tobacco companies knew that smokers generally received the same amount of nicotine and other toxins from these products as from their regular cigarettes. In fact, the companies designed cigarettes to score low on machine-based testing but still allow users to inhale their usual amounts of nicotine and tar. To accomplish this, manufacturers took such steps as adding ventilation holes that drew in diluting air on machine testing but were blocked by smokers during actual use. An Illinois judge recently called one company's actions in creating these brands "immoral, unethical, oppressive and unscrupulous."

While new "reduced risk" products are still in their infancy, there are warning signs that tobacco companies may again be deceiving consumers. In 2000, in an internal company email, a senior scientist at Brown & Williamson's corporate parent flatly dismissed the advertised advantages of the company's special "low nitrosamine" tobacco. He wrote to other company officials that the technology to make cigarettes "appreciably less lethal . . . does not exist." He added: "We should tone down future expectations. Firstly, it is not ethical and secondly we shall be asked to explain our failures at some point in the future."

On its website today, R.J. Reynolds claims to have evaluated its "reduced risk" product Eclipse using a rigorous four-step verification process. However, the Department of Justice recently determined that "all R.J. Reynolds did was look at all of the work it already had done to evaluate Eclipse to date, categorize it, and retroactively dub it a 'four step methodology.'" The head of the supposedly "independent" scientific effort reviewing Eclipse has received more than $1.5 million from R.J. Reynolds.

- **Marketing to Deter (or Reverse) Quitting**

Tobacco companies marketed "light" and "low tar" brands to the health-conscious smoker as viable alternatives to quitting. For example, Lorillard's brand True was advertised with the slogan, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True."

There are signals that similarly irresponsible marketing is occurring today. In 1998, Philip Morris introduced Accord as a tobacco product with less secondhand smoke. In January 2003, the Department of Justice determined that "to the extent that Philip Morris has sought to market Accord . . . there is evidence showing that it had its advertising agency assist in marketing Accord to those who want to quit or who have quit and are rejoining the cigarette market."

In 2000, the President of the U.S. Smokeless Tobacco Company wrote that a key company objective was "Promoting Dual Consumption" of smokeless tobacco among smokers frustrated by indoor air laws. Starting in 2001, the company began to market a

new product, Revel, with the slogan "a fresh new way to enjoy tobacco when you can't smoke." This marketing strategy, if successful, could sustain nicotine addiction and make it harder for smokers to quit.

- **Exploiting the Absence of Effective Regulation**

Health officials did not recognize the dangers posed by "light" and "low tar" cigarettes before it was too late. Without full access to information, some government officials even believed that substantial disease reductions were likely among "light" and "low tar" smokers. For decades, cigarette manufacturers advertised the numbers from the Federal Trade Commission's flawed machine-based testing method while simultaneously fighting effective tobacco regulation.

Today, tobacco companies are making a blizzard of health claims about new "reduced risk" products without any significant government oversight. No agency has the authority to assess the claims made by the companies before they are made, routinely review company research and documents, or set standards for what might justifiably pose a reduced risk to consumers. As a result, the unregulated promotion of "reduced risk" products threatens to undermine smoking cessation (which is proven to save lives), cause former smokers to resume their addiction, and even attract young people to tobacco products.

I. INTRODUCTION

For more than 75 years, U.S. tobacco companies have marketed tobacco products to health-concerned smokers using direct or implied health claims that are unsupported by evidence. In the 1920s, for example, American Tobacco claimed that "20,679 Physicians Say Luckies Are Less Irritating."[1] In the 1930s, R.J. Reynolds told the public that Camels "don't get your wind," and Philip Morris declared that "[o]n changing to Philip Morris, every case of irritation due to smoking cleared completely or definitely improved."[2] In the 1940s, Brown & Williamson advertised: "Head stopped up? Got the sneezes? Switch to KOOLS . . . the flavor pleases!"[3]

In the 1950s, as reports on the health effects of smoking increased, tobacco companies competed for market share by promoting the health benefits of "filtered" cigarettes.[4] Not only were the purported advantages of cigarette filters never proven, at least one was made of asbestos.[5] As one Philip Morris report later noted, "[t]he illusion of filtration is as important as the fact of filtration."[6]

In 1964, the U.S. Surgeon General's conclusion that smoking causes lung cancer created anxiety among smokers — and among tobacco companies.[7] To maintain their industry, cigarette manufacturers embraced a decades-long campaign to create doubt about the scientific evidence linking smoking to disease.[8] At the same time, they began to market new "filtered," "light," "low-tar," and "ultra low tar" cigarettes as viable health-conscious alternatives to quitting. As Brown & Williamson's advertising agency noted in 1967:

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[1]Richard Kluger, *Ashes to Ashes*, 75, 77 (1997).

[2]*Id.* at 87, 102.

[3]Institute of Medicine, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, 63 (2001).

[4]*See* National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, 200 (Oct. 2001).

[5]Richard Kluger, *supra* note 1, at 151.

[6]M.E. Johnston, *Market Potential of a Health Cigarette*, Special Report No. 248, Philip Morris (June 1966), as cited in National Cancer Institute, *supra* note 4, at 206.

[7]*See* National Cancer Institute, *supra* note 4, at 199.

[8]*See, e.g.*, Neil Francey and Simon Chapman, "*Operation Berkshire": The International Tobacco Companies' Conspiracy,* British Medical Journal, 371–74 (Aug. 5, 2000).

> Psychologically, most smokers feel trapped. They are concerned about health and addiction. Smokers care about what commercials say about them. Advertising may help to reduce anxiety and guilt.[9]

Millions of smokers switched brands. According to the most recent data, more than 85% of cigarettes sold are considered "low tar,"[10] and many of those who smoke "light" or "mild" brands believe they are reducing their risk from smoking.[11]

Yet these beliefs are misplaced. Nearly 40 years after the Surgeon General's report, "light" and "low tar" brands failed to reduce tobacco-related disease.[12] In an exhaustive review of available research, the National Cancer Institute recently found that "[t]here is no convincing evidence that changes in cigarette design between 1950 and the mid[-]1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population."[13] The National Cancer Institute concluded:

> The absence of meaningful differences in smoke exposure when different brands of cigarettes are smoked . . . and the resultant absence of meaningful differences in risk . . . make the marketing of these cigarettes as lower-delivery and lower-risk products deceptive for the smoker . . . . The reality that many smokers chose these products as an alternative to cessation — a change that would produce real reductions in disease risks — makes this deception an urgent public health issue.[14]

II. THE PURPOSE OF THIS REPORT

Today, tobacco companies are marketing a new generation of "reduced risk" products. Like "light" and "low tar" cigarettes, these new products are being sold as a potentially safer substitute for conventional tobacco products. The new "reduced risk" products include:

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[9]Oxtoby-Smith, Inc., *A Psychological Map of the Cigarette World* (Aug. 1967), prepared for the Ted Bates advertising agency and Brown & Williamson, as cited in National Cancer Institute, *supra* note 4, at 204.

[10]*See* Federal Trade Commission, *Cigarette Report for 2000*, 6 (2002).

[11]National Cancer Institute, *supra* note 4, at 193–97.

[12]*See, e.g.*, National Cancer Institute, *supra* note 4, passim.

[13]National Cancer Institute, *supra* note 4, at 146.

[14]*Id.* at 1.

- **Cigarettes with modified tobacco.** Brown & Williamson sells Advance Lights, a brand advertised with two safety features: a special filter and tobacco that is low in nitrosamines, a type of carcinogen. Vector Tobacco has marketed Omni cigarettes as lower in carcinogens and is selling Quest cigarettes as low in nicotine.

- **Substantially modified cigarettes.** Philip Morris has test-marketed Accord, a product that only burns tobacco on inhalation, and R.J. Reynolds sells Eclipse, a product that primarily heats rather than burns nicotine.

- **Smokeless tobacco products.** The U.S. Smokeless Tobacco Company (UST) has proposed marketing its conventional smokeless tobacco products as posing "significantly less risk" than cigarettes. Star Scientific is selling Ariva, a compressed tobacco product claimed to be low in nitrosamines.

An essential question about these new products is whether history is repeating itself. The tobacco industry asserts that the "reduced risk" products represent a new health "breakthrough." But this is essentially how the industry has promoted "light" and "low tar" cigarettes for decades.

At the request of Reps. Henry A. Waxman and Janice D. Schakowsky, this report compares the history of "light" and "low tar" cigarettes to available evidence about the new "reduced risk" tobacco products, including previously undisclosed internal company documents. The report finds four striking parallels between current "reduced risk" products and past experience with "light" and "low tar" cigarettes: marketing to counter health fears, deceiving of consumers, marketing to deter quitting, and exploiting the absence of effective regulation.

III. PARALLELS BETWEEN "LIGHT" AND "LOW TAR" CIGARETTES AND "REDUCED RISK" TOBACCO PRODUCTS

A. Marketing to Counter Health Fears

1. "Light" and "Low Tar" Cigarettes

Starting in the late 1960s, tobacco companies sold "light" and "low tar" brands as important scientific advances that addressed the growing anxiety smokers felt about their health. As a Brown & Williamson marketing study in 1977 noted, "Almost all smokers agree that the primary reason for the increasing acceptance of low 'tar' brands is based on the health reassurance they seem to offer."[15] Cigarette manufacturers created this reassurance through advertising.

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[15]Hawkins, McCain, and Blumenthal, Inc., *Low "Tar" Satisfaction* (July 25, 1977), Bates Numbers 775036039-6067 at 775036047 (available online at http://legacy.libary.ucsf.edu).

At times, health claims were explicit. In 1972, R.J. Reynolds marketed Vantage cigarettes as offering flavor:

> without the high 'tar' and nicotine. And since it is the high 'tar' and nicotine that many critics of cigarettes seem most opposed to, even they should have some kind words for Vantage.[16]

In 1976, Brown & Williamson launched Fact, "the low gas, low 'tar'" cigarette. Advertisements for Fact claimed that "some critics of smoking say it's just as important to cut down on some of the gases as it is to lower 'tar' and nicotine. No ordinary cigarette does both. But Fact does."[17]

More often, companies exploited the consumer's assumption that since nicotine and tar were health risks, any products offering less of these toxins had to be safer. A 1976 study prepared for Philip Morris found that 74% of smokers cited specific brands as "better for health" on the basis of "less/lower in tar and nicotine" or "less/lower in tar."[18] As the National Cancer Institute concluded in an extensive review of advertisements from the period, "The reductions in tar were marketed as a surrogate for reductions in risk."[19] When Philip Morris declared on the basis of machine-based tar and nicotine readings "Merit Science Works"[20] or Brown & Williamson stated "Latest U.S. Gov't Laboratory test confirms" that "Carlton is lowest,"[21] smokers heard a clear message about health.

As part of their campaign to promote "light" and "low tar" products, cigarette manufacturers courted health officials. For example, in 1982, Brown & Williamson proposed:

> activities designed to generate statements by public health opinion leaders which will indicate tolerance for smoking and improve the consumer's perception of ultra low 'tar' cigarettes (5 mg. or less) . . . Through political and scientific friends, B&W will attempt to elicit . . . statements sympathetic to the concept that

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[16]R.J. Reynolds, Advertisement: *Anyone Who's Old Enough to Smoke Is Old Enough to Make up His Own Mind* (June 25, 1972), Bates Number 502612446 (available online at http://legacy.libary.ucsf.edu).

[17]National Cancer Institute, *supra* note 4, 1976 advertisement reproduced at 215.

[18]The Roper Organization, Inc., *A Study of Smokers' Habits and Attitudes with Special Emphasis on Low Tar Cigarettes* (May 1976), Bates Numbers 2040543437-3734 at 2040543476 (available online at http://www.pmdocs.com).

[19]National Cancer Institute, *supra* note 4, at 70.

[20]*Id.*, 1979 advertisement reproduced at 214.

[21]*Id.*, 1985 advertisement reproduced at 224.

generally less health risk is associated with ultra low [tar] delivery cigarette consumption.[22]

These efforts were at least partially successful. In the 1970s and into the 1980s, some health officials, eager to address a growing epidemic of lung cancer, did express optimism about health benefits from "light" and "low tar" products.[23]

2. "Reduced Risk" Products

Today, the marketing of many "reduced risk" tobacco products is again premised on health reassurance through scientific progress. Brown & Williamson officials, for example, have declared Advance Lights to represent a "revolutionary breakthrough in cigarette technology."[24] The company's advertisements for the product proclaim: "All of the taste . . . Less of the toxins."[25]

Other companies are making similar claims. R.J. Reynolds has claimed "there's no cigarette like Eclipse" as "the toxicity of [Eclipse's] smoke is dramatically reduced compared to other cigarettes."[26] Vector Tobacco has marketed Omni as: "Reduced carcinogens. Premium taste."[27]

U.S. Smokeless Tobacco Company (UST), the nation's leading manufacturer of smokeless tobacco, has stated that based on extensive research, its product "involves significantly less risk of adverse health effects than cigarette smoking."[28] It even applied

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[22]Brown & Williamson, *What Are the Obstacles/Enemies of a Swing to Low "Tar" and What Action Should We Take?* Minnesota Trial Exhibit 26, 185 (1982), as cited in National Cancer Institute, *supra* note 4, at 218–19.

[23]*See, e.g.*, description of Dr. Gio Gori, National Cancer Institute, in Richard Kluger, *supra* note 1, at 428–34.

[24]Brown & Williamson, *Brown & Williamson Tobacco Tests New Advance Lights Cigarette, New Technologies Reduce the Levels of Many Toxins while Delivering Smooth Taste* (Nov. 5, 2001) (online at www.brownandwilliamson.com).

[25]*Softly Lit or Blunt, "Less Toxic" Cigarette Ads Hint at Health*, Advertising Age (Nov. 12, 2001).

[26] Eclipse Cigarettes, *The Eclipse Concept — The Eclipse Difference* (online at www.eclipse.rjrt.com/ECL/eclipse_difference.jsp).

[27]*Softly Lit or Blunt, "Less Toxic" Cigarette Ads Hint at Health, supra* note 25.

[28]Letter from Daniel C. Schwartz to the Honorable Donald S. Clark, Secretary, Federal Trade Commission (Feb. 5, 2002).

to the Federal Trade Commission for permission to make that statement in its advertising.[29]

Moreover, the companies again appear to be seeking the endorsement of the public health community for "reduced risk" products. For example, according to internal company documents, Brown & Williamson's parent company British-American Tobacco (BAT) has developed a public relations campaign aimed at developing support among public health leaders. This strategy involves "engagement and partnerships with key scientific and public health authorities [to] demonstrate that we are working effectively to develop lower risk products." BAT apparently allocated 545,000 British pounds to work on this effort.[30]

B. Deceiving Consumers

1. "Light" and "Low Tar" Cigarettes

By the late 1960s, major tobacco companies believed that the machine-based method of testing cigarettes for nicotine and tar did not measure actual intake by smokers.[31] Nonetheless, tobacco companies specifically designed cigarettes that scored low on machine-based testing without delivering substantially reduced amounts of tar and nicotine to smokers. Product features that permitted this deception included ventilation holes that diluted air on the machines but were blocked by smokers' fingers in actual use.[32]

Companies were also aware that smokers would "compensate" while smoking "light" and "low tar" brands by breathing more deeply, taking more puffs, or blocking the ventilation holes in cigarette filters.[33] In 1974, Brown & Williamson researchers had evidence indicating that "whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine

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[29] *Id.*

[30] British-American Tobacco, *Cora Plan* (2001).

[31] On May 24, 1968, research directors of major tobacco companies concluded, "We expect to be able to show that FTC Tar and Nicotine are of limited or questionable value as a measure of potential exposure to the smoker." *Minutes of the Meeting of Research Directors at the Liggett & Myers Operations Center in Durham, North Carolina on Friday, May 24, 1968*, Bates Numbers 0001609623-9624 (available online a: http://www.pmdocs.com).

[32] L. Kozlowski and R. O'Connor, *Cigarette Filter Ventilation Is a Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents*, Tobacco Control, I40–50, (Mar. 2002).

[33] National Cancer Institute, *supra* note 4, at 13–38.

requirements."[34] In 1975, Philip Morris even tested Malboro smokers and found that they "did not achieve any reduction in smoke intake by smoking a cigarette (Malboro Lights) normally considered lower in delivery."[35]

Despite this knowledge, all of the major tobacco companies persisted in marketing "light" and "low tar" cigarettes on the basis of machine-based testing. In one telling incident, Philip Morris employees in Holland published an advertisement pointing out that the tar measurements of a BAT brand dramatically misrepresented how much tar smokers actually received. The Chairman of BAT immediately sent a telex to the head of Philip Morris, stating: "I find it incomprehensible that Philip Morris would weigh so heavily the short-term commercial advantage from deprecating a competitor's brand while weighing so lightly the long-term adverse impact from an ongoing anti-smoking programme."[36] The next month, a top Philip Morris executive spoke with his counterpart at BAT, with notes of the conversation stating: "Essential Industry hang together. Holland activity was not PM company policy. They must try to prevent this happening in the future."[37]

The fact that "light" and "low-tar" cigarettes do not offer health benefits is now well understood. A comprehensive review by the National Cancer Institute found that while "[c]igarettes have changed dramatically over the last 50 years . . . the disease risks associated with smoking have not."[38] In March 2003, an Illinois judge found that Philip Morris's actions with respect to "light" and "low tar" brands were "immoral, unethical, oppressive and unscrupulous."[39]

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[34]*Notes on the Group Research & Development Conference at Duck Key, Florida (Jan. 28, 1974)*, Bates Numbers 680048892-8897 at 680048893 (available online at http://legacy.library.ucsf.edu).

[35]Memorandum from B. Goodman to L.F. Meyer, *Marlboro-Marlboro Lights Study Delivery Data* (Sept. 17, 1975), as cited in National Cancer Institute, *supra* note 4, at 71.

[36]E. Bruell, *Letter to All No 1s of Operating Companies* (Sept. 20, 1983), as cited in Jeffrey E. Harris, *Supplemental Expert Report, Iron Workers Local Union No. 17 Insurance Fund and Its Trustees, et al. v. Philip Morris Incorporated, et al.* (Nov. 6, 1998) (available at: http://www.pmdocs.com).

[37]*Telephone Conversation between H. Culman [sic] and E.A.A.B,* (Oct. 28, 1983), as cited in Jeffrey E. Harris, *Supplemental Expert Report, Iron Workers Local Union No. 17 Insurance Fund and Its Trustees, et al. v. Philip Morris Incorporated, et al.* (Nov. 6, 1998) (available online at http://www.pmdocs.com).

[38] National Cancer Institute, *supra* note 4, at 1.

[39]Judgment, *Price v. Philip Morris,* Cause No. 00-L-112 (Cir. Ct., Madison County, Ill. Mar. 21, 2003) (applying Illinois statute with element requiring that practice be immoral, unethical, oppressive, or unscrupulous).

2. "Reduced Risk" Products

Although the "reduced risk" products are in their infancy, there are warning signs that consumers are being deceived about their benefits. In November 2001, Brown & Williamson launched "Advance Lights," a new cigarette with a "Trionic" filter and tobacco cured by a process developed by Star Scientific. In the press release heralding the product's introduction, Brown & Williamson stated that the brand "has significantly less of many toxins than the leading Lights brand styles."[40] According to Star Scientific, the key advantage of "StarCured" tobacco is fewer nitrosamines:

> Scientific research has established that TSNAs are among the most powerful carcinogens in tobacco leaf and smoke. The curing process that Star has scaled up over the last several years results in significantly reduced TSNA levels.[41]

Despite Brown & Williamson's and Star's assertions that Advance Lights offer a significant advantage over conventional products, internal employee documents reveal that a senior scientist at the Brown & Williamson parent company BAT has raised serious doubts. In April 2000, the BBC radio show "Costing the Earth" looked at the issue of Star's reduced-risk tobacco.[42] After the show, BAT Senior Research Scientist Derek Irwin e-mailed managers in Research and Development:

> I disagree with just about every point made by every speaker, including our own.
>
> Our main problem appears to be the notion that "the technology exists to make cigarettes which are appreciably less lethal and that many tobacco companies appear to be looking for any excuse not to use it."
>
> <u>The technology does not exist . . . It will not exist</u>. . . Internal overstatement is one thing, externally it is even less in the Company's interests.
>
> <u>We should tone down future expectations. Firstly, it is not ethical and secondly we shall be asked to explain our failures at some point in the future</u>.[43]

None of these concerns are made available to consumers by the companies.

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[40]Brown & Williamson, *supra* note 24.

[41]Star Scientific, *What is StarCured?™* (Sept. 2002).

[42]*Tobacco Death Toll "Needlessly High,"* BBC News (Apr. 27, 2000) (online at http://news.bbc.co.uk/1/hi/sci/tech/727103.stm.)

[43]E-mail from Derek Irwin to Graham Read (May 2, 2000) (emphasis added).

Similar questions of consumer deception have been raised by the marketing of the "reduced risk" product Eclipse by R.J. Reynolds. Although R.J. Reynolds claims that Eclipse, which acts by heating tobacco, has lower toxicity compared to combusted cigarettes, these claims have been specifically refuted by a study commissioned by the Massachusetts Department of Public Health and performed by Labstat, a cigarette testing company. R.J. Reynolds's website had claimed a reduction of 80% in carcinogens in the smoke, but the Massachusetts study found that in all measurable categories of carcinogens tested, Eclipse frequently had similar or even higher levels than two other brands of cigarettes.[44]

In communications with the public, R.J. Reynolds claims to have based its assertions about the reduced risk of Eclipse on a "four-step scientific methodology" including "[c]hemical testing and analysis," "[b]iological and toxicological testing," "[h]uman testing," and "[i]ndependent scientific verification."[45] However, the Department of Justice has determined that this characterization greatly overstates the level of analysis that R.J. Reynolds undertook:

> R.J. Reynolds has represented to the public that the four step methodology was a well thought out, peer-reviewed-in-advance protocol established to overcome an "obstacle" and to fill a void created by government, scientific, medical and public health communities' failure to establish a standard for assessing potential risk reduction. On the contrary, the evidence reveals that all R.J. Reynolds did was look at all of the work it already had done to evaluate Eclipse to date, categorize it, and retroactively dub it a "four step methodology."[46]

The Department has also determined that no trained epidemiologist worked on any part of the "four step" analysis, despite R.J. Reynolds's conclusion that "[e]pidemiology is the only way ...of estimating relative risk."[47]

The fourth prong of R.J. Reynolds's four-step methodology is "independent scientific evaluation and verification." But in this area, too, the Department of Justice has raised serious questions. As late as October 2000, the expert scientific panel for Eclipse was chaired by Dr. Bernard Wagner of New York University. According to the Department of Justice, Dr. Wagner has been affiliated with R.J. Reynolds since the

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[44]Letter from Howard Koh, Commissioner, Massachusetts Department of Public Health, to the Honorable Robert Pitofsky, Chairman, Federal Trade Commission (Oct. 3, 2000).

[45]R.J. Reynolds Tobacco Company, *Eclipse and Premier* (online at http://www.rjrt.com/TI/TIpremier_eclipse.asp.)

[46]U.S. Department of Justice, *United States' Preliminary Proposed Findings of Fact, U.S. v. Philip Morris*, No. 99-CV-2496, 947 (D.D.C. filed Jan. 29, 2003).

[47]*Id.* at 951 (ellipsis in Department of Justice filing).

1980s. He served on R.J. Reynolds's Scientific Advisory Board beginning in 1985, developed R.J. Reynolds's scientific research on Premier (Eclipse's predecessor), and acted as a paid consultant to R.J. Reynolds from 1991 to 1997.[48] From 1992 to 1994 alone Wagner received over $1.5 million in fees and reimbursements from R.J. Reynolds; a minimum of $810,000 in fees was for consulting on the development of Eclipse.[49] When he left the consultant position in 1997, Wagner commented that "Eclipse represents the future and needs to be defended in the market place."[50]

C. Marketing To Deter (or Reverse) Quitting

1. "Light" and "Low Tar" Cigarettes

To sell "light" and "low tar" cigarettes, tobacco companies targeted health conscious smokers who might otherwise have quit. As the National Cancer Institute found, "these brands were targeted at those smokers who were thinking of quitting in an effort to intercept the smokers and keep them smoking cigarettes."[51] "To smoke or not to smoke," declared a Vantage ad for R.J. Reynolds in 1974:

> That is the question.
>
> With all the slings and arrows that have been aimed at smoking, you may well be wondering why you smoke at all.
>
> * * *
>
> The cigarettes of the past provided a lot of smoking pleasure but they also delivered a lot of the 'tar' and nicotine the critics have aimed at.
>
> * * *
>
> But now Vantage has entered the scene.
>
> Vantage is the cigarette that succeeds in cutting down 'tar' and nicotine without compromising flavor.
>
> * * *
>
> If you smoke, try a pack of Vantage. And if you don't, why not show this ad to someone who does.
>
> It might settle the question.[52]

Similarly, Lorillard's brand True was advertised with the slogan, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True."[53]

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[48] *Id.* at 949.

[49] *Id.* at 950.

[50] *Id.* at 949.

[51] National Cancer Institute, *supra* note 4, at 5.

[52] *Id.*, 1974 advertisement reproduced at 229.

[53] *Id.*, 1976 advertisement reproduced at 222.

Many internal industry documents show the explicit understanding of tobacco companies that "light" and "low tar" products deterred quitting. BAT noted that "[i]t is useful to consider lights more as a third alternative to quitting and cutting down — a branded hybrid of smokers' unsuccessful attempts to modify their habit on their own."[54] A study prepared for Philip Morris found, "In point of fact, smoking an ultra low tar cigarette seems to relieve some of the guilt of smoking and provide an excuse not to quit."[55]

2. "Reduced Risk" Products

There are indications that tobacco companies are again marketing new "reduced risk" products to deter quitting. Philip Morris has ostensibly sold Accord since 1998 for committed smokers.[56] But in fact, the company may also be targeting both smokers who want to quit and former smokers. According to the Department of Justice:

> [T]o the extent that Philip Morris has sought to market Accord, despite the company's statements that it will not get in the way of anyone who wants to quit smoking, there is evidence showing that it had its advertising agency assist in marketing Accord to those who want to quit or who have quit and are rejoining the cigarette market.[57]

Philip Morris may also be hinting to investors that it intends to use "reduced risk" products to increase its market share. In April 2002, financial firm Salomon Smith Barney initiated coverage of Philip Morris, a process that typically involves extensive interaction with the covered company.[58] An "Industry Note" from Salomon Smith Barney notes a 1% to 2% reduction in the "secular demand trend" for cigarettes over the preceding decade, but then suggests several reasons why this trend might not persist:

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[54]British American Tobacco, *Research & Development/Marketing Conference* (c. 1985), as cited in National Cancer Institute, *supra* note 4, at 221.

[55]Goldstein/Krall Marketing Resources, Inc., *A Qualitative Exploration of Smoker Potential for a New Entry in the Ultra Low Tar Market Category* (Jan. 1979), Bates Numbers 2040066742-6766 at 2040066754.

[56]*See* Philip Morris, *Philip Morris U.S.A. Begins Limited Retail Sales Test in Richmond on New Cigarette Smoking System* (Aug. 17, 1998) (online at http://www.philipmorrisusa.com/pressroom/content/press release/articles/pr_August_17 1998 PMUBLRST.asp.)

[57]U.S. Department of Justice, *supra* note 46, at 1112 (emphasis added).

[58]Salomon Smith Barney Industry Note, *Tobacco: Initiating Coverage of the Tobacco Industry* (Apr. 29, 2002).

> Because most of the so-called news is already priced in, we do not expect a major shift in the secular demand trend for cigarette consumption. If anything, we might see the secular demand trend increase, as technology will play an increasingly important role for this industry in the future. Often it is fun to speculate about what this industry will look like in five years. If Philip Morris or the other manufacturers [are] successful in developing, marketing, and selling a reduced-risk cigarette, we may start to see consumption closer to flat and maybe even increase slightly. Keep in mind that for the approximate 50 million adult smokers in the United States, we believe smoking is something that, for the most part, they truly enjoy. Therefore, if there is an opportunity to develop a reduced-risk cigarette that, of course, burns, and tastes very similar to conventional cigarettes, this could possibly prevent people from quitting and may encourage some people to start smoking . . . . As the leader in so many things, Philip Morris has been working on a reduced-risk product and may be ready to introduce something this year or next year.[59]

Other companies explicitly market their products as an alternative to quitting. For example, R. J. Reynolds's advertising for Eclipse declares: "the best choice for smokers who worry about their health is to quit. The next best choice is Eclipse."[60]

Although UST says publicly that it wants to promote smokeless tobacco as a safer alternative to cigarettes, internal documents suggest that it is actually pursuing a "dual use" strategy. In 2000, UST President Murray S. Kessler presented the company's "Strategic Plan." The first slide states: "Solid Fundamentals . . . Smoking Restrictions Fuel Category Growth." The second slide elaborates: "Solid Fundamentals . . . Promoting Dual Consumption." The slide indicates that "dual usage" rose from 27% in 1998 to 33% in 1999.[61]

UST's support for "dual usage" became explicit in August 2001 with the launch of Revel, a small pouch containing smokeless tobacco. UST markets Revel as "a fresh new way to enjoy tobacco when you can't smoke." One advertisement states, "If you are a smoker, here are two words that will transform the way you enjoy tobacco: Anytime. Anywhere." In describing the campaign, UST President Kessler has said, "Whether restricted on an airplane, in a meeting, on the factory floor, or in a shopping mall, we believe that Revel is the answer adult smokers have been seeking."[62]

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[59] *Id.* at 2 (emphasis added).

[60] R.J. Reynolds Tobacco Company, *Making the Switch* (online at http://www.R.J. Reynoldst.com/TI/TIpremier_eclipse.asp).

[61] Murray S. Kessler, *United States Tobacco Co. Strategic Plan* (2000) (emphasis added).

[62] *Smoke Screens: Alternatives to Traditional Cigarettes May Have Retailers Reassessing Their Display Priorities*, Tobacco Retailer (Dec. 2001) (online at http://www.retailmerchandising.net/tobacco/2001/0112/0112smk.asp).

The public health implications of encouraging dual use are profound. Dual use can offer smokers a way to sustain addiction to nicotine, diminishing the incentive to quit. A recent study of smokeless tobacco use among teenage boys in Sweden found that 71% of smokeless tobacco users also smoke cigarettes, and dual users smoke more than those who smoke cigarettes alone.[63]

Star Tobacco's smokeless product Ariva is also marketed for "when you can't smoke."[64]

D. Exploiting the Absence of Effective Regulation

Health officials did not recognize the dangers posed by "light" and "low tar" cigarettes before it was too late. Without full access to information, some government officials even believed that substantial disease reductions were likely among "light" and "low tar" smokers.[65] For decades, cigarette manufacturers used numbers from the FTC's machine-based testing method in advertisements, with Brown & Williamson promoting Carlton's numbers on the basis of the "Latest U.S. Gov't Laboratory test."[66]

The absence of effective regulation means that even now, after scientific consensus has been reached that "light" and "low tar" cigarettes are a fraud, these brands still dominate the market for cigarettes. While several countries have moved to ban the use of these misleading descriptors,[67] not a single tobacco company has voluntarily dropped the "light" or "low tar" label to communicate honestly with consumers. To the contrary, Philip Morris and other companies have fought public health efforts to bar these descriptors on the grounds of trademark rights.[68]

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[63]M. Rosaria Galanti, Seppo Wickholm, and Hans Gilljam, *Between Harm and Dangers: Oral Snuff Use, Cigarette Smoking and Problem Behaviours in a Survey of Swedish Male Adolescents,* European Journal of Public Health, 340–45 (2001).

[64]"When You Can't Smoke" is featured prominently on Ariva packages.

[65]*See* Judgment, *Price v. Philip Morris*, *supra* note 39.

[66]National Cancer Institute, *supra* note 4, 1985 advertisement reproduced at 224.

[67]*See, e.g., Canada to Ban "Light" Labels on Cigarettes,* Boston Globe (Aug. 14, 2001).

[68]For example, Philip Morris has recently argued that Canada's attempt to ban such descriptors as "light" and "mild" violates its trademark rights under the North American Free Trade Agreement and World Trade Organization Technical Barriers to Trade Agreement. Robert Weissman, *Philip Morris' Trade Card*, Multinational Monitor (Apr. 1, 2002).

Today, the lack of effective regulation has resulted in the proliferation of bold and sometimes contradictory claims for "reduced risk" products. Some companies, such as Brown & Williamson, insist that modified tobacco can be made into cigarettes that offer significant reductions in exposure and likely risk. Other companies, including UST, say that all combusted products pose an unacceptable risk, but oral products (like smokeless tobacco) do not. No agency has the authority to assess the claims made by the companies before they are made, routinely review company research and documents, or set standards for what might justifiably pose a reduced risk to consumers. Absent effective regulation, it may be impossible to determine whether the new products have helped or harmed public health for decades.

IV. CONCLUSION

The disastrous history of "light" and "low tar" cigarettes may be repeating itself in a new generation of "reduced risk" products. As in the past, tobacco companies are making claims about the health benefits of their products; there is evidence of deceptive practices by the companies; and there is reason to believe that companies are marketing their products to quitters and former smokers.

Absent effective regulation, it will be difficult if not impossible for consumers to sort through a blizzard of health claims. As a result, unregulated marketing of "reduced risk" tobacco products could undermine smoking cessation (which is proven to save lives), cause former smokers to resume their addiction, and even attract young people to tobacco products.

Mr. WAXMAN. What this report underscores is the need for comprehensive FDA regulation of any reduced-risk claim. If health claims are allowed for new reduced-risk products in the absence of effective regulation recording another public health disaster, these products can be deadly. They can deter cessation, cause former smokers to resume their addiction, and even attract young people to tobacco products. Let me put this as bluntly as I can. The tobacco industry cannot be trusted to regulate itself. These simple but indisputable facts should shape today's hearing. We cannot sit by while a wild west of companies hawking their allegedly new and improved products threatens the health of millions. Nor should we, as Members of Congress, try to figure out for ourselves which claims should be made by which companies and under what conditions.

Today's hearing will be most useful if we can work together to understand how comprehensive FDA regulation of tobacco products can be structured to best protect the public health. I believe the Institute of Medicine has set out a workable approach to potential reduced-risk products, and I am pleased that the Institute is represented here today. I am also pleased that the National Cancer Institute is testifying about the state of science, and that we have been joined by distinguished experts from across the country.

And I appreciate that Philip Morris CEO, Michael Szymanczyck, took the initiative to speak with me yesterday about some of these issues and is here today as well. I look forward to the testimony of all the witnesses and to working with my colleagues. This is not a partisan issue. There should be no Democrat or Republican views. We want what is best to protect the health of the American people and not go down that road again that we did decades ago, where the American people have been deceived into smoking a product that has caused so much death and disease.

Chairman TOM DAVIS. Any other opening statements? If not, we are going to move to our first panel of witnesses.

We have Scott Leischow, who is with the National Cancer Institute; Dr. Robert Wallace, from the Institute of Medicine who is not here. I understand he is still at the hearing over at Energy and Commerce. Do we have someone else from—come forward. Do you have the testimony to give? You can take questions. Why don't you identify yourself for the record.

Dr. STRATTON. My name is Kathleen Stratton.

Chairman TOM DAVIS. Dr. Stratton, thank you very much for being with us.

And, Mr. Lee Peeler from the Federal Trade Commission.

It is the policy of the committee that all witnesses be sworn before you testify. Please raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. In order to allow time for questions, your total statements are in the record; if you could try to keep it to 5 minutes. There will be a light on in front of you; when it turns orange, 4 minutes are up, and red at 5. And that will kind of be a guideline. Once it turns red, if you could move to sum up. Again, your total statements are in the record. Members and staff have read it and prepared questions based on that. So, we will give you 5 minutes to highlight.

I will start, Dr. Leischow, if you would move to your right.

STATEMENTS OF SCOTT LEISCHOW, CHIEF, TOBACCO CONTROL RESEARCH BRANCH, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH; LEE PEELER, DEPUTY DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; ROBERT WALLACE, CHAIRMAN OF THE COMMITTEE TO ASSESS THE SCIENCE BASE FOR TOBACCO HARM REDUCTION, INSTITUTE OF MEDICINE/NATIONAL ACADEMY OF SCIENCES; AND KATHLEEN STRATTON, INSTITUTE OF MEDICINE

Dr. LEISCHOW. Thank you.

Good afternoon. I am Dr. Scott Leischow, chief of the Tobacco Control Research Branch at the National Cancer Institute of the National Institutes of Health. Thank you, Representative Davis and distinguished members of the committee for the opportunity to be with you today to discuss the issue of tobacco harm reduction. Let me begin by emphasizing three fundamental facts: No. 1, all tobacco products are hazardous. No. 2, there is no safe level of tobacco use. And, No. 3, the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent its use and to help users quit.

In NCI's view, a product would be harm reducing if it actually reduces disease and death for both individuals and the population as a whole. This is an important distinction, because even if a tobacco product is shown to reduce disease risk in an individual, the availability of products that claim to reduce harm may have harmful consequences on the population. For example, smokers may see reduced harm products as a viable alternative to quitting, and put off making a quit attempt. Similarly, there is a risk that smokers who have quit will return to using tobacco because they think that these products may make it safe to do so.

The National Institutes of Health has funded many studies on the health effects of tobacco over the last 50 years, and currently funds a small number of investigator-initiated grants on tobacco product health effects. We have also added questions about tobacco product use and perceptions of tobacco products' health risk to NCI's Health Information National Trends Survey, which is in the record. Additionally, the Centers for Disease Control and Prevention laboratory is analyzing the chemistry of some newer tobacco products.

The tobacco industry also funds research on potential harm-reducing tobacco products. However, we know very little about their studies, and it is uncertain how many have been made available for objective scientific scrutiny.

A broad-based research effort involving numerous scientific disciplines is needed to answer critical questions about potential tobacco harm-reduction products. The Institute of Medicine report entitled Clearing the Smoke, and the conclusions of a 2001 reducing tobacco harm conference that were published by Dorothy Hatsukami and others recommend key research questions to be addressed.

We also need to be mindful of the lessons we learned from our experience with so-called low tar and low nicotine cigarettes. When

the causal relationship between cigarette smoking and lung cancer was first established in the 1950's, the tobacco industry began altering its products by first adding filters, and then in the 1960's began marketing so-called low tar and low nicotine cigarettes. However, because an extensive objective testing program of those products was not put into place, it took more than 30 years to conclude that smokers who switched to light cigarettes did not reduce their lung cancer risk. Research summarized in a recent NCI monograph shows that many smokers switched to lower yield cigarettes out of concern for their health in the belief that these cigarettes are less risky or are a step toward quitting. In fact, the monograph concluded that marketing and promotion of reduced yield cigarettes may delay genuine attempts to quit. The light cigarette experience taught us valuable lessons that we should not repeat in the future.

There are 46 million smokers in the United States, which represents just over 23 percent of the population. The prevalence of smoking has decreased considerably since the early 1960's, and during the 1990's, prevalence dropped approximately 1 percent per year. Today we have much to offer people who smoke and want to quit, including effective behavioral treatments and medications. Smoking cessation medications must undergo extensive testing for safety and effectiveness and be scrutinized through objective review prior to the release to the public. When used as directed, about 25 percent of those using such products are able to quit smoking. There is no clinical evidence that long-term use of nicotine replacement medications cause harm.

Unlike nicotine replacement products for smoking cessation, tobacco products do not undergo rigorous objective scrutiny either for their product constituents or tobacco industry claims. Tobacco contains many disease-causing substances, including tobacco specific nitrosamines, formaldehyde, arsenic, and benzopyrene. And restrictions on marketing are few. Thus, a new tobacco product might sit on a store shelf next to an FDA-approved nicotine replacement product which is marketed for smoking cessation. It is possible that the similarity of these products will be confusing to the public and imply that a tobacco product is safe and FDA approved when it is not.

The NCI developed a position in 1991 where we recommended that the public avoid and discontinue the use of all tobacco products, including smokeless tobacco. Additionally, the NCI stated that nitrosamines found in tobacco products are not safe at any level. Because the accumulated scientific evidence does not support a change, we continue to endorse those statements. Furthermore, we do not have enough evidence to conclude that smokeless tobacco is a less hazardous alternative to cigarettes. A framework needs to be developed and implemented for the independent and objective scientific collection, review, and interpretation of data on tobacco products purported to reduce harm. This approach is vitally important so that data are optimally synthesized and disseminated to scientists, health providers, policymakers, and the public.

This will ensure that the public has accurate, unbiased information on risk and harm prior to being faced with deciding whether

to use one of these tobacco products, an FDA approved medication or no product at all.

The evaluation of new tobacco products purported to reduce harm needs to be part of a broad tobacco control and prevention initiative. We know that smokeless tobacco use causes disease, and we do not know whether there may be any potential benefit in promoting to current smokers the use of any of these products purported to reduce harm. The only proven way to reduce the death and disease caused by tobacco use is to prevent youth from starting to smoke and to help smokers quit. These are and must remain our highest priorities.

Thank you again for this opportunity to provide comments regarding this very significant public health issue. And I am happy to answer any questions you may have.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Leischow follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

The Science of Reduced Risk Tobacco Products

Statement of
Scott J. Leischow, Ph.D.
Chief
Tobacco Control Research Branch
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

Good afternoon. I am Dr. Scott Leischow, Chief of the Tobacco Control Research Branch at the National Cancer Institute (NCI), of the National Institutes of Health. Thank you, Representative Davis and distinguished Members of the Committee for the opportunity to be with you today to discuss the issue of tobacco "harm reduction." Let me begin by emphasizing three fundamental facts: (1) all tobacco products are hazardous, (2) there is no safe level of tobacco use, and (3) the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent its use and to help users quit.

In NCI's view, a product would be "harm reducing" if it actually reduces disease and death for both individuals and the population as a whole. This is an important distinction because even if a tobacco product is shown to reduce disease risk in an individual, the availability of products that claim reduced harm may have harmful consequences on the population. For example, smokers may see reduced harm products as a viable alternative to quitting. Similarly, there is the risk that smokers who have quit will return to using tobacco because they think that these products make it safe to do so.

The National Institutes of Health has funded many studies on the health effects of tobacco over the past 50 years, and is currently funding a small number of

investigator-initiated grants on tobacco product health effects. We have also added questions about tobacco product use and perceptions of tobacco products' health risk to NCI's Health Information National Trends Survey. Additionally, the Centers for Disease Control and Prevention laboratory is analyzing the chemistry of some newer tobacco products. The tobacco industry also funds research on "harm reducing" tobacco products. However, we know very little about their studies, and it is uncertain how many have been made available for objective scientific scrutiny. A broad-based research effort involving numerous scientific disciplines is needed to answer critical questions about potential tobacco harm reduction products. The IOM Report entitled "Clearing the Smoke," and the conclusions of the 2001 Reducing Tobacco Harm conference that were published by Hatsukami and others, recommend key research questions to be addressed.

We also need to be mindful of the lessons we learned from our experience with so-called "low tar and low nicotine" cigarettes. When the causal relationship between cigarette smoking and lung cancer was first established in the 1950s, the tobacco industry began altering its products by first adding filters to cigarettes, and in the 1960s began marketing so-called "low tar and low nicotine" cigarettes. However, because an extensive objective testing program of those products was not put into place, it took more than 20 years to conclude

that smokers who switched to light cigarettes did not reduce their lung cancer risk. Research summarized in a recent NCI Monograph[1] shows that many smokers switch to lower yield cigarettes out of concern for their health in the belief that these cigarettes are less risky or are a step toward quitting. In fact, the Monograph concluded that marketing and promotion of reduced yield cigarettes may delay genuine attempts to quit. The light cigarette experience taught us valuable lessons that we should not repeat in the future.

There are 46 million adult smokers in the U.S., which represents just over 23% of the population. The prevalence of smoking has decreased considerably since the early 1960s, and during the 1990s prevalence dropped approximately 1% per year. Today, we have much to offer people who smoke and want to quit, including effective behavioral treatments and medications. Smoking cessation medications must undergo extensive testing for safety and effectiveness, and be scrutinized through objective review, prior to their release to the public. When used as directed, about 25% of those using such products are able to quit smoking. There is no clinical evidence that long-term use of nicotine replacement medications causes harm.

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[1] David Burns, M.D. and Neal L. Benowitz, M.D., *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine,* Smoking and Tobacco Control Monograph Series vol. 13, 2001.

Unlike nicotine replacement products for smoking cessation, tobacco products do not undergo rigorous objective scrutiny either for their product constituents or tobacco industry claims. Tobacco contains many disease-causing substances, including tobacco-specific nitrosamines, formaldehyde, arsenic, and benzopyrene, and restrictions on marketing are few. Thus, a new tobacco product - marketed for harm reduction might sit on a store's shelf next to an FDA-approved nicotine replacement product which is marketed for smoking cessation. It is possible that the similarity of these products will be confusing to the public, and imply that a tobacco product is safe and FDA-approved when it is not.

The NCI developed a position in 1991 where we recommended that the public avoid and discontinue the use of all tobacco products, including smokeless tobacco. Additionally, the NCI stated that nitrosamines, found in tobacco products, are not safe at any level. Because the accumulated scientific evidence does not support a change, we continue to endorse these statements. Furthermore, we do not have enough evidence to conclude that smokeless tobacco is a less hazardous alternative to cigarettes.

A framework needs to be developed and implemented for the independent

and objective scientific collection, review and interpretation of data on tobacco products purported to reduce harm. This approach is vitally important so that data are optimally synthesized and disseminated to scientists, health providers, policymakers, and the public. This will ensure that the public has accurate, unbiased information on risk and harm prior to being faced with deciding whether to use one of these tobacco products, an FDA-approved medication, or no product at all.

The evaluation of new tobacco products purported to reduce harm needs to be part of a broad tobacco control and prevention initiative. We know that smokeless tobacco use causes disease. We do not know whether there may be any potential benefit in promoting to current smokers the use of any products purported to reduce harm. The only proven way to reduce the death and disease caused by tobacco use is to prevent youth from starting to smoke, and to help current smokers to quit. These are and must remain our highest priorities.

Thank you again for this opportunity to provide comments regarding this significant public health issue. I am happy to answer any questions you may have.

Chairman TOM DAVIS. Mr. Peeler.

Mr. PEELER. Thank you for the opportunity to appear here today and discuss the FTC's role in the potential advertising in reduced-risk tobacco products. My prepared statement represents the views of the Commission, and my oral remarks and responses to questions today represent my own views and do not necessarily represent the views of the Commission.

The FTC's mission is to prevent unfair methods of competition and unfair or deceptive acts or practices in the marketplace. The Commission does this by ensuring that advertising and marketing claims are truthful and not misleading. Our jurisdiction over the advertising and marketing claims includes jurisdiction over claims for cigarettes, smokeless tobacco, and other tobacco products.

The FTC's law enforcement activities involving tobacco advertising and promotion date back to the 1930's. Congress has also given the Commission administrative responsibilities for the health warnings required on the cigarette packaging and advertising under the Cigarette Act, and both administrative and enforcement responsibilities for the health warnings required on smokeless tobacco packaging and advertising under the Smokeless Tobacco Act.

The Commission does not prescreen advertising or marketing claims for tobacco or any other product. Instead, the agency addresses deception through post-market law enforcement action.

The marketing of potential reduced-risk tobacco products is an important question. Despite the government and public health communities' efforts, millions of Americans smoke today and are addicted to nicotine. Many of these smokers will ultimately die of smoking-related illnesses if they do not change their behavior. In an ideal world, we would wish that all these people would choose to quit smoking and would be able to do so once they tried. The real world is quite different, however. If truthful and substantiated marketing claims that a product will significantly reduce health risk associated with smoking while satisfying the addicted smoker's craving for nicotine could provide a substantial benefit for those consumers who cannot or will not quit. Conversely, if those claims were untruthful, unsubstantiated, or misrepresented the extent of the benefit, they would harm consumers. For those reasons, we review the advertising for potential reduced-risk tobacco products on a case-by-case basis to try to ensure that the information consumers receive about reduced-risk products is accurate and substantiated.

First, we ask what messages consumers take away from the advertising in question. The next issue is whether those claims are truthful, including whether they are supported by the necessary substantiation. The Commission typically requires that health claims be supported by competent and reliable scientific evidence. In determining whether harm reduction claims are substantiated, the Commission would turn to experts both inside and outside the government science-based agencies for assistance in evaluating scientific evidence.

In addition to discussing the role that we play regarding tobacco advertising, the Committee has also requested that we address the status of the U.S. Tobacco Petition, whether we have examined statements by other tobacco products claiming to be less risky, and

what action the FTC intends to take on these issues. As indicated in our written statement, the U.S. Tobacco Petition was withdrawn in April 2002 prior to the Commission's ruling on it. UST has recently submitted additional information and requested the FTC consider holding a public forum to discuss the issues in the petition.

The FTC does monitor ongoing tobacco advertising, and has taken action to challenge claims it believes to be deceptive or unsubstantiated, including our 1999 settlement with RJ Reynolds resolving alleged unsubstantiated implied claims that their no additive cigarettes were less hazardous than other comparable cigarettes. I would caution, however, that the Commission investigations are nonpublic, and the fact that the Commission has not publicly challenged any particular claim does not mean that the Commission has approved it. We intend to continue to monitor tobacco advertising and conduct investigations where appropriate, in addition, in consultation with scientific agencies, we will consider UST's more recent request for a public forum to discuss reduced-risk tobacco products.

Let me close by mentioning that in our view the discussion of potential harm reduction tobacco products should also encompass the question of whether so-called nicotine replacement products, which are currently marketed only for smoking cessation purposes, have a larger role to play in the harm reduction arena. These products, which contain nicotine and no tobacco should certainly be further evaluated for use by consumers who are addicted to nicotine.

Thank you for the opportunity to discuss the Commission's role in this important area.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Peeler follows:]

Prepared Statement of

The Federal Trade Commission

Before the

Committee on Government Reform

United States House of Representatives

Washington, D.C.

June 3, 2003

Mr. Chairman and members of the Committee, I am Lee Peeler, Deputy Director of the Federal Trade Commission's ("Commission" or "FTC") Bureau of Consumer Protection. The Commission is pleased to have this opportunity to provide information concerning the potential advertising of reduced risk tobacco products.[1] This statement discusses the Commission's mission, our activities in the tobacco area, and then addresses the process the Commission would use in examining the advertising of these products.

FTC Jurisdiction Over Tobacco Advertising and Marketing

The FTC's mission is to prevent unfair competition and unfair or deceptive acts or practices in the marketplace. The Commission regulates national advertising, including the advertising and promotion of cigarettes, smokeless tobacco, and other tobacco products, pursuant to Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which prohibits "unfair or deceptive acts or practices in or affecting commerce." The Commission's activities promote informed consumer choice.

[1] The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

The FTC's law enforcement activities involving tobacco advertising and promotion date back to the 1930s.[2] In 1962, the FTC's request for technical guidance from the U.S. Public Health Service was among the factors that led the then-Surgeon General of the United States to establish an advisory panel to undertake a comprehensive analysis of the data on smoking and health. The work of the advisory panel, in turn, led to the historic 1964 Report of the Surgeon General finding that cigarette smoking presented significant health risks. In that same year, the Commission issued a regulation requiring tobacco companies to include health warnings in cigarette advertising and on packages.[3] The FTC's regulation was superseded in 1965, before it went into effect, by the Federal Cigarette Labeling and Advertising Act ("Cigarette Act"),[4] which required such warnings on cigarette packages.

In 1972, the Commission once again addressed the issue of health warnings in cigarette advertising. Pursuant to its Section 5 authority, the FTC issued consent orders mandating for the first time that the major cigarette manufacturers place health warnings in cigarette advertisements.[5]

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[2] *See, e.g., Julep Tobacco Co.*, 27 F.T.C. 1637 (1938) (stipulation prohibiting claims that Julep cigarettes help counteract throat irritations due to heavy smoking and never make the throat dry or parched).

[3] *See* Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8354 (1964).

[4] Pub. L. No. 89-92, 79 Stat. 282 (1965), as amended by Pub. L. No. 98-474, 98 Stat. 2204 (1984), and by Pub. L. No. 99-92, § 11, 99 Stat. 393, 402-04 (1985), current version at 15 U.S.C. § 1331 (1994).

[5] *See Lorillard et al.*, 80 F.T.C. 455, 460-65 (1972) (consent orders). Under the orders entered into with six tobacco manufacturers, the companies were required to disclose the

Surgeon General's warning in identified forms of advertising. The consent orders were modified in 1981, when the Commission sought civil penalties in federal district court against each of the cigarette companies for failure to comply with the 1972 orders. *See United States v. Lorillard*, No. 76-Civ. 814 (JMC) (S.D.N.Y. July 13, 1981).

In 1982, the Bureau of Consumer Protection notified the House Committee on Energy and Commerce that the staff supported a new system of rotational health warnings. Letter from Timothy J. Muris, Director, Bureau of Consumer Protection, *Federal Trade Commission*, to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, *U.S. House of Representatives* (Sept. 1, 1982). In May 1984, the Commission sent letters to Congress endorsing the concept of federal legislation to require a system of rotational health warnings that would appear in cigarette advertisements and on cigarette packages. Shortly thereafter, Congress amended the Cigarette Act to require rotational warnings for both advertising and package labeling.

Today, the Commission administers the Cigarette Act, and administers and enforces the Comprehensive Smokeless Tobacco Health Education Act ("Smokeless Tobacco Act").[6] The Cigarette Act instructs the Commission to take certain steps to implement the mandated Surgeon General's health warnings.[7] The Smokeless Tobacco Act directs the FTC to promulgate regulations governing the health warnings on packaging and advertising for smokeless tobacco products. The Commission's regulations specify the placement and rotation of the warnings, and require companies to submit plans to the Commission setting forth their rotation schedules.[8] Finally, the FTC enforces the ban in the Smokeless Tobacco Act on broadcasting smokeless tobacco advertisements on radio and television.

The Commission also publishes periodic reports on advertising and promotion activities in the cigarette and smokeless tobacco industries.[9] Those reports provide information on sales and on expenditures for various categories of marketing expenditures. The Commission issued

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[6] 15 U.S.C. §§ 4401-4408.

[7] Although the Commission administers the Cigarette Act, the Department of Justice enforces it.

[8] 16 C.F.R. § 307.

[9] In addition, the Commission issued a report on cigar advertising and promotion in 1999.

its first report on the cigarette industry in 1967 and on the smokeless tobacco industry in 1987.

In addition to its administrative and law enforcement responsibilities under the Cigarette Act and the Smokeless Tobacco Act, the Commission also has authority under Section 5 of the FTC Act to prevent unfair or deceptive acts or practices in connection with the marketing and sale of tobacco products. Pursuant to that authority, the Commission has taken a number of law enforcement actions against unfair or deceptive tobacco advertising and promotional practices. For example, in 1983, the Commission sued the Brown &Williamson Tobacco Corporation over ads that continued to describe Barclay as a 1 mg. of tar brand, even though the Commission had revoked Barclay's 1 mg. rating because the cigarette's unusual design prevented the cigarette test method from measuring Barclay's yields on a basis comparable to other cigarettes.[10] Moreover, in 1997, the Commission issued a complaint against the R.J. Reynolds Tobacco Co. alleging that the company's Joe Camel advertising campaign caused or was likely to cause many young people to begin or continue to smoke, thereby exposing them to significant health risks.[11] In 1999 and 2000, the Commission entered into consent agreements with several cigarette manufacturers, resolving charges that their advertisements implied that their "no additive" cigarettes were safer than otherwise comparable

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[10] *F.T.C. v. Brown & Williamson Tobacco Corp.*, 580 F. Supp. 981 (D.D.C. 1983), *aff'd in part, remanded in part*, 778 F.2d 35 (D.C. Cir. 1985).

[11] *R.J. Reynolds Tobacco Co.*, 127 F.T.C. 49 (1999). The Commission's complaint was issued on May 28, 1997. On January 26, 1999, the Commission dismissed the complaint without prejudice because the relief sought had been achieved through, *inter alia*, the master settlement between the major tobacco companies and the attorneys general for 46 states.

cigarettes because they did not contain additives.[12] In 2000, the Commission also entered into a consent agreement with a company claiming reduced health risks for its herbal cigarettes.[13]

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[12] *Santa Fe Natural Tobacco Co.*, Docket No. C-3952 (2000) (consent); *Alternative Cigarettes, Inc.*, Docket No. C-3956 (2000) (consent); *R.J. Reynolds Tobacco Co.*, Docket No. C-3892 (1999) (consent).

[13] *Alternative Cigarettes, Inc.*, Docket No. C-3956 (June 14, 2000) (consent). *See also Alan V. Phan*, 116 F.T.C. 162 (1993) (consent order settling allegations that advertisements misrepresented the health risks of smoking certain non-tobacco cigarettes).

Testing for the tar and nicotine yields of cigarettes is also conducted by the tobacco industry under a methodology adopted by the Commission in 1967. For the past several years, the FTC has also actively sought the views of the Federal government's public health agencies about what changes should be made in that methodology.[14] The agency has also recommended to Congress that authority for cigarette testing be given to one of the government's science-based public health agencies[15] and we renew that recommendation here.

"Reduced Risk" Tobacco Claims

As with other products, the Commission's primary role for tobacco products is to ensure that products are marketed in a manner that is truthful, not misleading, and adequately substantiated. The Commission does not pre-screen advertising claims for tobacco or any other product. Instead, the agency addresses deception in the marketing of tobacco largely through post-market law enforcement actions targeted against specific false or misleading claims or unfair practices, just as it does for other products.

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[14] Letter from Donald S. Clark, Secretary, *Federal Trade Commission* to the Honorable Donna E. Shalala, Secretary, *Department of Health and Human Services* (Nov. 19, 1998).

[15] *Federal Trade Commission Report to Congress For 1998 Pursuant to the Federal Cigarette Labeling and Advertising Act* 6 (2000) ("the Commission strongly recommends that Congress give cigarette testing authority to one of the Federal government's science-based, public health agencies"); *Federal Trade Commission Report to Congress For 1997 Pursuant to the Federal Cigarette Labeling and Advertising Act* 5-6 (1999).

Despite coordinated efforts of the government and the public health community, tobacco use in the United States continues to cause substantial health risks. Products that could significantly reduce those risks could provide a substantial health benefit. For example, products that satisfy a smoker's craving for nicotine with substantially fewer risks to health than cigarettes would have the potential to benefit consumers. At the same time, consumers may be injured if advertisers make harm reduction claims that turn out to be untrue or that exaggerate the benefits or safety of their products.

There are currently a variety of products being developed or already in test markets that are intended to reduce the risks associated with smoking. These products include Eclipse (an R. J. Reynolds Tobacco Company product that heats, rather than burns, tobacco) and Accord (a Philip Morris USA system in which special cigarettes are smoked in an electronic lighter); cigarettes and other tobacco products with reduced levels of nitrosamines (one category of constituents in tobacco that have been classified as known carcinogens), such as that developed by Star Scientific, Inc.; and Omni, which Vector Tobacco, Inc. has marketed as "the first reduced carcinogen cigarette."

There are also products termed "nicotine replacement therapies" ("NRT") that the Food and Drug Administration currently allows to be marketed for smoking cessation purposes: nicotine gums, transdermal patches, lozenges, inhalers, and nasal sprays. These nicotine delivery devices have been studied and approved only for short-term use to help smokers quit smoking, rather than for long-term "harm reduction" use by people who are unable or unwilling to quit smoking.

Finally, in February 2002, the United States Smokeless Tobacco Company ("USST")

petitioned the Commission for an advisory opinion regarding the acceptability of communicating in advertising a harm reduction claim for smokeless tobacco. USST withdrew the petition in August 2002, stating that it would provide the Commission with information from two upcoming scientific conferences that would be addressing issues relevant to the petition. On May 9, 2003, USST provided this additional information to the Commission, and asked that the Commission place this new information on the public record and hold a "public forum" to discuss these issues.

In considering advertising or other marketing claims by potential reduced risk tobacco products, the Commission would consider whether harm reduction claims may be deceptive using the same legal framework that it uses for all consumer products under Section 5 of the FTC Act: whether the advertising conveys a message that is likely to mislead reasonable consumers to their detriment, including claims for which the advertiser did not have adequate substantiation. The Commission's experience suggests that harm reduction claims are likely to raise difficult questions of advertising interpretation, as well as complex scientific and public health issues.

In examining a harm reduction claim, the first question that the Commission would address is what messages consumers take away from the advertising in question. Taking into account the full context of the advertising in which the claim appears,[16] the Commission would seek to identify the range of messages – both express and implied – that consumers would take

[16] The messages consumers take away from a particular statement in an advertisement depend on the overall context in which that statement appears. Accordingly, the Commission ordinarily evaluates each advertisement in its entirety. It is difficult to determine what messages consumers take away from a generic statement about a particular class of products without placing that statement in the context of an actual advertisement.

from the advertisement. These would include: (1) whether claims about a reduction in carcinogens and toxins in the product conveys risk reduction messages; and (2) whether consumers might take away from a harm reduction representation the message that a product containing known carcinogens was not just safer than cigarettes, but that it poses no risk or only a minimal risk.

Once the Commission has determined what messages consumers take away from a particular ad, the next issue is whether those claims are truthful and substantiated. The FTC Act requires that objective claims about products and services be substantiated before the ad is disseminated. When the advertisement does not claim to have a specific level of substantiation supporting its claims, the Commission determines what constitutes a reasonable basis for those claims by analyzing the so-called "Pfizer factors": the type of claim; the benefits if the claim is true; the consequences if the claim is false; the ease and cost of developing substantiation for the claim; the type of product; and the level of substantiation experts in the field would agree is reasonable. *Pfizer, Inc.*, 81 F.T.C. 23 (1972). In the context of safety claims, the FTC has typically required a substantiation standard of "competent and reliable scientific evidence."

Analyzing the evidence whether any particular tobacco product is safer than traditional cigarettes, or whether a reduction in exposure to known carcinogens is associated with reduced health risks, requires expertise in biology, chemistry, toxicology, and epidemiology, among other fields. Moreover, the scientific issues raised by purported reduced risk products are often not only extremely complex, but may take years to develop.[17] The Commission brings a unique

[17] The history of low tar cigarettes provides an example. One recent survey of current evidence concludes that although low tar cigarettes were initially marketed as safer alternatives

market-based expertise to its scrutiny of consumer protection matters and our work often requires review and analysis of scientific literature. Because the Commission is an agency of lawyers and economists, however, and not a science-based agency, we rely on assistance from other experts in evaluating scientific evidence.[18] Just as the Commission has requested the assistance of the Department of Health and Human Services in connection with the test method that produces cigarette tar and nicotine ratings, the Commission would require similar assistance in evaluating the substantiation for advertising claims made for reduced-risk tobacco products.

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than regular cigarettes, recent evidence suggests that they may convey no such benefit. *See* National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13, at 9 (2001) ("When all of the epidemiological evidence is considered in the context of what is currently known about cigarette design and compensation, it does not support the conclusion that a reduction in disease risks has occurred in the population of smokers due to the design changes that have occurred in cigarettes over the last 50 years.").

[18] Tobacco is not the only category of products for which the Commission turns to other federal entities that possess specialized scientific expertise. For example, the FTC works closely with the Food and Drug Administration in the dietary supplement field, and with the Environmental Protection Agency in the areas of energy conservation, gasoline marketing, and claims for pesticides.

Finally, although a determination that an individual risk reduction claim is truthful and substantiated would end the Commission's deception inquiry, broader public health issues may remain.[19] For example, some commenters on the USST petition focused on the overall impact on public health from the marketing of these products; these comments argued that smokeless tobacco promoted as a reduced risk product might degrade overall public health, depending on how consumers react.[20] Similarly, some commenters questioned whether such advertising and promotion might promote more widespread use of smokeless tobacco, rather than just as a replacement for smoking.[21] Others, however, believe that notwithstanding this empirical

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[19] *E.g.*, Institute of Medicine, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* 6 (2001) (potential reduced-exposure products "are potentially beneficial, but the net impact on population health could, in fact, be negative. The effect on public health will depend upon the biological harm caused by these products and the individual and community behaviors with respect to their use.").

[20] *E.g.*, Letter from Matthew L. Myers, President, *Campaign for Tobacco-Free Kids* to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (Feb. 25, 2002) (comparative health claims made for smokeless tobacco must not only be truthful, but should promote the public health); Letter from Henry A. Waxman, U.S. House of Representatives and Senator Richard J. Durbin, United States Senate to The Honorable Donald S. Clark, Secretary, *Federal Trade Commission* (June 4, 2002) (noting that the potential health benefits that might result from smokers switching to smokeless tobacco were offset by the risks that some smokers who would have quit might, instead, switch to smokeless tobacco; that smokeless tobacco might become more attractive to nonsmokers; and that some of those nonsmokers – once addicted to nicotine – might switch to cigarettes). *See also, e.g.*, WHO Scientific Advisory Committee on Tobacco Product Regulation, *Recommendation on Smokeless Tobacco Products* 3 (2003) (listing arguments against the use of smokeless tobacco for purposes of harm reduction); .

[21] *E.g.*, Letter from Matthew L. Myers, *supra* note 20 (despite USST's stated interest in making harm reduction claims to addicted adult smokers, FTC approval of petition would permit it "to disseminate these claims in ads whose primary appeal could be to young non-tobacco users"); Letter from Dileep G. Bal, M.D., Chief, Cancer Control Branch, *State of California Health and Human Services Agency – Department of Health Services* to The Honorable [Donald] S. Clark, Secretary, *Federal Trade Commission* (March 8, 2002) ("While USSTC [sic] claims that this health advisory is mean to claim harm reduction for the benefit of addicted adults, it

question, the potential harm to public health is not clear enough to justify depriving individuals of information they might use to reduce risks to their own health.[22] This debate on the public health effects of these alternative tobacco products is an important one the appropriate science-based agencies of the government need to address.

Health claims in advertising, including tobacco advertising, are of particular importance

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would allow USSTC [sic] and other companies to market their products with this claim to young, non-tobacco users as well).

[22] L. Kozlowski, *Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options*, Nicotine & Tobacco Research S55-S60 (2002) (noting that nicotine replacement therapies and snus [Swedish moist snuff] are much safer than cigarettes; that there is a basic human right to information that affects one's health; and that when the health risks from a product are relatively small, "the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high.") (citation omitted). *See also* Tobacco Advisory Group of the Royal College of Physicians, *Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority* 2-5 (2002) (supporting comprehensive regulatory approach to tobacco in order to promote public health and noting that emergence of reduced risk products presents multiple challenges for regulators; smokeless tobacco is "10-1,000 times less hazardous than smoking, depending on the product" but its potential marketing as a harm reduction option raises various questions that must be addressed, including minimizing its use as a starter product for young smokers).

to the Commission. The Commission welcomes the Committee's interest in the role that this agency will play in ensuring that the marketplace works efficiently to provide consumers with information that may enable them to reduce their risks of smoking-related disease, while protecting them from claims that are not supported by sound scientific evidence. The agency is committed to reviewing advertising for potential reduced risk tobacco products on a case-by-case basis to try to ensure that the information consumers receive about reduced risk products is truthful and non-misleading.

Conclusion

The Commission thanks this Committee for focusing attention on this important and evolving public health issue, and for giving us an opportunity to present our views.

Chairman TOM DAVIS. Dr. Stratton.

Dr. STRATTON. Good afternoon, Mr. Chairman, members of the committee. My name is Kathleen Stratton. I served as senior staff director to the committee to assess the science base for tobacco harm reduction of the Institute of Medicine. Dr. Wallace, whose testimony I am presenting today, served as vice chairman of that committee.

The work of the committee was conducted under a contract initiated by the Food and Drug Administration. The committee began its work in December 1999, and released its report, "Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction," in February 2001. The committee was asked to provide a framework for the assessment of tobacco and pharmaceutical products that might be used for tobacco harm reduction. However, the committee did not review specific products.

I would like to emphasize several of the committee's principle objections, conclusions, and recommendations.

First, for many diseases attributable to tobacco use, reducing the risk of disease by reducing the exposure to tobacco toxicants is feasible. Therefore, manufacturers should have the necessary incentive to develop and market products that reduce exposure to these toxicants and have a reasonable prospect of reducing the risk of tobacco-related disease. This incentive mentioned is the ability of manufacturers to make exposure reduction or risk reduction claims if they are true. However, I must note that the report is supportive of such claims only if made in the context of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment, and if under the harm reduction framework outlined by the committee, such as illustrated in the next three points. These potential reduced exposure products have not yet been evaluated comprehensively enough including for a long enough time to provide a scientific basis for concluding that they are indeed associated with the reduced risk of disease compared to conventional tobacco use. Regulation of all tobacco products is a necessary precondition for assuring a scientific basis for judging the effects of using the potential reduced exposure products, and for assuring that the health of the public is protected.

Finally, and most importantly, the public health impact of these products is all but unknown. They are potentially beneficial, but the net impact on population health, on public health could, in fact, be negative. Therefore, the health and behavioral effects of using these products must be monitored on a continuing basis. Basic clinical and epidemiological research must be conducted to establish their potential for harm reduction for individuals and for populations.

The committee outlined 11 principles for regulating these products as you have mentioned, Mr. Chairman. The principles address, for example, disclosure of product ingredients, toxicity testing, premarket approval of claims, and issues related to labeling, advertising, and promotion, and postmarketing surveillance of the effects of these products on the American public's health.

I would like to conclude this testimony by summarizing three key public health messages about the potential for improving health in

the face of the availability of the potential reduced exposure products.

First, the committee unanimously and strongly held that the best strategy to protect human health from the dangers of tobacco is to quit or not start tobacco use in the first place.

Second, with the appropriate and comprehensive research, surveillance, education, and regulation, these products could possibly reduce the risk of tobacco-related disease. However, the net health impact is, once again, I should say, all but unknown. Claims of reduced risk to the individual may well not translate into reduced harm to the population. Although a product might be risk reducing for the individual using it compared to conventional tobacco products, the availability of these products might increase harm to the population. This could occur if tobacco users who might otherwise have quit do not, if former tobacco users resume use, or if some people who would not otherwise have initiated tobacco use do so because the perception that the risk of these new products is minimal and therefore acceptability.

Third, a comprehensive and verifiable surveillance system is the crucial link between the availability of reduced exposure products and reduced risk to the individual and reduced harm to public health. It is imperative that we understand what the American people are doing with regard to these products and what is happening to their health.

Thank you for the opportunity to address you on this important topic. A copy of my testimony and a copy of the report, Clearing the Smoke, have been submitted for the record. I am happy to answer any questions about the report.

[The prepared statement of Dr. Wallace follows:]

A Framework for Scientific Assessment and Regulation
of Products for Tobacco Harm Reduction
Statement of

Robert B. Wallace, M.D., M.Sc.
Vice-Chairman of the Committee to Assess the Science Base for Tobacco Harm Reduction
Institute of Medicine/National Academy of Sciences
And
Irene Ensminger Stecher Professor of Epidemiology and Internal Medicine
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Before the
Committee on Government Reform

U.S. House of Representatives

June 3, 2003

Good morning, Mr. Chairman and members of the Committee. My name is Robert Wallace. I am Professor of Epidemiology and Internal Medicine at the College of Public Health, University of Iowa. I served as Vice-Chairman of the Committee to Assess the Science Base for Tobacco Harm Reduction of the Institute of Medicine. The Institute of Medicine operates under the 1863 charter by Congress to the National Academy of Sciences to advise the government on matters of science, technology, and health.

The work of the committee was conducted under a contract initiated by the Food and Drug Administration. The committee began its work in December 1999 and released its report, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, in February 2001. For the purposes of this report and in keeping with general definitions, tobacco harm reduction refers to decreasing the burden of death and disease, without completely eliminating nicotine and tobacco use. The committee was asked to provide a framework for the assessment of tobacco and pharmaceutical products that might be used for tobacco harm reduction. However, the committee did not review specific products.

I'd like to emphasize several of the committee's principal objectives, conclusions and recommendations.

1. For many diseases attributable to tobacco use, reducing the risk of disease by reducing exposure to tobacco toxicants is feasible. Therefore, manufacturers should 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.

This incentive is the ability of manufacturers to make exposure-reduction or risk-reduction claims. However, I must note that the report is supportive of such claims only if made in the context of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment, and if under the harm reduction assessment and regulatory framework outlined by the committee, such as illustrated in my next three points.

2. These potential reduced-exposure products have not yet been evaluated comprehensively enough to provide a scientific basis for concluding that they are associated with a reduced risk of disease compared to conventional tobacco use. Consumers therefore should be fully and accurately informed of all the known, likely, and potential consequences of using these products. The promotion, advertising, and labeling of these products should be firmly regulated to prevent false or misleading claims, explicit or implicit.

3. Regulation of all tobacco products is a necessary precondition for assuring a scientific basis for judging the effects of using the potential reduced-exposure products and for assuring that the health of the public is protected.

4. Finally, and most importantly, the public health impact of these products is all but unknown. They are potentially beneficial, but the net impact on population health, or public health, could, in fact, be negative. Therefore, the health and behavioral effects of using these products must be monitored on a continuing basis. Basic, clinical, and

epidemiological research must be conducted to establish their potential for harm reduction for individuals and populations.

The committee outlined several general principles for regulating these products. These principles address, for example:

- disclosure of product ingredients,
- toxicity testing,
- premarket approval of claims, and issues related to labeling, advertising, and promotion, and
- postmarketing surveillance.

I'd like to conclude my testimony by summarizing three key public health messages about the potential for improving health in the face of the availability of the potential reduced exposure products:

1. The committee unanimously and strongly held that the best strategy to protect human health from the dangers of tobacco is to quit - or not to start tobacco use in the first place.
2. With appropriate and comprehensive research, surveillance, education, and regulation, these products could **possibly** reduce the risk of tobacco-related disease. However, the net health impact is all but unknown. Claims of reduced risk to the individual may well not translate into reduced harm to the population. Although a product might be risk-reducing for the individual using it compared to conventional

tobacco products, the availability of these products might increase harm to the population. This could occur if:

- tobacco users who might otherwise have quit do not,
- former tobacco users resume use, or
- some people who would have not otherwise initiated tobacco use do so because of perceptions that the risk with these "new" products is minimal and therefore acceptable.

3. A comprehensive and verifiable surveillance system is the crucial link between the availability of reduced exposure products and reduced risk to the individual and reduced harm to public health. It is imperative that we understand what the American people are doing with regard to these products and what is happening to their health.

I thank you for the opportunity to address you on this important topic. A copy of my testimony and a copy of the report, *Clearing the Smoke*, have been submitted for the record. I am happy to answer any questions about the report.

Chairman TOM DAVIS. Thank you all very much.

Let me just start the questioning, Dr. Leischow, let me start with you.

I know that the NIH has funded many studies on the health effects of tobacco over the last 50 years, but we really don't know much about what is in cigarette smoke. Well, let me ask you this. How much do we know about what is in cigarette smoke causing smoking-related illnesses?

Dr. LEISCHOW. Well, actually, there has been a fair amount of research that was conducted at NCI in the 1970's that looked at tobacco products even with the intent to create a so-called safer cigarette. That program didn't continue. The scientific community has actually not conducted a lot of research in the last few years. Much of it has been done by the tobacco industry, and much of that research we don't know. I would have to provide some testimony after this on some of the specifics regarding tobacco products and what we know about the exact constituents.

Chairman TOM DAVIS. I understand your position, that no tobacco product that you can conceive of is safe today. But let me just ask you this. In your opinion, is it feasible to include tobacco products that, while not safe, provide a safer source of nicotine to the consumer as part of efforts to reduce tobacco-related morbidity and mortality?

Dr. LEISCHOW. There is no evidence that——

Chairman TOM DAVIS. I didn't ask that.

Dr. LEISCHOW. OK.

Chairman TOM DAVIS. We don't know at this point.

Dr. LEISCHOW. Right.

Chairman TOM DAVIS. But if it were possible, would that be something worth exploring? And if that were so, what agency would we call on to regulate that and make the call to balls and strikes?

Dr. LEISCHOW. Well, it wouldn't be NCI. I mean, we are a scientific agency. It would have to be a regulatory agency. That is not something that we would make a decision on. I'm afraid I just don't have a good answer for that one.

Chairman TOM DAVIS. And you don't know whether you could make it safer or not at this point.

Dr. LEISCHOW. We really don't know for sure. Certainly, the IOM report indicated that it is scientifically conceivable, but it is going to take a very extensive research and testing program. And, as the IOH folks indicated, looking at surveillance, the product itself, how people use the product, which we know is a critically important point. You can create a product that has various changes in the amount of nitrosamines or other carcinogens, and but how people use that product will oftentimes determine what impact it has on health. So there is a lot of research that needs to be done.

Chairman TOM DAVIS. Dr. Stratton, do you have any thoughts on that?

Dr. STRATTON. Dr. Leischow is correct, that the report said that it was within the scientific realm of feasibility, but that they haven't been demonstrated and that there is too much that is unknown. And more than the effects on the individual, the committee

was particularly concerned about the impact of the products on public health, which is even harder to understand.

Chairman TOM DAVIS. Right.

Dr. STRATTON. With regard to regulation, which I believe you asked Dr. Leischow, the committee didn't make a recommendation of which specific agency, although it should have the regulatory authority over these tobacco products, although it did say that the Food and Drug Administration is the most likely, and at this point, the most appropriate, although there could be another agency if the right expertise were brought to bear. But there was an implicit preference for the Food and Drug Administration to be given that authority over tobacco.

Chairman TOM DAVIS. There are products out there on the market right now that purport to be safer from their own advertising, lights, ultra lights, and the like. And we have no scientific, independently verifiable data at this point that indicates that is true; is that a fair statement?

Dr. LEISCHOW. That is exactly right. And that applies to both smoked tobacco products as well as smokeless tobacco products. One of the challenges, as you indicated, that these products are on the market—if I could even demonstrate. There is a product that is marketed called Ariva. And this is certainly no endorsement for products. But it is a tobacco product that is actually on the shelf oftentimes right next to an FDA approved smoking cessation medication. Both of these products are, you know, it is a lozenge. So this is a tobacco product, this is a pharmaceutical company FDA-approved product. Very similar. And we don't know much about this one. We know a lot about this one because it has gone through FDA review. But this one is out there and consumers are using it presumably and without again much information as to what the impact is of its use.

Chairman TOM DAVIS. But to some extent, doesn't that make the case that maybe this would be a good idea for the government to look at those products and try to independently verify whether in point in fact they do what they purport to do?

Dr. LEISCHOW. Well, clearly as a research question, yes. And NCI has conducted that research, and we funded research in that area. It is critical that we understand how these products are used, what their constituents are and what their health effects are, and then sort of answer some of the surveillance questions: How do populations use them and what are the health effects?

Chairman TOM DAVIS. I mean, one of the problems is that if you have a safer product but it is not a safe product, you have a hard time embracing that and trying to put any kind of approval on that. And I understand that. You are the National Cancer Institute, and you don't want to encourage somebody to do something that is harmful to them even though it may be less harmful than something else they would likely do otherwise. But the reality is today a lot of people are using these products under the impression that they are safer products, and there is no evidence that they are. And the question, do we stand back and say, well, gee, you know, we are going to wait for the ultimate-ultimate solution, which may be politically not viable? Or do we take in and take a step? And that is kind of the quandary we face here.

Dr. LEISCHOW. And it is an important question. And the scientific community has begun to look at what are the constellation of studies that need to be addressed. And in fact, there was a meeting in February that included tobacco industry scientists and representatives to even begin discussing how the tobacco industry may contribute and play a role in the testing of products in such a way that the public health community would find that acceptable. So there is some movement toward exploring how we might do this. We have to develop a framework and a set of parameters that are acceptable to all.

Chairman TOM DAVIS. And the tobacco industry has certainly done a lot of research.

Dr. LEISCHOW. Absolutely.

Chairman TOM DAVIS. The sharing and the verifiability and all that stuff remains to be seen.

My time is up. I am going to yield now to Mr. Waxman for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I think your questions are right on point. If there are products that are out there and people are being told these products are going to be safer in some way, if that is not accurate, I think the public should have some confidence that the government is regulating. And Dr. Leischow, you testified that these light and low tar cigarettes do not reduce the risk of lung cancer compared to regular tar cigarettes, and that many smokers switch to lower yield cigarettes out of concern for their health. Is that right?

Dr. LEISCHOW. Exactly.

Mr. WAXMAN. These are not new products. These have been out there for 30 years and light and low tar brands are still among the most popular cigarettes in the United States. And I believe and I think all evidence points to the fact that people think they are doing themselves a favor by smoking these brands as opposed to any other brand.

Dr. LEISCHOW. Exactly. In fact, the questions you raised are exactly why we have begun asking the public those questions through a survey that is assessing how people perceive health risks. And so we were asking about light cigarettes as well as the use of these new purported harm reduction products.

Mr. WAXMAN. Now Dr. Wallace, we are pleased that you are here with us along with Dr. Stratton. The chairman says he needs to swear you in before I ask you any questions.

Chairman TOM DAVIS. I just have to——

[Witness sworn.]

Mr. WAXMAN. The Institute of Medicine has looked at the issue of this harm reduction, tobacco harm reduction. Do you believe there is adequate evidence to address whether some of these newer products actually reduce risk to health?

Dr. WALLACE. No, sir. That was the conclusion of the committee, that there was not sufficient evidence in the general case. A lot of the evidence rests with the long-term health effects of the products. Other evidence has to do with the standardization and what really is coming, what really gets into the body when the product is used. And still other evidence has to do with the public health side of

this, which is, what is the impact of a particular product used on other people, on children, on changing practices by adults.

And so we felt that, while harm reduction was feasible, that, in fact, the evidentiary case, the scientific evidence has not been made yet.

Mr. WAXMAN. Dr. Leischow held up two packages of little capsules. One has been approved by the FDA as a nicotine delivery system to help people give up smoking. The other is a tobacco product with nicotine that is supposed to be sold to people with the idea, if they can't smoke, they should suck on this mint, tobacco mint with nicotine in it.

Dr. Leischow, one was approved by the FDA and the other was not.

Dr. LEISCHOW. Exactly.

Mr. WAXMAN. Now, this other product presumably is to encourage people not to give up smoking but to use this in addition to smoking and during the times when they can't smoke.

Dr. LEISCHOW. Right. In fact, the front of the box says: When you can't smoke, specifically.

Mr. WAXMAN. Now, there was a hearing in another committee I happened to be in attendance, and the people that make the smokeless tobacco are urging that they be allowed to advertise that they are safer than cigarettes. One, there is no evidence they are safer than cigarettes. But it seems to me that people who don't want to give up smoking but want something else will probably use that product and smoke as well. Any evidence on that?

Dr. LEISCHOW. Actually, at this point, we don't. It is our concern, and that is why we need to track the products, track how people use them, and again track the health effects of these products. So this is a very fast-moving field. And the science quite frankly is having a hard time keeping up with policy and with the use of the product.

Mr. WAXMAN. Excuse me for interrupting, but I see the yellow light. Rather than go to the FDA that has the scientific authority to evaluate some of these products from a medical point of view, people are going to the FTC because they say that the FTC should not stop them from making advertising claims. Now, these products that are out there, low tar and light cigarettes, were given a green light by the FTC 30 years ago. That was a big mistake. We certainly don't want to repeat that mistake with these new products.

Dr. Stratton, you said, the question is, who should regulate? Who should regulate if we are trying to protect the public from products that claim to be a safer alternative but are not a safer alternative? Maybe Dr. Wallace wants to respond to this. Should it be the FTC, the FDA? Who should regulate?

Dr. WALLACE. Sir, the report didn't take a position on which agency or agencies in the Federal Government should actually do the regulation. My own personal view is that they were leaning, our committee was leaning toward an FDA model, scientifically based informed model.

Mr. WAXMAN. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much. Mr. Lewis, any questions? Mr. Platts. Any questions over here on our side on this panel? Mr. Schrock.

Mr. SCHROCK. Thank you, Mr. Chairman. Let me associate myself with what Governor Janklow said. I'm a cancer survivor. And I chose to smoke. I am going to make that clear. Nobody forced me to do it, but when I was in Vietnam, they were free. Anything free has to be good. Right? So I smoked myself nearly to oblivion. But that doesn't mean I blame anybody but myself. I did, and I choose not to now, forcing my wife and son to choose not to, either.

But Mr. Peeler, I understand that Philip Morris USA has recently petitioned the FTC to issue rules regarding the use of the terms, as Mr. Waxman said, lights and low tars in light of conclusions recently expressed by the NCI. What is the status of that report? It may be in this volume of stuff, but I haven't read it.

Mr. PEELER. I don't think it is. It has been received by the FTC, and we will evaluate it. It is exactly the type of issue that we would seek out the opinions of the scientific agencies and the Federal Government in evaluating. And in fact, as indicated in our written testimony, the area of tar and nicotine testing is an area where the FTC has asked NCI's assistance in the past, and we are working with those agencies to try to develop an improved tar and nicotine test to replace the one that exists now.

Mr. SCHROCK. Do you think that will be soon, the results?

Mr. PEELER. Well, when we have asked, what we have been told is: You are an agency of lawyers and economists. You shouldn't be developing the scientific test methods. And we agree with that as long as that test method is at the FTC. And we've recommended that it be transferred legislatively. But as long as it stays at the FTC what we would do is seek the advice of the government's scientific agencies on how to modify it. So the question of whether that would be soon would be something you would have to ask Dr. Leischow.

Dr. LEISCHOW. Where it stands is this: After the Monograph 13 was released, we indicated that we were quite interested in working with the FTC, and we remain so today. The request to the FTC—the FTC request, I should say, initially went through the previous Secretary for Health and Human Services. And we are not clear whether NCI is still the agency that HHS would request to do this. So, our interest is in working with FTC and determining whether we are still the right agency, whether another one like CDC or some other may be the optimal one to move forward. So we are ready, willing, and able once we get a directive from the new administration to do so.

Mr. SCHROCK. Keep us posted on that. Let me ask one more question, Mr. Peeler. Given the criticism by the public health community of both the FTC test and the use of the terms like light, what additional actions does the FTC plan to take in this area?

Mr. PEELER. Well, the first thing, I want to make clear that the FTC has never approved of the use of the term low or light. Those are under industry descriptors that are used under industry guidelines. And as you may know, there is a significant amount of litigation ongoing including litigation as part of the U.S. Government's Justice Department suit that involves those issues right now.

In terms of fixing our tar and nicotine testing system, which produces the numbers but not the descriptors, as I said, that is something that we have been actively engaged in looking for answers

on. And we do want to work with the Federal Government scientific agencies to develop a fix to that system.

Mr. SCHROCK. OK. The government moves slow. It would be nice if they could move faster on this kind of stuff, that's for sure.

Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much. Any questions on this side? Mr. Ruppersberger.

Mr. RUPPERSBERGER. Thank you.

Well, this issue will go on for a long time. And really the issue is, how far does the government go to regulate a habit that has harmed a lot of Americans. But we have the issue now where people are smoking, where there is addiction; and how do we deal with it. There has been a lot of settlements, a lot of lawsuits involved. I think the States are putting a lot of money into education and to helping people understand where we need to go to deal with the issue involving children.

I want to talk, just address a couple issues concerning consumption, and reduce the consumption and maybe the eventual stopping of smoking. Do the cigarettes attempt to reduce the amount of tar and nicotine help smokers both reduce consumption and lead to the eventual stopping of their habit? Any data as it relates to that issue?

Dr. LEISCHOW. No.

Mr. RUPPERSBERGER. Does the entire panel agree with that? And no statistics or research one way or another?

Dr. LEISCHOW. If I understand your question, I mean, the evidence that was summarized in our Monograph 13 on light cigarettes indicates that, in fact, that we have, in effect, sustained smoking, you know, by having these products available. People get a sense that they are using something that is safer, and they are really not, ultimately.

Mr. RUPPERSBERGER. Let me ask you, how effective are items like the patch and nicotine gum in reducing or assisting people to stop smoking?

Dr. LEISCHOW. They can be quite effective. When used as tested in the trials that got them approved by the FDA, 15 to 25 percent, sometimes even higher quit rates. The challenge is in getting people who buy them on the market and then altering the environment to use them according to the label. And that is one of the challenges that again the scientific community and the pharmaceutical companies have before them. But these products can be effective when used appropriately. And we certainly hope that more and new medications are developed in the future that are even more effective.

Mr. RUPPERSBERGER. Let me ask you this: Besides the patch, education, nicotine gum, are there any other remedies available to help people quit?

Dr. LEISCHOW. Nicotine inhaler, nicotine nasal spray.

Mr. RUPPERSBERGER. What kind of inhaler? Is that a prescription inhaler?

Dr. LEISCHOW. It is actually right now prescription in the United States. In some other countries, it is actually over the counter. Nasal spray, which is a prescription product. And then the product called Zyban that is a brand name which is a nonnicotine medica-

tion is also approved and has been shown to be effective for smoking cessation.

Mr. RUPPERSBERGER. What would you like to see, as a group or individually, what do you think needs to be done by the Secretary of Health and Human Services to deal with the issue of first the smoking addiction, and then second, to get into the issue that we are talking about here today?

Mr. PEELER. Well, for FTC's standpoint, I would reference you to our prepared statement where we did say that we thought exploring a greater range of possible claims for nicotine replacement products would be something that we thought was valuable.

Mr. RUPPERSBERGER. Do you think we need more cooperation from the Federal Government with the States, since the States seem—the States have settled with the tobacco industry or have programs themselves? Do you think the programs that you have seen nationally are effective, or do you think one is different than the other? How would you look at the pictures as relates to cooperation between State and Federal and individual States?

Dr. LEISCHOW. It is variable. But, quite frankly, there is quite a bit of cooperation that is happening now. CDC is the lead agency in that respect. They are doing an absolutely bang-up job linking the States and bringing various Federal partners into the mix. For example, there is a group of States that have quit lines, toll free quit lines. And so there has been an effort between the States and Federal agencies to link those quit lines to see how we can most effectively use those to help the millions of smokers in the United States to quit.

Mr. RUPPERSBERGER. I see my time is almost up. I want to ask this last question: Who is more likely to quit their addictions, smokers or smokeless tobacco users?

Dr. LEISCHOW. To my knowledge, there has not been a head-to-head comparison that way. Both involve——

Mr. RUPPERSBERGER. Should there be?

Dr. LEISCHOW. That's a great idea. That's a good research study. And some of the other folks this afternoon may have answers to that, Dr. Henningfield or others. But the challenge is that addiction to nicotine is fundamental to both of them. Nicotine is exceedingly addicting, and quitting either of those products is hard.

Mr. RUPPERSBERGER. In your opinion, do you think one is different than the other?

Dr. LEISCHOW. I have no evidence that one is easier or harder. They are both difficult to quit in most cases.

Mr. RUPPERSBERGER. Thank you.

Chairman TOM DAVIS. Any other questions on this side? Mrs. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

Dr. Stratton, I think I would like to begin with you and then I have a question for Dr. Wallace. And I want to talk with you a little bit about timeframes and also what we can do at looking at some of these incentives. You mentioned, Dr. Stratton, in the testimony that you gave for us, that the committee had some objectives, some conclusions, and some recommendations. And in this, at point No. 1 for you, you said that for many diseases that are attributable to tobacco use, reducing the risk of disease by reducing exposure

to tobacco toxicants is feasible. Therefore, manufacturers should have the necessary incentive to develop.

Now, in talking about this, looking at incentives, do you feel like it is the government role to incentivize, that it should be the private sector's role to provide the incentive? Or what exactly do you mean with that statement?

Dr. STRATTON. First, I would like to say that although it is the first listed in my testimony, it is certainly not the primary or most important. It does, however, set the stage for the following three points: In my testimony, I hope I mentioned that the incentive that the committee clearly intended was the ability to make exposure reduction claims or risk reduction claims if they are true, and if it is done in the context of comprehensive tobacco control and comprehensive tobacco regulation. So the incentive is the ability to make claims, if they are true.

Mrs. BLACKBURN. Thank you.

And then Dr. Wallace, going to the IOM report, it is stated frequently that it will be difficult and time consuming to determine the degree of exposure reduction achieved. Now, do you have any timeframe at all before a product could truly make a claim of reducing risk; and how long are you talking there? Weeks, months, years? And how can some of the delays be avoided?

Dr. WALLACE. First of all, there has to be I think enough of a scientific base so that the product would be either out there already or some tentative claim about exposure might be made. In terms of the health outcomes, these, of course, can be many, many years. Unfortunately for pregnant women, you can sometimes get answers fairly quickly about the health of the fetus, for example. Certain—for heart attacks, you might get an answer in a few years because, in fact, there is a reasonable relationship between smoking cessation for harm reduction and the risk of heart attack. For the cancers, for the chronic lung disease, for some of the other very important outcomes of tobacco smoking, it could take decades. There may be no way to compress that.

Mrs. BLACKBURN. Thank you very much.

Chairman TOM DAVIS. Anyone else on this side like to be recognized? Yes, ma'am, go ahead. The lady from California.

Ms. WATSON. Thank you, Mr. Chairman.

To the panel. In California, in the 1980's we started doing intense policymaking. Our ranking member was a leader in that effort. We finally got down to where we disallowed smoking on airplanes. I just heard recently where a gentleman died of an asthmatic attack after asking to be removed from the smoking section.

I want to know if the Institute—anyone who would like to respond—has looked into if there are any advanced methods of clearing the air in an airplane. Since most of us are global, and I believe this is a Greek airline, I am not sure of the facts. I was just really discouraged to hear that, A, they were allowing smoking; and, B, someone who asked to be moved was not accommodated and he ended up dying. I've always been concerned about that secondhand smoke and smoking aboard planes. So have we done any more research on clearing the air in that can or that plane of cigarette smoke? Anyone that wants to respond.

Dr. LEISCHOW. I'm unaware of that, and we can certainly explore it and get information to you after this meeting.

Ms. WATSON. I believe at this time that most airlines internationally prohibit smoking, but I found that possibly there are a few and there might be some coming from the Far East, but I would like any information on that, if you know of any of the airlines. I think we need a drive internationally with the WHO about prohibiting smoking on airlines because those airlines do come to our shores and our airspace, and I'm very concerned. So if someone can provide me that information at later time, I'd appreciate it. Thank you.

Chairman TOM DAVIS. Anyone else who wishes to be recognized before we hear the next panel?

The gentleman from Missouri.

Mr. CLAY. Thank you, Mr. Chairman. Real quickly, just for anyone on the panel, would someone who continues to smoke cigarettes and has not been successful trying medicinal nicotine products be better off switching to smokeless tobacco? And any one of you can try to answer that one.

Dr. LEISCHOW. We don't have evidence on that. We don't have adequate evidence on that. There have been some claims made that may be safer, but we still have a long way to go to understand what the impact might be of a person doing that. So we just don't have the data.

Mr. CLAY. OK. The Royal College of Physicians in London has concluded that the consumption of noncombustible tobacco is of the order of 10 to 1,000 times less hazardous than smoking, depending on the product. Does this conclusion provide substantiation for a statement? Advertising that smokeless tobacco is significantly less risky than cigarette smoking?

Mr. PEELER. When you look at substantiation in advertising, you have to look at what the expressed claims are and the implied claims. When you look at what claims consumers take out of advertising, you look at both what the expressed claims are and what the implied claims are. So if that claim was made in advertising, we would want to know—we would want to answer two questions.

The first thing is we'd want to know was that recommendation itself based on confident, reliable scientific evidence; and the second thing we would want to know is did that advertisement convey a broader claim that has proven that smokeless tobacco would reduce the risk? And in answering those questions, we would turn to government scientific agencies to assist us in the evaluation of the science.

Mr. CLAY. OK. Thank you. Thank you, Mr. Chairman. That's all the questions.

Chairman TOM DAVIS. Thank you very much.

Any other questions from Members?

The gentleman from Connecticut.

Mr. SHAYS. The gentleman asked the question about the Royal College of Physicians. I would just like to ask the IOM, do you envision any circumstance that would allow a product to be made, reduced exposure claims initially to make those later be followed by actually reduced claims once the claims have been verified? In other words, intuitively you say these are reduced claims, but you

don't have the documentation to establish it. Can you envision that happening?

Dr. WALLACE. In fact, again we said that the answer is yes. We said that this was feasible. We just don't feel that the evidence is in place yet for any of the products and that in the context of a national tobacco control program and followup of populations to know what's happening to the community at large, to Americans in general in their tobacco use habits that it's entirely feasible that these claims can at some point be made.

Mr. SHAYS. Does the panel basically accept that people will smoke no matter how serious they believe the physical results can be a negative? I mean, is there just a basic acceptance on the fact that people are going to smoke? And that's my question. I mean, do any of you envision a world in which a country simply will not have smokers? I'd like each of you to answer.

Dr. WALLACE. Just to start, we didn't address the issue of prohibition, if that's where you're going, but we certainly look at differences in populations, differences among countries, effects of treatments as they become available; and it's not outside the realm of possibility that in fact we can suppress the use of tobacco products to a substantial degree.

Mr. SHAYS. The basis for my asking this question is that when you deal with an issue of a product being less harmful, we're saying it is harmful but it's less harmful, the logic of having a less harmful product is people are going to smoke and therefore better that they smoke a less harmful or that they chew a less harmful product to satisfy their desire to have tobacco, and all I'm doing is just trying to understand the mindset. It's not about prohibition.

Is there generally an acceptance on the part of you in the positions you're in that we're going to have a country in the world where you're going to have smokers, whether they smoke tobacco or they chew it, and that better that it be—that there is a logic to the process that we then try to encourage them and encourage the companies to develop a less harmful product?

I can tell you what my answer is. My answer is, yes, they are going to smoke and, yes, better that they have less harmful. I want to know what you think. That's what I'm asking. I will start with you, Dr. Stratton.

Dr. STRATTON. Dr. Wallace and I actually represent the same organization, so hopefully we'll give the same answer.

Dr. WALLACE. You can pass if you'd like.

Dr. STRATTON. I will pass to Dr. Wallace on this.

Mr. SHAYS. This might be the only fun we have today.

Dr. WALLACE. No. I wouldn't do that to her.

Mr. SHAYS. I will defer to the chairman's guidance, and you should clearly.

Dr. WALLACE. Thank you. Just very quickly, I believe that the very notion of harm reduction implies that at least in the foreseeable future that there will be tobacco use and we did accept that; and the committee, with all the caveats and programs that we recommended, accepted the notion of harm reduction as being feasible, but it has to be scientifically proven and regulated, etc., and—but we did accept that.

Mr. SHAYS. Mr. Peeler.

Mr. PEELER. As we said in our written testimony, there are about 50 million Americans that smoke regularly, and I think there was testimony this morning that quitting rates—while people quit, quitting rates are pretty low. So we think that a large number of Americans will continue to smoke and that if there were risk reduction products that can make truthful substantiated risk reduction claims, that could be beneficial to those smokers, but that leaves open to the question that I think has been discussed here this morning which is, you know, are there products that we are confident enough will produce a risk reduction?

Mr. SHAYS. I will be finished just with your answer, Doctor.

Dr. LEISCHOW. I don't see tobacco going away anytime soon, but certainly within the realm of possibility that alternatives could be created, there are pharmaceutical products that could deliver some of the same constituents that people use nicotine products for, tobacco products for, but without all the harmful substances. So certainly it's within the realm of possibility. Scientifically how it will play out is, of course, unclear.

Mr. SHAYS. Thank you, Mr. Chairman.

Thank you, gentlemen.

Chairman TOM DAVIS. Thank you, Mr. Chairman.

The gentleman from Maryland, Mr. Van Hollen.

Mr. VAN HOLLEN. Thank you, Mr. Chairman.

I just have a few questions for Mr. Peeler, trying to get a sense of the difference in responsibilities and oversight with respect to FDA versus the FTC. Because if we're going to get truthful answers to these scientific questions, it seems to me we're better off if we get them before the fact than after the fact, and you said the FTC can only really jump in here after a claim has been made for the most part. So, just to be clear, FDA can assess the scientific claims before approving a product; is that right?

Mr. PEELER. For most products that FDA regulates—I mean, it varies with the product, but for most products, particularly if it was a risk reduction claim, FDA would preapprove that claim before it was made.

Mr. VAN HOLLEN. Right. And the FTC does not have that authority?

Mr. PEELER. No. The FTC does not have the authority to preapprove claims.

Mr. VAN HOLLEN. And with respect to marketing claims made before the marketing of the product and the ability to put restrictions on the claims that are made, FDA has that authority now; is that right?

Mr. PEELER. Not for tobacco products. I mean, that's why you're here.

Mr. VAN HOLLEN. No. I understand that. But with respect to other products, where scientific claims are made about the medical efficacy of those products.

Mr. PEELER. With respect to drug products, that's true of other types of products, not for all the products FDA regulates. The FTC's authority, again, is to take action if the advertising is either deceptive or if it's unfair, and it's really the deception analysis that applies primarily to advertising.

Mr. VAN HOLLEN. When you look at that, do you look at just the very narrow question about whether someone has made an outright false statement or do you also look at the broader question about whether people might be misled about a particular product?

Mr. PEELER. We clearly look at the broad question of whether people will be expressly or implicitly misled. But as we indicated in our testimony, there are a number of public health questions that have been raised that go beyond, that look at deception which have been discussed here this morning that we would not necessarily look at after determining that there was adequate substantiation.

Mr. VAN HOLLEN. Right. I guess maybe—correct me if I'm wrong. My understanding was with respect to light and low tar cigarettes that FTC has not disputed those claims, is that right, that have been made with respect to advertising of those products?

Mr. PEELER. I would not say that's correct. We have reports going back as early as 1981 questioning low and light claims and raising concerns about them. We continue to operate our tar and nicotine testing system, and we're seeking advice on how to change the numbers. We have never officially endorsed low or light cigarette claims.

Mr. VAN HOLLEN. Not endorsed, but I mean the advertising that's been going on for years and years now, you've never stopped it, have you?

Mr. PEELER. We have not taken any law enforcement actions against it. I believe that those claims are subject to the Justice Department's ongoing litigation.

Mr. VAN HOLLEN. Let me ask you, do you believe that people have been misled into thinking that those products are safer than the other cigarette products?

Mr. PEELER. Well, I think, given the fact that's in litigation between the United States and the companies right now, I just leave it with that.

Mr. VAN HOLLEN. I just think it points to the weakness sometimes in protecting public health through the FTC, which is that you're only able to get into the game after a product is being advertised. In this case, it's been advertised for years, and I think common sense will tell you most people think that the claims of low tar and light cigarettes means it's in fact healthier when in fact it has not been proven.

Mr. PEELER. Right, and we have put out consumer education saying that is not right, that the only way to reduce your—the only safe cigarette is not smoking.

Mr. VAN HOLLEN. It's not right, but they continue to be able to advertise that; right? Right?

Mr. PEELER. There are still claims on packages, yes.

Mr. VAN HOLLEN. Thank you.

Chairman TOM DAVIS. Any more questions of this panel before we move on to the next panel?

If not, let me dismiss this panel with our thanks. Thank you very much. You've added greatly to our wealth of information.

We'll take about a 3-minute recess as we switch. We'll be back in about 3 minutes.

[Recess.]

Chairman TOM DAVIS. We now move to our second panel.

We have Michael Szymanczyck, CEO of Phillip Morris USA; Dorothy Hatsukami from the University of Minnesota; Dr. Jack Henningfield from Johns Hopkins University School of Medicine; Dr. Lynn Kozlowski from Penn State University. David Sweanor is still at the other hearing. He's from the Non-Smokers' Rights Association.

Excuse me. He just came. Perfect timing.

Do you need a minute or anything or are you OK?

Mr. SWEANOR. I'm fine.

Chairman TOM DAVIS. David Burns from the San Diego School of Medicine, and Mr. Richard Verheij from U.S. Smokeless Tobacco. He's here as well now. Great.

As the policy of our committee, we swear in all the witnesses before you testify.

[Witnesses sworn.]

Chairman TOM DAVIS. In order to allow time for questions, if you would limit your testimony to 5 minutes or thereabouts. When it turns orange, 4 minutes is up. When it's red, your 5 minutes are up and move to summary.

Mr. Szymanczyck, I will start with you, and we'll move straight down the row. Thank you for being a witness. You're testifying here today voluntarily, and we're happy to have you. Thank you.

STATEMENTS OF MICHAEL E. SZYMANCZYCK, CHAIRMAN AND CEO, PHILIP MORRIS USA, INC.; DOROTHY K. HATSUKAMI, PROFESSOR, UNIVERSITY OF MINNESOTA; JACK HENNINGFIELD, PROFESSOR, DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE; LYNN T. KOZLOWSKI, PROFESSOR AND HEAD OF DEPARTMENT OF BEHAVIORAL HEALTH, PENNSYLVANIA STATE UNIVERSITY; DAVID T. SWEANOR, SENIOR LEGAL COUNSEL, NON-SMOKERS' RIGHTS ASSOCIATION; DAVID M. BURNS, PROFESSOR, SAN DIEGO SCHOOL OF MEDICINE, UNIVERSITY OF CALIFORNIA; RICHARD H. VERHEIJ, EXECUTIVE VICE PRESIDENT, U.S. SMOKELESS TOBACCO CO.

Mr. SZYMANCZYCK. Thank you, Mr. Chairman and members of the committee. On behalf of the more than 12,000 employees of Philip Morris USA, I am very honored today to respond to the thoughtful questions that the chairman posed regarding the development of potentially reduced risk and reduced exposure of tobacco products. I think these issues are important and timely, especially in the context of the unique dangers of tobacco.

There is no safe cigarette. Smoking causes lung cancer, heart disease, emphysema, and many other diseases; and the best way to reduce the risks of these diseases is to quit. Smoking is addictive, and the public health community unanimously encourages people to quit smoking. Nevertheless, many adults continue to smoke, and these millions of adult smokers should not be discarded by our national tobacco policy. In addition to preventing you from smoking and encouraging cessation, the government should seek products that will be of potential benefit to these people.

These issues have been significant factors in leading us to strongly support passage of meaningful and effective regulation of tobacco products by the Food and Drug Administration, like that contained in the chairman's bill H.R. 140 and like a great majority of the bill introduced in the last session by Senators Kennedy and DeWine, S. 2626.

We believe that these objectives can best be achieved by FDA regulation. Guided by the Institute of Medicine's landmark report on reduced risk and reduced exposure to cigarettes, that report commissioned by the FDA suggested 11 regulatory principles as a road map to the development and the scientific and social evaluation of these products.

At Phillip Morris USA one of our highest priorities has been and continues to be the development of cigarettes that have the potential to reduce harm caused by smoking, and the lessons we have learned reaffirm the Institute's recommendations. Simply put, the public health community has identified a number of compounds that are harmful to smokers without definitively settling on any specific one or combination as the recognized cause of lung cancer or other diseases. Accordingly, our strategy at Philip Morris USA is to try to reduce smokers' exposure to as many of these compounds as we can with products that are acceptable to consumers and don't cause unintended consequences in the marketplace. If we are successful in finding ways to reduce harmful compounds and smokers' actual exposure to them under real world conditions, we believe that, although it will take some time, the FDA will be in a position to help us evaluate whether our product development efforts are actually reducing the risk of tobacco-related diseases among current smokers.

At Philip Morris USA we have extensive internal and external research programs, and we believe that we are making progress with two distinct types of products. One product, called Accord, is an electronically heated cigarette, heating tobacco to a lower temperature which yields lower quantities of certain potentially harmful compounds. A second product is a traditional cigarette with a state-of-the-art activated carbon filter which likewise reduces some of the compounds in smoke.

We strongly agree that the Federal Government should help determine what is and what is not a reduced exposure or a reduced risk tobacco product. The best approach is for the FDA to make such determinations based on the best available scientific information and to encourage innovation and competition in the development of new technologies. Then the FDA should play an important role in overseeing any claims, explicit or implied, made by manufacturers regarding potential benefits.

As I remarked earlier, there is a real urgency to this legislation. As the IOM noted, novel tobacco products are being introduced and marketed today without significant regulatory oversight, and we are convinced that the status quo doesn't serve smokers or society.

As an example, we may soon face a serious dilemma. If we become convinced that a product is potentially better for the consumer, presenting real reduced exposure, that may one day reduce the risk of a disease, the fact is that until FDA oversight is in place we will not have an accepted and official external process to review

our work. We intend to responsibly bridge this transition period and to continue to take our research to a number of government agencies and scientific organizations for review and comment, but in the context of this situation, the sooner we have FDA regulation the better for everyone.

These issues are complex and controversial, but we pledge to be a constructive force in shaping this policy and to work with anyone and everyone who wishes to join into this challenge, and we thank the committee for holding this hearing and for attention to this matter.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Szymanczyck follows:]

Embargoed for release until 2 p.m.
June 3, 2003

STATEMENT OF MIKE SZYMANCZYK

CHAIRMAN AND CHIEF EXECUTIVE OFFICER

PHILIP MORRIS USA

on

REDUCED EXPOSURE/REDUCED RISK TOBACCO PRODUCTS: AN EXAMINATION OF THE POTENTIAL PUBLIC HEALTH IMPACT AND REGULATORY CHALLENGES

Submitted to the Committee on Government Reform
United States House of Representatives
June 3, 2003

Written Statement of Mike Szymanczyk
Chairman and Chief Executive Officer
Philip Morris USA
Submitted to the Committee on Government Reform
June 3, 2003

I. Introduction

On behalf of the more than 12,000 employees of Philip Morris USA, I am honored to submit these remarks regarding reduced exposure and reduced risk tobacco products, including their potential health impact and the challenges of sensibly regulating them. In particular, I'm here to emphasize our strong support for passage by the 108th Congress of meaningful and effective regulation of tobacco products by the Food and Drug Administration. We believe that legislation empowering the FDA to act should fully implement the thoughtful, comprehensive and rigorous regulatory principles articulated by the Institute of Medicine in its landmark report, *Clearing the Smoke,* which was commissioned by the FDA itself.

We applaud the Committee for its leadership in holding this hearing. We agree with the Committee's interest in seeking a bipartisan way to fashion a coherent national tobacco policy. We look forward to working with you and your colleagues in the full House towards the passage of legislation that is designed to benefit adult consumers by reducing the harm caused by tobacco consumption, and to establish clear rules that will be applied to, and enforced uniformly throughout the tobacco industry.

We very much appreciate having been invited to testify at today's hearing, and hope to use the opportunity to convey three critical points that we believe are relevant to the issues the Committee is considering:

- Philip Morris USA strongly supports legislation that would provide the FDA with comprehensive, meaningful and effective authority to regulate tobacco products. The FDA should have the power to fully implement all of the 11 regulatory principles – including those relating to potentially reduced exposure/reduced risk products -- recommended by the IOM Report.

- For many years now, we have been hard at work trying to develop and consider ways to successfully market innovative tobacco products that have the potential to reduce smokers' exposure to harmful compounds in cigarette smoke. Our progress has been encouraging thus far, and we have high hopes for these products as we move forward.

- We would like very much to be able to bring these products to market in the regulated environment contemplated by the IOM Report, subject to FDA review of both the underlying science and the communications about this science that we would make to consumers. In the absence of FDA authority in this area, we are forced into making a difficult choice between making claims that haven't been validated by a government agency, on the one hand, and not providing smokers with information that may be important to them, on the other. Neither of these alternatives would be ideal, in our view, either from our own perspective or as a matter of public policy. Clearly, FDA regulation would be the best approach.

We hope that today will mark the beginning of a new and much better chapter in our nation's effort to feel confident that tobacco products, and the tobacco industry, are properly regulated, given both the dangers of the products and the acknowledgement that adults should continue to be able to make informed decisions about smoking for themselves.

We are mindful that it has been nearly eight years since Dr. Kessler made his initial rulemaking proposal, and two years since the IOM published its report.

Yet today, there is still no FDA authority to regulate tobacco products. My company wants very much to be a part of resolving the impasse and is convinced that the remaining policy differences can be resolved through mutually respectful discussions that seek such a resolution. We believe that a coherent, national tobacco policy can be crafted that will effectively deal with tobacco issues, without unintended consequences for the millions of consumers, employees, tobacco growers and retailers who will be dramatically affected by the results of Congressional action.

II. Our Support of Tobacco Products Regulation by the FDA, Including Authorities Based on IOM's 11 Regulatory Principles

The Importance of FDA Regulation of Tobacco Products

FDA regulation of tobacco products is an important Federal initiative that is certainly needed. For more than three years now, we have urged passage of an effective and comprehensive FDA regulatory policy, and we remain determined to be a constructive force in the effort that lies ahead to shape this policy.

When we say that we strongly support "effective" regulation by the FDA, we mean it. We're not playing word games or referring to a weak or watered-down plan. "Effective", to Philip Morris USA, means a regulatory plan that is designed and funded in a way that can fully accomplish its stated objectives, including:

- Providing smokers with additional information about what's in their cigarettes, and about the dangers of smoking --both now and on an ongoing basis -- as the science evolves and new information becomes available;

- Aiding in the development of products that meaningfully reduce the harm caused by smoking;
- And guiding the accurate communication of any implications of switching to reduced risk or reduced exposure products that may be developed, which includes being sure to communicate that there is no "safe" cigarette, and the best thing to do from a health standpoint is to quit smoking.

"Effective" to us does not mean regulations that are loophole-ridden or intentionally weak, punitively cumbersome, or likely to generate unintended negative consequences...it means real reforms that get the stated and agreed upon job done.

We believe that additional regulation makes sense for a number of reasons. Although these efforts are not often the focus of public attention, the fact is that we at Philip Morris USA devote enormous resources to developing products that have the potential of reducing the harm caused by smoking, running our factories, working with our suppliers, making our payroll and paying our taxes. We are asking for new regulation because today there are simply not sufficiently clear and consistent guidelines for the manufacture and performance of cigarettes. It is not clear, for example, how we and the rest of the tobacco industry should communicate to consumers about our products. What rules there are increasingly arise at the state level, which will inevitably lead to conflicting standards that could confuse consumers, disrupt interstate commerce and significantly complicate orderly and uniform manufacturing and distribution processes.

Meaningful, effective and uniform FDA regulation would better align our business practices with society's expectations, and would further our goal of

being a responsible, effective and respected manufacturer and marketer of tobacco products for adults who smoke. We believe Americans support meaningful and effective new regulation of tobacco product manufacturing processes, performance standards and how we communicate with consumers, especially about potentially reduced exposure and reduced risk products. The public also supports efforts to continue to build the momentum that has developed toward reducing the incidence of youth smoking. However, we don't believe that there is strong support in the country for the new rules to go too far, and significantly intrude on adults' continued ability to smoke if they want to.

When Philip Morris USA first announced its support for FDA regulation of cigarettes, some were understandably surprised and skeptical, in part because our company – along with other major manufacturers, retailers and advertising groups – had opposed the agency's assertion of jurisdiction over tobacco products under the medical device statute in 1996. Our opposition to FDA's unilateral initiative was not disagreement with regulation *per se*, but rather disagreement with *that specific* kind of regulation. We continue to believe that regulation of tobacco products as medical products would be a mistake – despite the fact that nicotine is a drug, and we agree that cigarette smoking, and nicotine in cigarette smoke, are addictive –because tobacco regulation needs to focus on how we can reduce the harm to society of a dangerous, agriculturally-based product that is nonetheless legal for adults to use, and the medical device rules simply are not suited to that purpose.

That is why we believe it is most appropriate that *both* major legislative proposals that have attracted attention in the past year – H.R. 140, sponsored by Chairman Davis and Representative McIntyre, and S. 2626 from the last Congress, sponsored by Senators Kennedy, DeWine and others -- regulate tobacco products under a new chapter of the Food, Drug & Cosmetic Act designed especially for such products. We're convinced that this is the right approach, and are extremely encouraged by the enormous similarities between the two bills. We believe that there is far more common ground in our views than there are differences. And, although on some issues there are some important divergences of opinion among the various stakeholders on a few issues, they are truly differences in degree only.

Our Support of Regulation by the FDA of Potentially Reduced-Exposure and Reduced-Risk Products, Based on IOM's 11 Regulatory Principles

The IOM Report "recommends strengthened federal regulation of all modified tobacco products with risk reduction or exposure reduction claims, explicit or implicit", and proposes 11 regulatory principles to "build on the foundation of existing food and drug law, with appropriate adaptations to take into account the unique toxicity of tobacco products."

Philip Morris USA has, for more than three years, been advocating many of the elements encompassed by the 11 regulatory principles contained in the IOM Report; many of these elements are already contained in bills such as H.R. 140 from this Congress and S. 2626 from the 107th Congress. As a step in moving forward to a thorough discussion of what we believe are the best

components of an FDA regulatory process, we respectfully offer the following observations about IOM's 11 principles, the degree to which they are already reflected in bills like H.R. 140 and S. 2626, and ways in which we think that the legislation can be improved so as to better translate the IOM Report's principles into legislative language:

IOM Principle #1

> ***The Principle.*** *Manufacturers of tobacco products, whether conventional or modified, should be required to obtain quantitative analytical data on the ingredients of each of their products and to disclose such information to the regulatory agency.*

- ***Philip Morris USA's Position.*** **We support the principle of providing quantitative information about the ingredients used in the manufacture of our cigarettes, with appropriate safeguards to protect trade secrets. We think that the FDA should be able to provide smokers with confidence that the ingredients added to cigarettes do not increase the inherent health risks of smoking, including increasing addiction. And, as discussed below regarding Principle #8, we have no objection to disclosing the results of our own ingredients testing to the FDA, so it can assess every ingredient we use.**

- ***Translation into Legislative Language.*** This principle is specifically covered by section 904 of the new FDA title in both H.R. 140 and S. 2626, which require all tobacco product manufacturers to provide to the agency, on an annual basis, "A listing of all tobacco ingredients, substances and compounds that are, on such date, added by the manufacturer to the tobacco, paper, filter, or other component of each tobacco product by brand and by quantity in each brand and subbrand", as well as "All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer..."

IOM Principle #2

> ***The Principle.*** *All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption; when necessary to support*

claims, human exposure to various tobacco smoke constituents should be assessed using appropriate biomarkers. Accurate information regarding yield range and human exposure should be communicated to consumers in terms that are understandable and not misleading.

- ***Philip Morris USA's Position.*** **We support this principle. We believe that the FDA should be authorized to require the disclosure of information about individual compounds in cigarette smoke, in addition to tar and nicotine, that it believes would be meaningful to consumers, as long as the information can be generated according to validated, standardized and commercially feasible test methods that reflect actual circumstances of human exposure, or reliably calculated on the basis of the test results obtained from such methods.**

- ***Translation into Legislative Language.*** There are a number of provisions in H.R. 140 and S. 2626 that specifically embody this principle. Section 511(b) of H.R. 140 and section 917(b) of S. 2626, for example, both require the FDA – within 24 months – to create rules covering "the testing, reporting, and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health. Such constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appropriate." In addition, the bills' provisions empowering the FDA to assess health claims are discussed in more detail in several of the Principles below.

IOM Principle #3

The Principle. *Manufacturers of all potential reduced-exposure products should be required to conduct appropriate toxicological testing in preclinical laboratory and animal models as well as appropriate clinical testing in humans to support the health-related claims associated with each product and to disclose the results of such testing to the regulatory agency.*

- ***Philip Morris USA's Position.*** **We support this principle. In order to support marketing claims relating to reduced exposure or reduced risk, we believe that the best approach would be for a manufacturer to (i) design a cigarette that significantly reduces various harmful compounds in the inhaled smoke; (ii) provide scientific evidence that this change reduces biological activity in appropriate cellular and laboratory animal models; (iii) measure or model adult smoker exposure to the smoke from these cigarettes; (iv) share these results with the scientific and public health communities to seek to gain their agreement that the test results are scientifically valid and**

relevant to adult smokers, and also support a conclusion that the new cigarette design may, in fact, reduce the risks of smoking; and (v) work with regulatory agencies to appropriately communicate these results and their significance to adult smokers.

- ***Translation into Legislative Language.*** This principle is largely embodied in the two major FDA bills, where section 912(a)(2) of H.R. 140 and section 913(a)(2) of S. 2626 both authorize the FDA to designate a tobacco product as "reduced risk" based on a manufacturer's application that, among other things, "demonstrates through testing on animals and short-term human testing that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances" than other tobacco products, and "if required by the Secretary, includes studies of the long-term health effects of the product." We believe that this language would more fully reflect the IOM Report's principle if, in addition to referring to "reduced risk" products, it specifically mentioned "reduced exposure" products. Clearly, as the IOM Report indicates and as its principles as a whole demonstrate, it is likely that the scientific data will support reduced-exposure claims before the FDA, or the scientific community in general, is prepared to conclude that a particular new cigarette will actually reduce the risk of contracting a tobacco-related disease.

IOM Principle #4

The Principle. *Manufacturers should be permitted to market tobacco-related products with exposure-reduction or risk-reduction claims only after prior agency approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with whatever benchmark product the agency requires to be stated in the labeling. The "substantial reduction" in exposure should be sufficiently large that measurable reduction in morbidity and/or mortality (in subsequent clinical or epidemiological studies) would be anticipated, as judged by independent scientific experts.*

Philip Morris USA's Position. **As noted above, we support the principle that the FDA should regulate "reduced risk" claims. In addition, we support the principle that claims about reduced exposure to specific tobacco toxicants (i.e., harmful compounds in cigarette smoke) should be subject to FDA oversight. We agree with the IOM Report that government analysis of proposed exposure-reduction claims, and the data that should be required from**

manufacturers to support them, should be different than with respect to claims of actual risk reduction.

- ***Translation into Legislative Language.*** Section 912(a)(3) of H.R. 140 and section 913(a)(3) of S. 2626 both partially reflect this principle, as they provide the FDA with full authority to regulate risk-reduction (but not specifically exposure-reduction) claims, including requiring that the product carry "a label prescribed by the Secretary concerning the product's contribution to reducing harm to health" and comply "with requirements prescribed by the Secretary relating to marketing and advertising of the product." H.R. 140 also reflects the IOM Report's judgment that accurate, non-misleading claims should be permitted rather than suppressed. We would respectfully suggest that the language in both bills could be improved by adding clauses that would both specifically incorporate IOM's exposure-reduction concept, and adopt this Principle's specific language regarding the proper standard for what evidence would support either an exposure-reduction or risk-reduction claim.

  We also note that S. 2626 could be interpreted to permit FDA to refuse to permit *any* truthful, non-misleading claim regarding "reduced risk" or "reduced exposure" – even if a valid scientific showing has been made – if the agency speculates that the claim could, for example, discourage quitting at some point in the future. This is a legitimate concern, but it is contrary to IOM Principle #4, and, we believe, should be addressed by clearly communicating the claim so that consumers are not misled, and accompanying the claim with a clear reminder that the best option from a health perspective is to quit. IOM also proposes dealing with this concern through post-market surveillance, which is discussed in Principle #6 below. Finally in this regard, both the Supreme Court and several Courts of Appeals have strongly indicated that the kind of suppression of truthful information advocated by some in the tobacco control community cannot withstand scrutiny under the First Amendment. A white paper discussing these cases in greater detail is attached to this Statement as Annex 1.

<u>IOM Principle #5</u>

The Principle. *The labeling, advertising, and promotion of all tobacco-related products with exposure-reduction or risk-reduction claims must be carefully regulated under a "not false or misleading" standard with the burden of proof on the manufacturer, not the government. The agency should have the authority and resources to conduct its own surveys of consumer perceptions relating to these claims.*

- ***Philip Morris USA's Position.*** **We support this principle for the reasons stated regarding Principle # 4 above.**

- ***Translation into Legislative Language***. In addition to the analysis above regarding Principle #4, we note that H.R. 140 – through its linkage of FDA regulation to a tobacco quota buyout and a user fee that would fund both the buyout and the new regulatory regime – is the only major legislative proposal currently under consideration that would ensure that, as the IOM Report's Principle #5 urges, the FDA will in fact have "the resources to conduct its own surveys of consumer perceptions relating to these claims." We would also respectfully suggest that both section 912(a)(3) of H.R. 140 and section 913(a)(3) of S. 2626 be amended so as to specifically incorporate IOM's "not false or misleading" standard for all claims regarding exposure or risk-reduction.

IOM Principle #6

The Principle. *The regulatory agency should be empowered to require manufacturers of all products marketed with claims of reduced risk of tobacco-related disease to conduct post-marketing surveillance and epidemiological studies as necessary to determine the short-term behavioral and long-term health consequences of using their products and to permit continuing review of the accuracy of their claims.*

- ***Philip Morris USA's Position***. **We support this principle as articulated and further believe it should be expanded to clearly include application to products with reduced exposure claims. As noted above, the effects of these products on the overall harm caused by tobacco is a legitimate and valid public health concern, and one which needs to be monitored and studied. And, as we believe that the FDA should be able to determine which marketing claims are appropriate, it is sensible that it should make use of the sort of surveillance and studies noted in this principle.**

- ***Translation into Legislative Language***. Both major FDA bills contain provisions that fully embody this principle. Section 912(e)(1) of H.R. 140 and section 912(a) of S. 2626 broadly empower the FDA to "require a tobacco product manufacturer to conduct postmarket surveillance for reduced risk [of] a tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product." For clarity, as indicated above regarding other provisions, we would suggest also adding an explicit reference to exposure-reduction claims, to ensure that the FDA is authorized to require post-market surveillance of them, too.

IOM Principle #7

The Principle. *In the absence of any claim of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and certifying that the product could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects or other adverse health effects, compared to similar conventional tobacco products, as judged on the basis of the most current toxicological and epidemiological information.*

- ***Philip Morris USA's Position.*** **We support this principle. As IOM notes in its report, it is logical that the regulatory agency charged with evaluating the relative risks presented by different tobacco products – which we believe is most appropriately the FDA -- should not be overwhelmed with what would be the enormous task of pre-approving every introduction of a new line extension using existing product designs, when such products do not make reduced risk or reduced exposure claims, and are certified by the manufacturer to present the same issues of public health as predicate tobacco products. Requiring pre-market approval of such products would not serve the public health interests identified by the IOM Report, and would pose substantial burdens on both the regulators and the manufacturers.**

  Moreover, we support the IOM Report's concept of placing the burden on manufacturers to certify that any new product (including any existing brand which is introduced with changed characteristics) would not present increased risk, and then, on the basis of such certification, to introduce the product (without reduced risk or exposure claims) into the marketplace. As the IOM Report suggests, the FDA would then have the authority, if upon investigation it disagrees with the manufacturer's certification and concludes that there is in fact an increased risk, to seek the product's removal from the market. We do not advocate – and we do not believe Principle #7 would require – that pre-market approval provisions "grandfather" today's tobacco products from further regulation. In whatever form they eventually take, performance standards (see Principle #9 below) would apply to *all* tobacco products (whether on the market today or introduced in the future).

- ***Translation into Legislative Language.*** All of the existing legislative proposals relating to pre-market approval are very complex, but we believe that the provisions of section 910 of H.R. 140 come the closest to fully embodying this principle. First, section 910 reflects the IOM Report's

suggestion that products carrying exposure-reduction or risk-reduction claims be treated separately from new products that do not. Second, it requires manufacturers to submit extensive information about any such new product to the FDA at least 90 days prior to commercial introduction, and empowers the agency to "suspend the distribution of the tobacco product that is the subject of that report if the Secretary determines that there is a reasonable likelihood that the tobacco product is not substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States..." Finally, the concept of "substantial equivalence" is defined in section 910(a)(2) of H.R. 140 – consistent with IOM's "no increased risk" concept -- as being a product that either "has the same characteristics as the predicate tobacco product" or, in the alternative, "has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product could not reasonably be expected to increase the health risks to consumers compared to a conventional tobacco product that is commercially marketed in the United States..."

IOM Principle #8

The Principle. *All added ingredients in tobacco products, including those already on the market, should be reported to the agency and subject to a comprehensive toxicological review.*

- ***Philip Morris USA's Position.*** **We support this principle for the reasons stated regarding Principle #1 above and Principle #9 below.**

- ***Translation into Legislative Language.*** From a legislative perspective in the major FDA bills, toxicological assessment of ingredients is part and parcel of the agency's performance standard authority, which is discussed below in the context of IOM Principle #9.

IOM Principle #9

The Principle. *The regulatory agency should be empowered to set performance standards (e.g., maximum levels of contaminants; definitions of terms such as "low tar") for all tobacco products, whether conventional or modified, or for classes of products.*

- ***Philip Morris USA's Position.*** **We support this principle, and have been actively advocating a Congressional grant of authority to the FDA to reduce harm by imposing mandatory performance standards on tobacco products, even including those that would require design changes that consumers might not like. Our main concern with this**

concept is that, if not translated carefully into legislative language, it could permit – or even require -- the agency to do what nobody should want: to impose performance standards requiring changes that are so radical that tobacco products are effectively banned, or consumers are driven away from the legitimate market and towards illicit, completely unregulated products. We think that consumers, tobacco growers and many other stakeholders support our view that these standards should not make tobacco products unpalatable for adult smokers; no one would benefit from performance standards so radical that they further increase the demand for counterfeit or other illicit products.

Specifically, we believe that the FDA should have the authority to ensure that ingredients used in the manufacture of tobacco products do not increase their inherent health risk or addictiveness; because the ingredients are under the manufacturers' control, this authority should, in our view, *include the power to prohibit the use of any ingredient shown to increase health risks even if the ban would impact the product's taste.* Apart from ingredients, we also support authority for the FDA to impose changes to the other design or inherent characteristics of a tobacco product – including the inherent properties of tobacco leaf itself -- that it finds will protect public health, so long as the changes are technically feasible and would not negatively impact adult consumers' enjoyment of the product in a significant way. There is no public consensus supporting FDA actions that force radical changes on the design or inherent characteristics of today's tobacco products that adult smokers may not be prepared to accept. We believe that instead, FDA should use its enormous persuasive powers and regulatory tools to encourage consumers to quit, or – by utilizing the reduced risk/reduced exposure authorities contemplated by IOM's other principles -- to switch to products whose design and composition the agency favors from a public health perspective.

Ingredients. The major legislative proposals currently under consideration – including both H.R. 140 and S. 2626 -- contemplate the use of "performance standard" authority by the FDA to regulate ingredients used in the manufacture of tobacco products based on its belief of what would be appropriate to protect public health. We believe that this is a legitimate role for the agency to the extent it is used to ensure that ingredients do not increase the inherent risk of cigarette smoking, including by increasing its addictiveness. Tobacco products are inherently dangerous, but the government should have authority to make sure that nothing is used by manufacturers to make them even more so. Philip Morris USA stands ready to submit all of its ingredients to rigorous FDA review

and testing, to share the results of testing it has previously conducted, and to work with the agency as it makes its own assessment of any added risks they may present.

An approach that focuses on increased risk from ingredients has been explicitly adopted by the IOM Report, which asserts that "...[FDA] should...have the authority to remove from the market ingredients...that do not meet [a] test of no increased risk..." To be clear, we think that FDA authority to test and, if necessary, prohibit the use of specific ingredients it finds to increase the inherent risks of smoking should apply to ingredients currently in use as well as to new ones. There should be no "grandfathering."

However, FDA authority over ingredients should not, in our view, extend beyond the concept of "increased risk". A broader scope – for example, based purely on what would be "appropriate to protect public health" -- could permit the agency, for example, to prohibit specific ingredients solely because they improve the taste of a tobacco product, on the theory that, by trying to make the products taste bad, consumption will drop and public health will be benefited. Under such an approach, the FDA could even order that bad-tasting ingredients be *added* to cigarettes, so as to decrease their palatability. These powers would be, we respectfully submit, simply incompatible with the principle that tobacco products are legitimate and that adults should continue to be permitted to consume them if they wish. To quote from the preamble to the FDA's own proposed tobacco rule from 1996:

> *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.*

If regulation of cigarettes is to be based purely on eliminating their known inherent dangers, we readily agree that it would be best if nobody smoked at all. But Americans want to see a new regulatory regime that incorporates other values as well – tolerance, adults' continued ability to make their own decisions about issues that affect their health, law enforcement considerations, and the degree to which government should intrude generally into the realm of personal issues.[1] If Congress is to reflect this consensus and balance these competing concerns, it will need to tailor FDA's

[1] Indeed, the reason that the Supreme Court rejected FDA's initial "medical device" tobacco rule is that it determined that, under that approach, the agency would have *been required* to ban tobacco products, and that such a ban could not be squared with the overall national tobacco policy already put in place by Congress.

authority so that it is focused on encouraging quitting and harm reduction for adults who continue to smoke, rather than trying to force Americans to adopt tobacco-free lifestyles.

Smoke Constituents and Other Performance Standards. **For the same reasons, we believe that the FDA should have broad power to require the reduction or elimination of smoke constituents (the compounds produced by tobacco when burned), that will seek to reduce harm while ensuring that the agency will not order mandatory performance standards that are technically infeasible, or could only be met by design changes in tobacco products that adult smokers find unacceptable. For example, if there is no limitation whatsoever contained in the performance standard authority, the agency could force rapid, radical reductions in tar and nicotine yields, or require that manufacturers utilize filters that would eliminate the products' taste. Strategies such as these may well be legitimate in the effort to reduce harm, but we respectfully suggest that the strategies are best dealt with under the FDA's authority over reduced exposure and reduced risk tobacco products, discussed above.**

- ***Translation into Legislative Language.*** H.R. 140 and S. 2626 both fully embody -- with one important difference between them -- IOM's suggestion that the FDA be provided with specific authority to impose performance standards, including those relating to added ingredients and smoke constituents. Section 907(a) of both bills empower the agency to

> adopt performance standards for a tobacco product if the Secretary finds that a performance standard is appropriate for the protection of the public health. This finding 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. A performance standard established under this section for a tobacco product shall include provisions to provide performance that is appropriate for the protection of the public health, including provisions, where appropriate--(i) for the reduction [or elimination][2] of nicotine yields of the product; (ii) for the reduction or elimination of other harmful constituents or harmful components of the product...

The authority this language confers over ingredients extends beyond the concept of "increased risk". By permitting the FDA to change any ingredient if it concludes that such action is "appropriate to protect public

[2] This bracketed language appears only in S. 2626.

health" (so long as the removal does not render the tobacco product "unacceptable for adult consumption"), H.R. 140 would appear to permit FDA, for example, to prohibit or reduce specific ingredients solely because they improve the taste of a tobacco product, on the theory that, by trying to reduce the product's palatability, consumption will decline and public health will benefit. We're pleased that the notion of adult acceptability appears in H.R. 140, because it is compatible with the principle that tobacco products are legitimate and that adults should continue to be permitted to consume them if they wish. We respectfully suggest, however, that Congress consider revising this language, insofar as it relates to ingredients, to more fully reflect IOM's "no increased risk" concept.

For the same reasons, we appreciate the fact that H.R. 140's performance standard authority applies the concept of adult acceptability to FDA's power to require the reduction or elimination of smoke constituents, or to order other mandatory design changes in tobacco products. Sensibly, the bill appears to contemplate that the FDA will use its authority regarding reduced risk and reduced exposure products – including those with low initial consumer acceptability -- to encourage the proliferation of new product designs that have the potential of reducing the harm caused by smoking. Using this authority, the agency will have enormous ability to use its credibility with the American people to persuade adult smokers to switch to any alternative product designs of its choosing. New products that achieve a critical mass of adult consumer acceptance would then be ready to move to the next regulatory phase. If FDA concludes, after monitoring the marketplace in the manner suggested by IOM, that such a product innovation has been proven to reduce harm in the long term, the agency could – and, in our view, should – incorporate the results of the technology into a performance standard so that it becomes the new baseline for the entire category of tobacco products.

The performance standard authority in S. 2626 does not contain any concept of adult acceptability, or any other limitation on the FDA's authority to radically re-design tobacco products "to protect the public health." There is clearly a difference of opinion between those who believe that there needs to be specific policy direction from Congress to the FDA regarding consumer acceptability, and others who view health impact as the sole issue that the agency should be permitted to consider when it sets performance standards for tobacco products. We would note in this regard that every regulated consumer product is governed by a statutory standard reflecting Congress' policy judgment as to the values governing the rulemaking process. Just as medical devices need to be "safe and effective", a motor vehicle standard may only be imposed if it is "reasonable, practicable, and appropriate for the particular type of motor vehicle...", and standards under the Consumer Products Safety Act

require a finding regarding "...the probable effect of such rule upon the utility, cost, or availability of such products to meet such need."

Our view is that FDA's performance standard authority should recognize tobacco products as legitimate for adults to use if they wish; that the agency should operate within some reasonable boundaries making it clear that its mission is not to phase them out entirely. To us it seems entirely plausible that, under a pure "public health" standard, FDA could (or could be forced to) conclude that it is better for public health overall to ban tobacco products; that Prohibition would result in millions of people quitting, and that having millions more seeking black market products is an acceptable trade-off. Even if valid from a health perspective, this conclusion would not be good policy.

The opposition by some to any notion of "consumer acceptability" for tobacco products has been justified by concerns that the term's vagueness will lead to "endless litigation", and that "a reduction of tobacco consumption by 1% or less could be the basis for an industry claim that a new performance standard has left the product unacceptable to adults."[3] There are responses to these concerns: many countries around the world have clearly demonstrated that it is possible to gradually impose performance standards on cigarettes that governments deem beneficial within the realm of what adults will accept; for example, the European Union has, over the past several years and taking a step-by-step approach, established increasingly lower ceilings on tar, nicotine and, more recently, carbon monoxide yields as measured by machine tests. Moreover, it is unclear why "consumer acceptability" should be any more susceptible to court challenge than equally-vague standards endorsed by the same advocates (and included in both S. 2626 and H.R. 140), such as "the increased or decreased likelihood that existing users of tobacco products will stop using such products", and, under the well-known *Chevron* doctrine, FDA would be afforded substantial deference by the courts in determining what the language means. In any case, there surely ought to be some language that can be worked out that would introduce some notion of reasonableness into the FDA's performance standard calculus, avoid unintended consequences, and serve the public health objective of tough, meaningful authority that will lead over time to real changes in tobacco products, and a significant reduction in the harm that they cause.

IOM Principle #10

The Principle. *The regulatory agency should have enforcement powers commensurate with its mission, including power to issue subpoenas.*

[3] Written statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, to Senate HELP Committee (September 19, 2002).

- ***Philip Morris USA's Position.*** **We support this principle. We have spoken extensively about the need for meaningful and effective regulation of tobacco products; such regulation can be neither "meaningful" nor "effective" without adequate enforcement powers for the FDA.**

- ***Translation into Legislative Language.*** H.R. 140, like S. 2626 before it, fully incorporates the existing enforcement authorities that the FDA is provided under the Food, Drug & Cosmetic Act, and applies those powers to enforcement of the new tobacco products chapter that the bill would create. We would respectfully suggest, in light of the recent influx of inexpensive foreign tobacco products – some of which are not in compliance with existing Federal and State laws applicable to all tobacco products, domestic or foreign -- into our country, that these mechanisms be examined to ensure that the FDA will be both authorized and directed to ensure that *all* manufacturers and importers are required to fully comply with the full panoply of restrictions, requirements and standards that the agency decides to impose.

IOM Principle #11

The Principle. *Exposure reduction claims for drugs that are supported by appropriate scientific and clinical evidence should be allowed by the FDA.*

- ***Philip Morris USA's Position.*** **We support this principle. Our belief in the ability of adults to make their own decisions about smoking – and not smoking -- encompasses cessation of tobacco use, including the use of pharmaceutical therapies for those smokers who want to quit, are having difficulty, and believe that the treatments might help.**

- ***Translation into Legislative Language.*** IOM correctly notes that, under current U.S. law, the FDA already has authority in this area for drugs and medical devices; this issue need not be addressed legislatively as Congress considers a new chapter of the law relating to tobacco products. We believe strongly that cigarettes should be regulated as cigarettes, and not as medical products. This means that, as both H.R. 140 and S. 2626 provide, cigarettes should be regulated by FDA, but under a separate chapter of its governing statute. We're convinced that any legislation that attempts to shoehorn tobacco products into the existing medical categories is, as the Supreme Court has already found, simply taking the wrong approach.

III. Our Efforts to Develop Tobacco Products that Could Eventually Reduce the Harm Caused by Smoking

Having described the regulatory regime that we believe should be built to apply to all tobacco products – both conventional and novel -- we now turn to the status of Philip Morris USA's efforts to develop products that we hope will be subject to these new regulations. One of our highest priorities today continues to be the development of cigarettes that have the potential to reduce the harm caused by smoking. The IOM Report exhaustively examines many of the issues involved in attempting to achieve this goal by reducing smokers' exposure to harmful compounds in cigarette smoke.

Simply put, the public health community has identified a number of compounds – out of the thousands present in cigarette smoke -- that are potentially harmful to smokers, without definitively settling on any specific one (or combination of them) as the recognized cause of lung cancer or other smoking-related disease. Accordingly, our basic strategy is to reduce smokers' exposure to as many of these compounds as we can, by means of products that will provide continued enjoyment to our consumers. If we're successful in finding ways of both reducing potentially harmful compounds and reducing smokers' actual exposure to them under real-world conditions, we believe that – although it will take some time – the FDA will be in position to help us evaluate whether our product development efforts are actually reducing the risk of tobacco-related diseases among current smokers. Then, determinations can ultimately be made about whether any reduced-risk tobacco product results in overall harm reduction

across the population, because its risk-reduction potential is not offset by other factors, such as changes in smoking behavior, discouraging current smokers from quitting or encouraging nonsmokers to start.

Our goal – which we believe provides *both* societal *and* shareholder value -- is to design the best products that we can, and then, ideally under the regulatory oversight of the FDA, to convince as many adult smokers (who don't quit) as possible to use them. 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 are successful at developing and making available tobacco products that reduce smokers' exposure to harmful compounds compared to conventional cigarettes, and second, that current smokers are given a reason – through the communication of truthful, non-misleading information that avoids unintended consequences – to switch to these products, even though they may be less enjoyable than the cigarettes that most adults smoke today. For people who continue to smoke, we believe that this is the best way to assure that the overall harm caused by smoking will be meaningfully reduced.

We have extensive research programs, both external and internal, that are focused on advancing our knowledge about tobacco smoke, including the compounds of smoke and smokers' actual exposure to them, to support our efforts to develop new product designs. We are continuing to devote substantial research and development efforts to develop and launch cigarettes that significantly reduce smokers' exposure to compounds that have been identified

by public health authorities as harmful or potentially harmful. We are making progress in this area, and hope to introduce new products with appropriate consumer communications as quickly as possible.

For example, one current result of our efforts is the introduction of an electrically heated cigarette smoking system (EHC), called Accord, in a limited test market without communications to consumers regarding reductions in potentially harmful compounds. The specially-designed lighter heats the EHC to a lower temperature than that at which a lit cigarette burns; the lower the temperature of the tobacco, the lower the quantities of certain harmful compounds. In comparing the EHC to a standard lit-end industry reference cigarette, we first made evaluations of smoke chemistry, Ames activity (a measure of damage to DNA), cytotoxicity (a measure of cell damage and tissue irritation), and inhalation exposure in laboratory rats. Philip Morris USA scientists have shared many of these results with their colleagues in the scientific community; examples of their presentations are available on online at http://www.ehcss-science.com.

More recently, we have conducted tests – including both clinical studies to assess the levels of potentially harmful compounds that smokers are actually exposed to, and machine tests that we believe more closely approximate actual smokers' behavior than the existing FTC method -- comparing the results of smoking the EHC to those of smoking various commercially available conventional cigarettes. While we are still in the process of evaluating these

tests, we hope that they will show that smokers of the EHC were exposed to substantially lower amounts of certain harmful compounds present in tobacco smoke than smokers of the conventional brand styles that were tested.

In addition, we are working very hard on the development of a conventional lit-end cigarette which includes a state-of-the-art filter, that uses activated carbon that we hope will be shown to reduce certain harmful compounds in smoke. It works like a carbon water filter, which reduces some of the unwanted things in the water that people drink. This prototype cigarette design also includes flavor components to add flavor to replace tobacco flavors trapped by the carbon.

Neither the EHC nor the cigarette with the new filter has been proven to reduce the risk of smoking-related disease, and smokers of these products would still be inhaling many compounds that are potentially harmful. But we believe that these product technologies show promise for the future, and that the FDA should be empowered as quickly as possible so that the agency can begin to work with us to evaluate their potential for reducing the risk of contracting smoking-related disease, and the overall harm to the population caused by smoking.

As we consider the details of the various legislative proposals that are active today, we respectfully urge Congress to keep in mind that innovation in developing new products are crucial to their ultimate success. In order to have any real impact, reduced exposure products must be acceptable to adult

smokers. We see little overall benefit to consumers or society if harm reduction is not pursued in the context of cigarettes that adult consumers will continue to enjoy smoking. As the 1998 Canadian Experts' Committee on this subject concluded, "[i]f smokers would not buy these products, product modification initiatives would fail."

IV. The Wisdom of the IOM Principles, and the Need for Action.

We now turn to a general overview of the policy issues relating to potentially reduced exposure and reduced risk tobacco products. This portion of our statement discusses our strong belief that FDA regulation -- in line with the IOM Report's recommendations -- is an essential component to an effective overall harm reduction strategy, the debate over whether this strategy is a good one, and the consequences of simply preserving the status quo.

The Need for FDA Regulation of Innovative Tobacco Products

We strongly agree with the IOM Report that governments should help determine what is, and what is not, a "reduced exposure" or "reduced risk" tobacco product. Clearly, the best approach is for regulatory authorities to make such determinations, based on the best available scientific information. As the IOM Report indicates, a product should be designated and marketed as "reduced exposure" or "reduced risk" upon an adequate showing of potential exposure or risk reduction to current smokers. Whether a product offers potentially reduced exposure or risk to an individual smoker is a purely scientific (as opposed to a

policy) question that FDA should determine based on the data; the policies of encouraging quitting, discouraging nonsmokers from starting and assessing overall harm reduction across populations is a separate question, and can and should be dealt with through post-market surveillance, educational programs and appropriate labeling.

Moreover, we believe that the purpose of regulation in this area – and the specific details of the FDA's legislative mandate -- should be to encourage innovation, not to stifle competition and the development of potentially beneficial new technologies. We hope that everyone can agree that the FDA should not inadvertently be directed or permitted to actually *inhibit* the development of these products, and in the process to deny millions of today's smokers a genuine opportunity to potentially reduce their chance of contracting smoking-related diseases.

Once, as a matter of science, the FDA concludes that a new product has the potential to offer reduced exposure or reduced risk, the best approach would be for the agency to play an important role in overseeing any claims – explicit or implied -- made about it by its manufacturer regarding exposure or risk-reduction.

Crafting appropriate claims regarding these tobacco products is an undertaking requiring great care and attention; we are mindful of the critical need for manufacturers to work with the FDA so that marketing messages clearly communicate that all smoking can be harmful, and that the best option from a health perspective is to quit. Once again, as with determinations regarding the

scientific issues of potential exposure and risk-reduction, we believe that the best approach is for the FDA to decide what communications to consumers are appropriate on this subject.

On the one hand, regulation should ensure that consumers are not mistakenly led to believe that a particular product may be an acceptable alternative to quitting from a health perspective. On the other hand, regulation should not be utilized as a tool to suppress legitimate, accurate and objective information about product developments that individuals may find to be beneficial or important. The key here is for all communications to consumers to be truthful and not misleading in the context of the fact that there is no safe cigarette.

The Debate Over Harm Reduction as a Strategy

The IOM Report was commissioned by the FDA to (in the Report's words) "address the science base for harm reduction from tobacco. The committee concluded early in its deliberations that the science base for harm reduction will evolve over time."

We're 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, because they are concerned that their availability might discourage smokers from quitting or encourage them to start smoking. These advocates appear to believe that the *only* acceptable message for the government to communicate, irrespective of potential alternatives, is a

directive to not consume tobacco products at all. Philip Morris USA respectfully disagrees with this way of thinking, and strongly believes that it would be wrong, if products that could ultimately reduce the harm caused by smoking are developed, to deny adult smokers access to information about their potential benefits. We're convinced that information about potentially reduced-exposure or reduced-risk products – that is truthful and not misleading – should be disclosed to consumers, so that they can consider the information and then decide for themselves which path to take.

The IOM Report has some important things to say about the debate over whether "reduced exposure" and "reduced risk" tobacco products should be pursued:

> **Some public health officials oppose the adoption of harm reduction strategies because of concerns that promoting this approach will not, over the long term, prove to be beneficial to public health or to the individual tobacco users who might otherwise have quit. Whatever the merits of this position, marketplace forces already at work have put this issue on the policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products...Manufacturers should be permitted to market tobacco-related products with exposure reduction or risk reduction claims only after [FDA] approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, compared with whatever benchmark product [FDA] requires to be stated in the labeling... [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...**

The IOM Report recommends, among other things, that manufacturers be given "the necessary incentive to develop and market products that reduce exposure to tobacco toxicants"; that consumers be "fully and accurately informed" about the health consequences of these products; that claims about their potential for reducing harm be regulated; and that research be conducted to ascertain the products' "potential for harm reduction for individuals and populations."

In the absence of the regulatory oversight recommended by the IOM Report, Philip Morris USA is, as discussed in section III of this statement, making a genuine effort to develop potentially reduced exposure products in accordance with the Report's recommendations, recognizing that there is currently no regulatory agency to validate Philip Morris USA's research and development efforts, or any independent scientific experts available to fully assess these efforts without funding from either the government or ourselves.

The Status Quo is Unacceptable

The questions regarding the IOM Report's recommendations and harm reduction as a strategy are important ones, worthy of thorough discussion, and we urge Congress to find the common ground and to pass legislation which will finally resolve them.

Without Congressional action, Philip Morris USA will continue to face a genuine dilemma. We're aware that it would not be ideal to begin to communicate to consumers about our new products' potential benefits in the absence of FDA regulation; this is an important reason that we have been

seeking it for such a long period of time. However, without new legislation and the regulatory oversight that would follow, we are faced with the choice of making good faith communications about our new products based solely on our rigorous internal and external scientific processes and our scientists' engagement with external stakeholders, or not communicating information that may prove to be important to over 40 million consumers across the country. We note in this regard that time is not standing still – many of Philip Morris USA's competitors are already communicating directly with consumers about their new product designs; as the IOM itself said in its report, "marketplace forces already at work have put this issue on the public policy agenda, and new products are being developed and offered as harm-reducing alternatives to conventional tobacco products."

Without new legislation that implements the IOM Report's principles, we would undoubtedly face criticism no matter which path we choose to take – but it is truly the millions of adult smokers in this country who have the most at stake here; we strongly believe that we would all be doing them a real disservice if we fail to come together to support the passage of legislation that will implement the IOM Report's recommendations, and place the FDA in the center of the critical decisions about tobacco products that, with or without regulation, are going to need to be made in the months and years ahead.

V. Conclusion

We believe that Congress has the opportunity to forge a new national tobacco policy that will create substantial new authority for the FDA to adopt regulations for tobacco products in accordance with the principles articulated in the IOM Report, while continuing to permit adults who wish to use them to do so legally. The issues you are considering today could make a substantial contribution to progress towards that goal. We hope this statement provides you with helpful input, and makes it clear that our company truly is supportive of a comprehensive and effective new regulatory regime that includes every area addressed by the IOM Report, and in practice will actually result in what we think everyone should be able to agree upon as a primary objective: reduced harm from tobacco consumption for both current and future generations.

We also hope that you agree with our conclusion that the status quo simply is not serving the needs of American smokers, and that, as the IOM Report has noted, novel tobacco products are being – and will continue to be – marketed under whatever regulatory regime is in place. The issue before us is not whether such products will come into being; but rather what the degree of the governmental oversight of them will be. These issues are complex and controversial, but we pledge to work with anyone and everyone who wishes to join in this challenge, and commend this Committee for the progress this hearing represents as a critical next step.

Annex 1

THE DEBATE OVER REDUCED-EXPOSURE AND REDUCED-RISK TOBACCO PRODUCTS: *Full Disclosure vs. Government Suppression of Truthful and Non-Misleading Information*

Competing proposals to give FDA regulatory authority over tobacco products take different approaches to regulating potentially "reduced-exposure" and "reduced-risk" tobacco products. These products have the potential to reduce the health risks associated with conventional tobacco products by, for example, lowering the smoker's exposure to toxic substances in the smoke. This paper takes the view that the approach most consistent with sound public policy and First Amendment protections is that which provides consumers with more information, rather than less or none at all. The public health safeguard in this approach is that FDA would decide both whether a product does indeed present reduced exposure or reduced risks, and what marketing claims may be made about the product. But once this determination is made, neither FDA nor any other government body could gag *truthful and non-misleading information about the product.*

Executive Summary

The debate over how to regulate these products has resulted in a debate over consumer communications. On one side are those who share the view that the government should simply evaluate claims based on their scientific merits and deal with any public health concerns by providing for ***full disclosure to consumers*** and through other public health measures. On the other side are those who fear that the very existence of these products, despite the fact that FDA would review, approve and regulate any accompanying claims, would have a net adverse public health impact by encouraging more people to start smoking in the first place and/or by discouraging from quitting people who adopt the misguided view that smoking is now "safe." Therefore, this contingent supports giving the ***government authority to suppress*** reduced-exposure and reduced-risk claims about tobacco products.

The government suppression tact flies in the face of the First Amendment and sound public policy. The Supreme Court has made clear that suppression of information is not a useful or suitably tailored restriction on commercial speech.

The notion that benefits would result from suppressing truthful and non-misleading information tobacco products is premised on the speculation that adults might use this information in a manner that is disfavored by the government. A benefit deriving

from this kind of paternalistic assumption, however, is not one that the Constitution recognizes as legitimate. Further, even if suppressed by the government, information concerning novel tobacco products is likely to reach consumers through any number of alternative sources. And FDA or another government agency will not have scientifically vetted this information.

Moreover, suppressing information on reduced-exposure and reduced-risk tobacco products would not necessarily advance the government's interest in protecting public health. In order to provide this speculative benefit to certain individuals, the government would have to impose clear harms on others -- specifically, on those people who will use tobacco products regardless and who, because of the suppression of information, would be denied the ability to select products with demonstrated potential benefits. Thus, a significant part of the population may be denied crucial information in order to "protect" a speculative segment of the population.

In addition, the government has available to it more narrowly tailored means of advancing its public health interests. For example, it could:

- ensure that consumers are given all necessary information to ensure that they are not misled regarding the health risks that remain with reduced-exposure and reduced-risk tobacco products, or that quitting or not starting is still the most risk-free approach; and
- stress other public health programs to encourage smoking cessation and prevention.

In short, to quote the Supreme Court, ***"the preferred remedy is more disclosure, rather than less,"*** Bates v. State Bar of Arizona, 433 U.S. 350, 375 (1977) (emphasis added), and "[i]f the First Amendment means anything, it means that ***regulating speech must be a last -- not first -- resort***." Thompson v. Western States Medical Center, 122 S.Ct. 1497, 1507 (2002) (emphasis added). Indeed, "if the [g]overnment [can] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment ***must*** do so." Id. at 1506 (emphasis added). Accordingly, legislation should task FDA with reviewing claims based on their scientific merits. FDA also should have ample authority to ensure that consumers are provided with full disclosure regarding such products. Other public health tools should supplement these efforts by continuing to encourage smoking cessation and prevention. This approach is consistent with the approach outlined by the Institute of Medicine: "The regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, as long as steps are taken to ensure that consumers are not misled . . . ." Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (2001), at 7-13.

I. BACKGROUND

In 2001, the Committee to Assess the Science Base for Tobacco Harm Reduction (the "Committee") of the Institute of Medicine ("IOM") issued a report on reduced-exposure and reduced–risk tobacco products commissioned by the Food and Drug Administration ("FDA").

The Committee made clear that it recommends a regulatory approach based on *sound science* and *full consumer disclosure*. Prior to detailing its principles for the regulation of reduced-exposure and reduced-risk tobacco products (which the Committee referred to as "potential reduced-exposure products," or "PREPs"), the Committee stated:

> "The committee did come to conclude that regulation of PREPs is necessary and feasible . . . . *[R]egulation is needed to ensure that the product labeling and advertising do not mislead consumers and accurately describe the products' risks, including the uncertainties that can only be resolved after long-term use.* Consumers should not use these new products on the basis of explicit or implicit claims that these products carry less risk than traditional tobacco products unless such claims are true. Absent careful regulation of industry claims about these products, informed choices by consumers will not be possible, the potential benefit of harm reduction strategy is likely to go unrealized, and the long and unsettling saga of light cigarettes may well be repeated."

IOM Report, at 7-2 (emphasis added).

Notwithstanding IOM's recommendations, however, certain legislative proposals to grant FDA authority to regulate tobacco products appear to authorize FDA to suppress information about PREPs even if FDA has verified that these products actually have the potential to present potential benefits for consumers. For example, some proposals would permit manufacturers to make reduced-exposure or reduced-risk health claims only if

FDA determines that the product actually reduces the risk of harm to individuals as a matter of science and is otherwise "appropriate" for the "public health."[1]

This type of two-prong standard -- with a "scientific merits prong" and an "appropriateness" prong -- appears to respond to those segments of the public health community that have called for FDA discretion to suppress reduced-risk claims, notwithstanding their veracity, based on their potential effect on consumer behavior. See, e.g., National Cancer Society et al., Why the FDA Should Regulate Tobacco Products (June 27, 2002) (stating that FDA should have the authority "to prohibit or restrict . . . claims that discourage people from quitting or encourage them to start using tobacco"); Campaign for Tobacco Free Kids, Critical Elements of FDA Authority Over Tobacco (Feb. 18, 2000) ("FDA should have the authority to prohibit . . . health claims that have an adverse effect on the overall risk to the American public . . .").[2]

Thus, under this two-prong standard, even if valid scientific evidence demonstrates to FDA's satisfaction that a product presents potential benefits, the agency could prohibit truthful and non-misleading information about the product's reduced-exposure or reduced-risk potential from being communicated to consumers in the marketplace.

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[1] See e.g., H.R. 936, 108th Cong. § 572(a)(1), (2) (stating that FDA must determine that "based on the best available scientific evidence the product significantly reduces the *overall health risk to the public* when compared to other tobacco products," and that in approving reduced-risk claims, FDA must "ensure [the claim's] accuracy and, in the case of advertising, . . . *prevent such statement from increasing, or preventing the contraction of, the size of the overall market for tobacco products*" (emphasis added).

[2] For example, H.R. 936 provides that FDA must prevent reduced-risk advertising claims from "increasing, or preventing the contraction of, the size of the overall market for tobacco products." H.R. 936 § 575(a)(2).

II. THE FIRST AMENDMENT PRECLUDES THIS KIND OF SUPPRESSION OF INFORMATION

This approach to the regulation of PREPs would violate the First Amendment and sound public policy. First, the suppression of information would not materially and directly advance the government's legitimate interests in encouraging tobacco cessation and prevention. Instead, the suppression of information would harm a clearly identifiable group of individuals. Second, the government has far more tailored means at its disposal to address any impact of PREPs on the rates of smoking cessation and initiation. Such alternatives include the mandatory use of public health disclaimers to ensure that PREPs are not perceived as safe, and the pursuit of other public health programs to encourage tobacco cessation and prevention.

The Supreme Court repeatedly has held that once a product is legally sold in the United States, the government may not deny adults truthful and non-misleading information about the product. Rather, the government must adopt more tailored restrictions to achieve its legitimate purposes. As the Supreme Court stated in its seminal commercial speech case:

> "There is, of course, an alternative to [a] highly paternalistic approach [to regulating commercial speech]. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them . . . . It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

"[B]ans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." Thompson v. Western States Medical Center, 122 S.Ct. 1497, 1508 (2002), citing 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996) (plurality opinion).

In Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the Supreme Court struck down certain restrictions on the advertising of tobacco products because those restrictions were not sufficiently tailored to fit the government's objective of protecting children. This holding reaffirmed that the Court will carefully scrutinize commercial speech restrictions, including in the case of tobacco products, to determine if less restrictive means are available to achieve the government's purpose. The Reilly Court also made clear that commercial speech restrictions continue to be subject to the following four-part inquiry developed by the Supreme Court in the Central Hudson case:

> "For commercial speech to come within [the First Amendment], it at least must concern a lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the government interest asserted, and whether it is not more extensive than is necessary to serve that interest."

447 U.S. 557, 566 (1980). "We have said that the last two steps of the Central Hudson analysis basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." Rubin v. Coors Brewing Co., 514 U.S. 476, 486 (1995).

Simply put, the suppression of information about PREPs does not fit the government's interest in encouraging tobacco cessation and prevention.

A. The Suppression of Reduced-Risk Information Would Elevate Presumed Paternalistic Benefits for Some Over Real Harms for Others

The premise behind providing FDA with authority to suppress truthful and non-misleading information appears to be that the costs associated with the possible changes in the rates of cessation and initiation might outweigh the benefits resulting from communications about PREPs. To tilt the balance in this fashion, however, one would have to value the presumed benefits that may be provided to some individuals over the real costs that would be imposed on others. Such conjecture, however, cannot justify the suppression of truthful and non-misleading commercial speech under the First Amendment. "Such speculation certainly does not suffice when the [government] takes aim at accurate commercial information for paternalistic ends." 44 Liquormart, 517 U.S. at 507.

Moreover, as detailed below, an abstract discussion about costs and benefits fails to illuminate the serious consequences of suppressing truthful information about PREPs.

1. The Paternalistic and Speculative Benefits Provided by the Suppression of Information Are Insufficient to Pass Constitutional Muster

The suppression of information presumably would be intended to benefit that segment of the population that would quit or never initiate smoking if information about PREPs is not available, but who would choose to switch to or begin using them if they were made aware of these products. Viewed from a "paternalistic" perspective, this segment of the population would be benefited by the suppression of information.

Attempting to justify the suppression of information on this basis, however, is at odds with the Constitution, because paternalism is not a legitimate governmental interest, and because the realization of this paternalistic benefit would be impermissibly speculative.

The government "does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes . . . ." 44 Liquormart, 517 U.S. at 510. Indeed, the Supreme Court has "rejected the notion that the [g]overnment has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." Western States, 122 S.Ct. at 1507. "[T]he argument [for suppression] assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public . . . . [W]e view as dubious any justification that is based on the benefits of public ignorance." Bates v. State Bar of Arizona, 433 U.S. 350, 374-375 (1977). "To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection . . . is practically an engraved invitation to have the restriction struck." Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 70 (D.D.C. 1998) (judgment vacated on other grounds). "[T]he government may not restrict speech because it fears, however justifiably, that the speech will persuade those who hear it to do something of which the government disapproves." David A. Strauss, Persuasion, Autonomy, and Freedom of Expression, 91 Colum. L. Rev. 334, 334 (1991).

Moreover, this justification for suppression of information would fail the third prong of the Central Hudson test because it would require the court "to engage in the sort

of 'speculation or conjecture' that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the [government's] asserted interest." 44 Liquormart, 517 U.S. at 507. For example, in Rubin v. Coors Brewing Co., 514 U.S. 476 (1995), the Court concluded that the government's prohibition on displaying alcohol content on beer labels failed the third prong of Central Hudson because it would not sufficiently advance the government's interests in preventing "strength wars" in the marketing of alcoholic beverages. The Court reasoned that the government's burden "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Id. at 487, quoting Edenfield v. Fane, 507 U.S. 761, 770-771 (1993).[3]

It is far from clear that suppressing information would "in fact alleviate" the perceived harms that might arise from the introduction of PREPs. Any information suppressed by the government likely would find its way to consumers through other channels, though almost certainly in a less accurate form that has not been subject to scientific verification. As the IOM Report notes, "marketplace forces already at work have put this issue on the public policy agenda," and consumers will seek out PREPs "with or without scientific guidance." IOM Report at 7-1, 7-2. Moreover, as discussed

[3] When viewed from a more "utilitarian" perspective, these individuals are not benefited at all by the suppression of information. From this perspective, adults are better off if they are left free to make their own decisions based on full information. As University of Chicago Law School Professor Cass Sunstein puts it, "people should be allowed to select their preferred mixes of risk, employment, salary, medical care, and so forth." Cass R. Sunstein, Informing America: Risk, Disclosure, and the First Amendment, 20 Fla. St. U. L. Rev. 653, 659 (1993); see also Martin H. Redish, Tobacco Advertising and the First Amendment, 81 Iowa L. Rev. 589, 592 (1996) ("The asserted justifications for such regulation of the truthful promotion of a lawful product derive exclusively from a premise of governmental paternalism that is fundamentally inconsistent with both the purposes served by free speech and the democratic system of which free speech is a central element.")

below, any advance in the public health that purportedly results from the suppression of information would be undermined by the adverse effects of such suppression on individuals who would have used PREPs had the suppressed information been available to them.

2. Real Harms Would Be Imposed by the Suppression of Information

Though the benefits to be derived from the suppression of information about PREPS are speculative, it is clear that a separate group of individuals would be harmed by the suppression of such information. This group consists both of smokers who would have switched to PREPs instead of continuing to use conventional tobacco products, and nonsmokers who would have begun using PREPs instead of conventional tobacco products if they had been provided with information about PREPs. Regardless of one's philosophical bent, everyone should agree that this group, which ends up taking on more risks solely because of the suppression of information, is substantially harmed by that suppression.

It is neither sound public policy nor constitutionally permissible for the government knowingly to harm a certain group of individuals by suppressing information for the presumed benefit of others. The Supreme Court held in the Western States decision that such a suppression of commercial speech cannot be reconciled with the First Amendment. Western States, 122 S.Ct. at 1508-09. In this decision, the Court invalidated provisions of the Food and Drug Modernization Act ("FDAMA") that prohibited advertising of "compounded drugs,"[4] which the government argued were

[4] Drug compounding, a "traditional component of the practice of pharmacy," is a process by which a pharmacist or doctor combines or alters drug ingredients to create a medication typically not commercially

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necessary to ensure that drug compounding was not used to circumvent the new drug approval requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Id. at 1504-06.

The Supreme Court found that the prohibition on advertising of compounded drugs was impermissible, *inter alia*, because of "the amount of beneficial speech" that it prohibited without furthering the asserted governmental objective. Id. at 1508.[5] Specifically, the Court pointed out that the prohibition would prevent pharmacists with "no interest in mass-producing medications" in circumvention of FDCA from telling doctors about alternative drugs available through compounding that would be useful in treating patients with special medical needs. Id. at 1508-09. The fact that such "useful speech" would be suppressed even though doing so would not "directly further" the government's asserted objective was "enough to convince" the Court that the challenged provisions were unconstitutional. Id. at 1509.

Following Western States, the suppression of information about PREPs would be unconstitutional because it would result in real harm for certain groups of people without furthering a substantial governmental interest. The suppression of truthful, non-misleading claims clearly would redound to the detriment of certain individuals -- i.e., those who, had they been exposed to the claims, would have switched to PREPs from conventional tobacco products. Moreover, the only motivation for suppressing truthful

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available and which is tailored to the needs of a particular individual, e.g., an individual that is allergic to an ingredient in a mass-produced product. Id. at 1500.

and non-misleading reduced-risk information would be the government's desire to prevent people from using the information to make choices that the government disfavors. Yet, as discussed above, the Constitution does not recognize such a motivation as a legitimate basis for restricting commercial speech. Under these circumstances, not only would the government impermissibly be saying that it knows what is best for certain of its citizens, but in doing so, it would affirmatively harm other citizens.

The government's decision to suppress reduced-risk information also has severe consequences for the individual and, indeed, for our system of government as a whole:

> [T]he fundamental premise of the First Amendment—indeed, of the very democratic system of which the First Amendment is such an important part—is that citizens must be trusted to make their own lawful choices on the basis of a free and open competition of ideas, opinions, and information. If government is permitted paternalistically to shield its citizens from such open debate as a means of controlling their behavioral choices, it will have simultaneously affronted individual dignity and stunted the individual's personal and intellectual growth, a developmental process that lies at the heart of the free speech right. It will simultaneously have contributed to an intellectual atrophy of the citizen that ultimately will undermine her effective participation in the democratic system.

Redish, Tobacco Advertising and the First Amendment, supra, at 636.

B. More Targeted Approaches Are Available to Address Public Health Concerns About PREPs

Far more targeted approaches are available for the government to address concerns about the impact that PREPs might have on the rates of smoking cessation and

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[5] In response to the Western States decision, FDA issued a Federal Register notice seeking comments to "ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law." 67 Fed. Reg. 34,942 (May 16, 2002).

initiation. FDA should ensure that information about the product's reduced-exposure or reduced-risk potential is presented to consumers in a truthful and non-misleading manner. Indeed, authority to prevent false and misleading product information is a standard FDA regulatory tool that currently applies to all product labeling and promotional materials regulated under FDCA, and that would be extended to tobacco products by proposals granting FDA authority to regulate such products. In addition, other public health tools to encourage tobacco cessation and prevention are available and currently in use.

1. FDA Should Consider Appropriate Use of Disclaimers to Address Public Health Concerns

The Supreme Court held in Western States that "if the [g]overnment can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the [g]overnment *must* do so." Western States, 122 S.Ct. at 1506-07 (emphasis added) (holding that the government failed to demonstrate that preserving the integrity of the FDCA drug approval process could not be achieved through means that imposed a lesser burden on speech than the FDAMA prohibition on advertising compounded drugs). Consequently, the advertising prohibition challenged in that case failed to satisfy the fourth prong of the Central Hudson test requiring that the restrictions not be more extensive than is necessary to serve the governmental interest. Id. See also Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (there cannot be "an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive"); Wash. Legal Found. v. Friedman, 13 F. Supp. 2d at 73 (FDA restrictions on particular forms of manufacturer promotion of off-label uses for FDA-approved drugs were considerably more extensive than necessary, and "[t]he most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer").

In Western States, the Supreme Court identified the use of so-called "disclaimers" as an alternative way to ensure that consumers are not misled by advertisements. Western States, 122 S.Ct. at 1508 (a governmental interest in preventing misleading advertising could be achieved by "the far less restrictive alternative" of requiring compounded drugs to bear warnings stating that the drugs are not FDA-approved and that their risks are unknown). The D.C. Circuit made the same conclusion in Pearson, stating that "we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness . . .". Pearson, 164 F.3d at 659-660; see also In re R.M.J., 455 U.S. 191, 203 (1982) ("[T]he remedy in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation."). Furthermore, this principle is "consistent with a well-established body of law that points to First Amendment limits on federal agencies' restrictions on commercial speech where less restrictive alternatives are available." Steven B. Steinborn & Kyra A. Todd, The End of Paternalism: A New Approach to Food Labeling, 54 Food & Drug L.J. 401, 402 (1999). "Pearson stands as [a] reminder that regulatory agencies in general, and FDA in particular, must adopt a regulatory approach that recognizes the consumer's right to receive pertinent information." Id. at 413-414.

Indeed, the Federal Trade Commission has long supported the position that disclaimers must be considered as an alternative when determining whether health claims about a product are misleading. See Nat'l Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977); Margaret Gilhooley, Constitutionalizing Food and Drug Law, 74 Tul. L. Rev. 815, 827 (2000); see also FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, 28,393 (1994) (noting that the "significant scientific

agreement" standard in the Nutrition Labeling and Education Act of 1990 (NLEA) is the appropriate standard to determine if health claims are misleading only in situations where the claims are *unqualified*).

Providing consumers with additional information, such as through the use of disclaimers, is thus a more tailored means to address the potential impact of PREPs on smoking cessation and initiation. "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*." Rubin, 514 U.S. at 497 (Stevens, J., concurring) (emphasis added). FDA could require, for example, that every tobacco product designated as a PREP include labeling that reminds consumers that no tobacco product is safe and that the best option is to quit or not to start in the first place. [6]

2. Other Public Health Tools are Available to Address Concerns Related to Smoking Cessation and Prevention

An FDA-imposed restriction on the communication of information about PREPs is not the only policy tool available to address concerns related to tobacco use. As the Institute of Medicine noted, the regulatory system should not be viewed in isolation, but rather "as an essential component of a package of public policy initiatives (including research, education and surveillance) that this committee believes is necessary to realize whatever benefit tobacco or pharmaceutical product innovation can offer in reducing the nation's burden of tobacco-related illness and death." IOM Report at 7-21, 22. "Harm

[6] Of course, FDA could prohibit any reduced-risk or health claims for tobacco products that have not been approved by FDA. See, e.g., Whitaker v. Thompson, 239 F.Supp. 2d 43, 54 (D.D.C. Jan. 3, 2003) (holding that claims concerning the therapeutic effects of a dietary supplement on an existing disease condition that were not approved as permissible reduced-risk claims for the product were unlawful health claims).

reduction [should be] implemented as a component of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment." Id. at 7-21.

In this regard, Congress appropriated more than $100 million to the Centers for Disease Control for its tobacco control efforts in FY 2003. Further, many states have increased their spending on tobacco control efforts in the wake of the state attorneys general tobacco settlements (the "MSA"). These state and federal tobacco control programs are in addition to the $1.5 billion that was earmarked in the MSA to fund tobacco control efforts through a national public health foundation, the American Legacy Foundation, which is overseen by the state attorneys general.

Indeed, the government would have the burden of demonstrating that programs such as these could not adequately address the public health concerns raised by PREPs, which would obviate the need to suppress truthful, non-misleading information. "If the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort." Western States, 122 S.Ct. at 1507.[7]

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[7] The Supreme Court ruled in Western States that the government must consider non-speech related alternatives before resorting to restrictions on commercial speech. In the decision, the Court identified several non-speech alternatives to FDAMA's compounded drug advertising prohibition that might be effective in achieving the government's interest of ensuring the integrity of FDCA's drug approval process. Id. at 1506. These were (1) banning the use of commercial scale manufacturing or testing equipment for compounding drug products; (2) prohibiting pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received; (3) prohibiting pharmacists from offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale; (4) limiting the amount of compounded drugs that a pharmacist may sell out of State or sell or make in a given period of time; or (5) relying on the non-speech related provisions of FDAMA, which include requiring that compounding only be conducted in response to a prescription or a history of receiving a prescription, and limiting the percentage of a pharmacy's total sales that out-of-state sales of compounded drugs may represent. Id. at 1506. The government's failure to explain why these alternatives would not be adequate led the Court to conclude that FDAMA's advertising prohibition was more extensive than necessary. Id. at 1506-07.

III. CONCLUSION

Based on these precedents and the IOM Report's recommendations, proposals to grant FDA authority over tobacco products should ensure that adult consumers are provided with truthful and non-misleading information about PREPs. "[P]erhaps the first and most basic problem is that Americans lack the necessary information . . . . [P]erhaps the first goal ought to be to ensure genuinely informed choices, rather than to dictate outcomes from Washington." Sunstein, supra, at 654.

An outright ban on such information concerning PREPs would be inappropriate and unconstitutional. Instead, FDA should be empowered to assess and approve PREPs based on the scientific merits of the claims and then ensure that consumers are not misled about the risks associated with those products. Additional public health programs should continue to encourage smoking cessation and prevention.

Chairman TOM DAVIS. Dr. Hatsukami.

Dr. HATSUKAMI. Mr. Chairman, I want to thank you for the opportunity to present before this committee.

My name is Dorothy Hatsukami, and I'm a professor at the University of Minnesota Medical School. I have conducted research in the area of tobacco dependence for over 20 years. During the past 4 years I've been funded by the National Institutes of Health to study approaches and measures for reducing tobacco toxin exposure. I also served on the Institute of Medicine committee that examined the issue of tobacco harm reduction. I've been asked to answer questions on the feasibility and acceptability of reduced exposure, reduced risk products as an alternative to smokers and the research challenges that are related to tobacco harm reduction.

At the present time, the feasibility or acceptability of reduced exposure, reduced risk products as an alternative for smokers unable to quit is simply unknown. It is important to keep in mind that assessment of these products and any claims of reduced exposure of risk involve examining the impact on the individual as well as the population at large. For example, individuals may show a reduction in tobacco toxin exposure. However, if more people start tobacco use or fewer people quit because they perceive these alternative products as safer, the total net harm may be increased.

The following four steps should be taken to assure public health and to avoid public health disaster. To date, quitting tobacco is the only known way to reduce tobacco-related mortality and morbidity. Thus, strong messages for tobacco prevention and cessation should continue to be the primary focus with the public. Furthermore, priorities should be given to continued efforts to develop, promote, and provide treatments for cessation. Currently, medicinal nicotine products yield a significantly better safety profile than any tobacco products. In our study, subjects assigned to the nicotine patch condition experience significantly less carcinogen levels than those assigned to reduced exposure smokeless tobacco or cigarette products. Therefore, the priorities should be to provide and promote the safest product for our tobacco users and to increase the success rates for abstinence by improving on our existing treatment methods.

Second, a strong research agenda should be developed that addresses, one, understanding tobacco addiction and developing the best treatments possible to achieve abstinence; two, developing and testing biomarkers that measure tobacco toxin exposure and that are related to the development of disease states; three, determining the extent of reduction in tobacco toxin exposure that will result in reduced risk for disease; four, determining the absorption of tobacco toxins from these tobacco products in humans and understanding the reasons for individual differences in the degree of exposure and disease susceptibility; five, determining how messages regarding these potential reduced risk products can be conveyed to the public so that the prevention or cessation efforts are not compromised; and, six, examining the prevalence and pattern of use of these reduced exposure products either alone or in combination with conventional tobacco products. To date, current knowledge in these areas is very limited.

Third, organizations independent of the tobacco industry should test and determine the impact of these products. These organizations should test for toxins within the product itself and in the case of cigarettes, as it is burned. In addition, the uptake of tobacco toxins in these reduced risk products and the consequences of this exposure should be assessed. An independent organization could also be responsible for conducting postmarketing surveillance in order to assess for prevalence and pattern of use of tobacco products with purported reduced exposure.

Finally, regulatory authority over tobacco products is essential. An organization such as the FDA that can critically evaluate the evidence base for exposure reduction claims as well as regulate marketing efforts is crucial to protect the public health. Without oversight, the public could not be assured of the validity of the industry claims of reduced risk or informed about tobacco toxin constituents to which they are exposed; and therefore informed decisions could not be made.

Tobacco companies need to be required to submit their novel products and claims to the FDA prior to the appearance of these products and claims regarding these products in the marketplace.

The FDA should also be given the authority to establish manufacturing standards for all tobacco products so that development of less toxic cigarettes or other tobacco products can become standard rather than the exception. To me, it is unconscionable that we currently have the technology to potentially reduce toxin in tobacco products and yet do not have a mechanism in place to require that all tobacco products meet these lower levels. Requiring the reduction of tobacco toxins in all tobacco products would be important should they be demonstrated to lead to potential reduction in risk for disease.

In summary, the answer to the questions regarding whether reduced exposure, reduced risk products are alternatives for smokers who are unable to quit depends on the effects of these products on the individual and the population at large, which is information that we do not yet have. Therefore, understanding the impact of these products on public health will require research. In addition, we need to develop the infrastructure and the resources to conduct the necessary research and to evaluate these products at all levels. But to fully protect public health, we need FDA regulatory authority over tobacco products.

Thank you again for this opportunity to present to you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Hatsukami follows:]

Written Testimony
Committee on Government Reform
United States House of Representative
Hearing on Reduced Exposure/Reduced Risk Tobacco Products:
An Examination of Potential Public Health Impact
and Regulatory Challenges
June 3, 2003

Dorothy K. Hatsukami, Ph.D.
Professor of Psychiatry
University of Minnesota Medical School

As an invited participant to the Committee on Government Reform hearing entitled, ***Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Public Health Impact and Regulatory Challenges***, I have been asked to address the following four questions.

In your opinion, do reduced exposure/reduced risk products represent an acceptable alternative for current smokers who have been unable to quit smoking?

The best scientifically known intervention to reduce harm among smokers is cessation. Whether reduced exposure/reduced risk products represent an acceptable alternative for current smokers who are unable to quit is dependent on whether or not we have been able to develop and provide the best cessation methods to treat smokers. *Therefore, greater resources and time should be devoted to research that increases our understanding of factors associated with tobacco addiction. This understanding, in turn, will inform us of how to develop more effective treatments for smokers who are unable to quit.*

If smokers continue to be unable to quit given the best interventions, whether or not reduced exposure/reduced risk products represent an acceptable alternative depends also on scientific knowledge. The science needs to show that the extent of reduction that is achieved with these products is associated with a significant reduction in disease risk and that the impact of these products at the population level is not negative. Furthermore, it is imperative that these areas of investigation be conducted by organizations that are independent of the producers and marketers of these products.

To determine if reduced risk products are suitable alternatives, several aspects contributing to harm reduction must be examined. For harm reduction to occur, there must be a significant reduction in morbidity and mortality even with the continued use of tobacco products or constituents of tobacco products. However, in order to demonstrate harm reduction, several years of investigation must be conducted with that particular product. Because this type of study is not likely to be feasible, other methods for assessing the impact of these products on public health must be considered. In the Institute of Medicine report, *Clearing the Smoke, Assessing the Science Base for Tobacco Harm Reduction*, a model was described that would help to assess total harm associated

with reduced exposure/reduced risk products. First, the *toxicity of the product itself* should be determined. Toxicity should be measured in the tobacco product itself and in the case of cigarettes, when the tobacco product is heated or combusted. Furthermore, toxins resulting from combined use of tobacco products should also be examined based on observations of how individuals actually combine the use of these products.

Second, the *uptake of these toxins*, using animal and human models, should be assessed. Measurements of toxin exposure or biomarkers for disease risk must also be biologically relevant and must be associated with a disease state or risk for disease. The extent of tobacco toxin exposure must not solely rely on machine measurement, but must rely on human measurement that takes into account use patterns and amounts. These human measurements should also take into account differences in individual susceptibility to disease and biological differences, such as metabolism, that will determine the amount of tobacco toxins exposure. Prior studies with "light" and "mild" low yield cigarettes have shown that reduction of mortality and morbidity did not accompany the use of these lower tar and nicotine yield cigarettes because smokers compensated for the lower yield of nicotine by puffing longer, inhaling more deeply, or smoking more cigarettes (National Cancer Institute, 2001). The lesson learned from the lower yield cigarette story is that an accurate measure of tobacco toxin exposure is only determined by observing the amount of exposure among human cigarette smokers.

Third, the prevalence of use and population effect must be determined. Even if the toxin exposure is reduced on an individual level, the total amount of exposure and therefore harm on a population level may be increased. That is, because these products may be perceived as safer, individuals who may have never smoked may initiate smoking, smokers who are considering or will be considering cessation may continue to smoke or those who have quit may relapse. Again, using the lower yield cigarettes as an example, a significant number of smokers believed that these cigarettes were safer, which may have led to a number of smokers choosing to continue smoking, rather than quit (Stratton et al., 2001).

To date, the only proven methods to reduce the tobacco-related mortality and morbidity are prevention and cessation. No information is currently available indicating the amount of tobacco toxin reduction that is necessary in order to achieve a reduction in disease risk or whether the population interested in using these products would derive any beneficial effects given their long history of tobacco use or current disease state. Furthermore, no information is available on whether efforts at prevention and cessation would be compromised as a result of advertising products as reduced risk. Therefore, it is imperative that a system be in place not only to assess the harmful or beneficial effects of these products on an individual level, but also on a population level and that messages of cessation or prevention are not compromised.

Is it feasible to develop a combusted, cigarette-style product that is less harmful to the individual smoker and to the public at large?

The same issues that are discussed with the reduced exposure/reduced risk products pertain to the combusted, cigarette-style product.

Does smokeless tobacco represent an acceptable alternative to smoking cigarettes? Could it be considered a reduced-risk product?

The data is currently not sufficient or available to allow a yes response to this question. On a superficial level, the answer appears to be yes because use of the product does not involve combustion. However, when exploring the issue in more depth, many significant concerns are evident. Smokeless tobacco is not a harmless product. The use of smokeless tobacco results in addiction and smokeless tobacco use results in increased disease states (e.g., oral, throat and neck cancer, oral pathologies, increase in cardiovascular risk factors, and fetal toxicity). The extent of these harms to health is dependent on the toxins in the product as well as the duration and amount of use. The products in the United States vary in toxin levels (Hoffman et al., 1995). The most widely used smokeless tobacco product contains the greatest amount of toxins. Other products, typically those products that are not widely used, contain less amounts of toxins. It is important to note that even smokeless tobacco products with the lowest amounts of nitrosamines have levels that are thousands times greater than the permissible limits established for consumer products (USDHHS, 1986). Determining whether smokeless tobacco could be considered a reduced risk product involves looking at the impact of marketing this product as such on an individual as well as population level.

On an individual level, the amount of toxin exposure will depend on the amount and pattern of use. For example, the effect of dual use of smokeless tobacco and cigarettes is unknown. Potentially, dual tobacco users can achieve higher levels of exposure compared to those who use only one product (Wetter et al., 2002), leading to greater risk for disease. Additionally, little is known as to whether any beneficial effects can be experienced among cigarette smokers who have switched to smokeless tobacco, particularly after years of exposure to cigarettes. Minimal reduction in disease may be particularly true if the population of smokers who decide to use smokeless rather than quit are already a more physically compromised population of users. Therefore, it is important that these issues be examined prior to determining whether smokeless tobacco products confer reduced risk.

On a population level, the impact these products have on health will depend upon type and amount of marketing they receive. If tobacco companies are allowed to market their products as reduced risk, the ensuing public perception of these products and the impact resulting from these perceptions is unknown. We do not know if there would be a higher number of smokeless tobacco initiates, as observed in the United States between the 1970s and 1990s when significantly more advertisements for smokeless tobacco were evident. Furthermore, it is unknown whether ex-smokers, who are struggling to remain abstinent or to quit, would resort to smokeless tobacco products, rather than medications that have been proven to result in significantly less toxin exposure (Hatsukami et al., 2003). Finally, it is unknown whether individuals who decided to take up smokeless tobacco because of its relative safety, would not graduate to cigarette smoking, which in

some studies has been shown to occur (Tomar, 2002; Haddock et al., 2001). Interestingly, in the United States, few people have switched from cigarettes to smokeless tobacco. In this competitive market among tobacco companies, the most likely scenario would be an increase in initiation of smokeless tobacco use and no decrease in smoking, particularly if the marketing efforts continue to be aggressive and claims are unbridled.

What are the research challenges related to tobacco harm reduction?

A *strong research agenda* is necessary prior to recognizing or allowing claims for reduced risk products. The main research challenge is to insure a mechanism that will allow for testing of these products independent of the tobacco companies, whether by existing governmental agencies, a newly formulated one or by independent research scientists. These agencies or testing sites would be responsible for testing the toxicity of the products, examining the effects of exposure of these toxins using animal models and examining the absorption of these toxins in humans. In addition, independent organization(s) or scientists could also examine the effects of different marketing strategies on public perception and consider and test methods to minimize potential harm. An organization would also need to conduct post-marketing surveillance to determine prevalence and use patterns using strategies that are not unlike ones that are developed to monitor drugs that have potential abuse liability (e.g., Schuster et al., 2003).

The six areas that represent research challenges are the following and have been excerpted or more fully described elsewhere (Stratton et al., 2001; Hatsukami et al., 2002).

- Developing reliable and valid surrogate biomarkers that measure level of toxin exposure and disease risk or disease states. Currently, there are a limited number of biomarkers that are available that will allow researchers to begin to examine reduced exposure products, however more sophisticated and relevant biomarkers need to be developed. One of the challenges is that the use of modified tobacco products, a novel delivery system, or a combination of products can result in unique toxin mixtures that remain undetected by existing measures.
- Determining the extent of reduction that is necessary to experience any reduction in risk for disease. For example, it is unknown whether a 30% reduction in exposure to nitrosamines has any beneficial effect.
- Examining how characteristics of the product interact with tobacco use behavior to affect tobacco toxin exposure and disease risk.
- Examining how and what individual differences impact response to a product and disease susceptibility as a result of product use. For example, tobacco users may vary in their degree of dependence and this difference may determine the extent of tobacco toxin exposure. Tobacco users may have specific genetic polymorphisms that will make them more sensitive to the effects of particular carcinogens.
- Examining the impact of messages and marketing of reduced exposure products on consumer and healthcare provider attitudes, knowledge, perception, and beliefs. Finding ways and avenues to communicate information that will lead to the greatest net public health benefit.

- Developing a comprehensive surveillance system so that prevalence, pattern and consequence of use of these products and conventional tobacco products are determined across age groups, gender, race or ethnicity.

Conclusion

In summary, in order to protect public health and avoid public health disaster, the following steps must be taken: 1) Strong messages about tobacco prevention and cessation should continue to be made to the public. Priority should be given to efforts to develop, promote and provide effective methods for tobacco cessation; 2) A strong research agenda must be developed; 3) Scientists or organizations that are independent of the tobacco companies must test, assess and determine the impact of these products on individual and population levels. Most importantly, regulatory authority over these novel tobacco products or claims of reduced risk is essential in order to insure critical evaluation, accurate information of these reduced risk products, and to minimize harm to the individual and society. It is critical that companies are required to submit their products and claims to the Food and Drug Administration *before* the products and claims are in the marketplace.

Thank you for the opportunity to present this material to you.

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Chairman TOM DAVIS. Dr. Henningfield.

Dr. HENNINGFIELD. Thank you very much.

I am speaking here on my own behalf and not as a representative of the organizations of which I am a member or serve.

I am professor of the Johns Hopkins Medical School, director of the Robert Wood Johnson Foundation Innovators Awards Program, and vice president of Pinney Associates. In addition, I consult on treatment products such as nicotine gum and patch, and I share a patent on a potential new product. This gives me real-world experience on the challenges of product development and the challenge of threading the eye of the regulatory needle.

Let me start with a few fundamental facts.

Chairman TOM DAVIS. I want to make sure your mic is on. Is it on?

Dr. HENNINGFIELD. It is.

Chairman TOM DAVIS. Put it a little closer to you.

Dr. HENNINGFIELD. Is this better? I'm sorry. Should I start over or keep going?

Chairman TOM DAVIS. Go ahead. Keep going.

Dr. HENNINGFIELD. Thank you.

A few fundamental facts. Tobacco addiction is the most pernicious and persistent form of all forms of drug addiction. It leads the majority of users to daily, deadly use with 50 percent of regular smokers dying prematurely. Tobacco cessation is the only scientifically proved route to reducing disease risks, and the benefits are powerful and fast for one of the biggest killers of tobacco users, heart disease. Cessation also benefits children. It reduces the risk of asthma and other diseases and keeps them from smoking.

Comprehensive tobacco control efforts are based on solid public health principles. They reduce tobacco use, and they save lives.

We've seen striking increases in cessation and declines in tobacco use by kids in recent years. Tobacco programs work, especially in individual States that have implemented the programs most dramatically.

Could we reduce the risk of disease with products that are less poisonous? This was the premise of the Federal Trade Commission's approach to encourage reduced tar and nicotine cigarettes beginning in the 1960's. It was also the implied premise of smokeless tobacco products marketed to high school college athletes beginning in the 1970's. What happened? Light cigarettes delayed quitting, and supposedly safer smokeless tobacco was a magnet for athletes who were considered to be at very low risk for any form of tobacco use. Both experiments on the American people were disasters and went awry for decades before individual independent researchers and not the companies revealed the public health damage.

This experience is a reminder that the road to harm reduction is paved with good intentions but littered with land mines. It should be navigated with science and regulatory oversight. This was the core path articulated in the 2001 IOM report.

FDA regulated cessation products are tested for safety and efficacy. Their labeling and marketing is regulated to promote proper use and discourage harmful use. They improve public health by helping people achieve freedom from tobacco. None are known to

cause problems such as initiating nicotine dependence, fostering tobacco use or delaying cessation.

On the other hand, in the vacuum of FDA regulation of nonmedicinal nicotine products, the 19th century days of snake oil have reemerged with a vengeance. Some of these products are before you, in front of me. New products have been released every 3 to 4 months, with no sign of letting up.

These products include nicotine delivery devices that are heated by carbon fuel and electronic ignition systems, a Tic Tac-like tobacco lozenge, and smokeless products marketed to help smokers remain smokers with slogans such as "Any Time Any Where" or for "When You Can't Smoke." There are cigarettes implying safety with health claims of "reduced carcinogens," "the next best thing to quitting," "80 percent less second-hand smoke." One has a misleading claim of "nicotine free." By Internet, there are lollipops—complete with "lollipop luggage;" nicotine water; and, most recently, nicotine wafers. Some of these products have Web sites amounting to virtual versions of horse-drawn patent medicine carts. Absent meaningful nicotine regulation, absent the science foundation, Americans are guinea pigs for these products.

Is it possible that some of these products are real advances toward improved public health? Perhaps, but there is no way for consumers, public health officials, or Congress to know. Why? Because these products have not been rigorously studied by independent scientists, and we lack an FDA system of regulation built around the key principle of premarket evaluation. FDA regulation can expedite a drug to help people quit, it can expedite development, or it can crush it.

The agency's flexible, encouraging approach to AIDS medicines development helped lead the world away from the view of AIDS as a death sentence to the understanding of AIDS as a treatable and manageable disease. Unfortunately, with tobacco treatment products, FDA has not kept pace with the public demand or potential new treatment developments.

Tobacco users want and need increasingly flexible products. Much more is possible. Medications could be used to reduce smoke exposure, but FDA inflexibility has left such applications on shelves.

With support from NIH, small developers have made great progress on a vaccine-like long-acting medicine to help people stay quit if they quit, but this may require an entirely new model of FDA evaluating efficacy.

In short, FDA has existing authorities that could unleash improvements in treatment, appeal, diversity and availability. It just needs to apply them.

In conclusion, I urge that you consider the wisdom of former Surgeon General C. Everett Koop who testified in support of over-the-counter marketing of nicotine gum and patch. In summary, he said, it's easy to get the disease, hard to get treatment. As a Nation we must reverse this.

FDA issued its rule to regulate tobacco in the same year it approved over-the-counter nicotine gum and patch. Time has proved that FDA was on target from the perspective of science and health. We need to get back on track. We need FDA to be appropriate and

flexible. We need it to be engaged. We need it to be supported by equally engaged CDC and NIH efforts to provide the science and surveillance to assure that we are on the path to better health in America.

Thank you very much.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Henningfield follows:]

Statement of

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Before the

Committee on Government Reform

United States House of Representatives

Hearing on

Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Public Health Impact and Regulatory Challenges

June 3, 2003

Thank you for the opportunity to testify on the issues and opportunities raised by the diversity of nicotine delivery systems that have been marketed or are in development. There are surely few other areas of health in which there are actions that could be taken by the Congress and regulatory agencies that have such great potential to either improve or harm public health. I will focus on the questions posed in my invitation to testify.

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 serve. I am 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 drug addiction and have focused on tobacco-related issues for 25 years. From 1980 to 1996, I directed tobacco and other drug research at the National Institute on Drug Abuse (NIDA). While at NIDA, I was the primary liaison 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 am past president of the Society for Research on Nicotine and Tobacco and have served on national and international committees addressing the challenges posed by the plethora of nicotine delivery systems that have been marketed or are possible. I presently serve on the World Health Organization (WHO) Scientific Advisory Committee on Tobacco Product Regulation. I am a recipient of a Robert Wood Johnson Foundation Innovators Award and presently am director of this program which is intended to recognize and foster innovations to reduce substance abuse and addiction in America.

Fundamental facts

Tobacco addiction is the most pernicious and persistent of all forms of drug addiction leading the majority of users to deadly daily use with 50% of continuing smokers prematurely dying of smoking caused disease. Nonetheless, with support and encouragement many tobacco users can achieve freedom from tobacco and dramatically improve their chances of longer, healthier, and more productive lives. Others need treatment to achieve these goals and increased treatment access has helped millions of Americans quit smoking and other forms of tobacco use.

Smoking cessation is accompanied by rapid and significant reductions in risk of heart disease, as well as reduced risk of lung cancer and other diseases over time. The earlier in life that lasting tobacco cessation is achieved, the greater the benefits. Cessation also benefits non smokers, children in particular, who suffer far higher rates of asthma, respiratory infections, and sick days when they are exposed to smoke. In fact, when parents quit smoking their children are half as likely to start smoking and twice as likely to try to quit smoking if they have already begun. The lesson is clear: adult cessation and youth prevention go hand in hand.

Comprehensive tobacco control efforts based on solid public health principles reduce tobacco use and save lives. With increased education, tobacco costs, restrictions on

smoking, and access to treatment, more smokers are quitting than ever before. On a parallel front, although youth tobacco use remains unacceptably high, adolescent smoking and smokeless tobacco use has steadily declined in the past 3-4 years. From a public health perspective these trends are precious and encouraging, they spell improved health for millions of Americans in the near term and in future generations. We must be very careful to do nothing to reverse these trends.

Exposure reduction products could save lives or cost lives. What about people who are unable to completely give up tobacco? Could we reduce their risk of disease with products that are less poisonous? This was the premise of the Federal Trade Commission (FTC) approach to encouraging the development and use of reduced tar and nicotine cigarettes beginning in the 1960s. This was also the implied premise of smokeless tobacco marketing to high school and college athletes beginning in the 1970s. Of course motivation of FTC was to enable disease reduction whereas the motivation of tobacco companies was to grow their markets. Nonetheless, both experiments on the American people were health disasters as documented in reports of the Surgeon General, the Institute of Medicine, and National Cancer Institute. Both experiments went awry for decades before independent researchers – not the companies that were marketing the products – revealed the extent of the damage.

Light cigarettes delayed quitting and supposedly safer smokeless tobacco was a magnet for athletes who had been considered at low risk for any form of tobacco use prior to the healthy image product marketing of the 1970s. This experience, although sobering, should not discourage our nation from making progress on all fronts to reduce tobacco caused disease but it is a stark reminder that unintended consequences are a mine field that should be negotiated with supportive science and regulatory oversight. This is the core path articulated in the 2000 Institute of Medicine report on the topic and this is the core path that I support as a rational one towards improved health in America.

The spectrum of nicotine delivery products – FDA regulation makes a difference
Since 1985, nicotine gum has been available as an FDA approved smoking cessation aid This product has been joined by a slowly increasing number of additional forms of FDA approved Nicotine Replacement Therapy (NRT) products including patch, nasal spray, oral inhaler, and lozenge. Each product differs in form, dosing, side-effects, and instructions for smoking cessation. Determining the conditions of safe and effective use and then overseeing labeling and marketing to minimize unintended consequences such as situational use for the purpose of avoiding smoking cessation, misuse by children, and providing special guidance for youth, pregnant women, and persons with heart disease, is a science guided process overseen by FDA.

In the vacuum of FDA regulation for non medicinal nicotine products, the 19th century days of snake oil have re-emerged with vengeance since FDA was rebuked by the Supreme Court in 2000. Correctly gauging FDA's reluctance to act, companies, big and small, have unleashed new products every 3-4 months with no sign of letting up. These include the nicotine delivery devices "heated" by carbon fuel and electronic ignition systems, a "Tic Tac"-like tobacco lozenge", and smokeless tobacco products marketed to

help smokers remain smokers by using slogans such as "Any Time Any Where"™ and for "When You can't smoke."™ There are cigarettes implying safety with claims of "reduced carcinogens", "the next best thing to quitting," "80% less second hand smoke", and one with a misleading claim of "nicotine free" that is marketed for quitting by imitating the three step program of nicotine patches. By internet, there are nicotine lollipops (complete with "lollipop luggage"), nicotine water, and most recently, nicotine wafers.

Some of these products are placed next to FDA approved cessation aids in drug stores and have websites amounting to virtual versions of the old horse drawn patent medicine carts. None of these products have clinically tested and approved protocols for dosing, guidance for use to achieve health benefits (even where health benefits are implied) or guidance to minimize unintended consequences or dangerous forms of use (such as dual use to perpetuate smoking). Absent meaningful regulation, absent a science foundation, Americans are the guinea pigs for these products.

Yet, it is theoretically possible that some of these products could be useful to help people quit smoking. Some might be useful advances towards less deadly tobacco products for those who are unable to quit tobacco altogether. Presently there is no way for the consumer to know. There is no way for public health officials to know. There is no way for Congress to know. Yet, there is a rather straightforward path to this end. It is the path of scientific study and FDA regulation built around the key principle of pre-market evaluation of the products and the claims. It is a proven path towards products that are less harmful and possibly even helpful.

Regulation can stifle or foster the treatment pipeline

FDA regulation of medications is the world's premier model for pre-market approval of safe and effective medicines, as well as maintaining safe and usefully labeled food. Some of its most striking successes are the result of flexible adaptation of its authorities to foster drug development such as helping lead the world away from the view of AIDs as a death sentence to the understanding that AIDs is increasingly a manageable disease.

One size does not fit all: Unfortunately with respect to tobacco treatment products, the FDA approach has not kept pace with public demand or potential treatment developments. Tobacco users want and need increasingly flexible products to meet their diverse needs on the road to tobacco cessation. Yet at present, all products are approved based on the same 6 week cessation model that has served for nearly two decades, and the labeling has been homogenized to the point that consumers and health professionals alike do not understand how the different product forms may address differing needs. Worse, overly harsh labeling results in ironics such as people removing patches so they can "safely" smoke cigarettes.

So much more is possible. Medications could be used to reduce smoke exposure on the road to complete cessation but FDA inflexibility has left such applications on shelves. With support from the National Institute on Drug Abuse, small developers have made great progress on "vaccine-like" long acting medicines that could help former tobacco

users remain tobacco free the rest of their lives but this may require an entirely new model for evaluating efficacy. One developer is even working on a nicotine water based cessation aid – but there will be little incentive to properly evaluate it, develop clinically tested guidance, and obtain FDA approval if people can already get an untested version by Internet from a company that has dodged FDA oversight.

If FDA does not become more actively engaged and more flexible in the application of its authorities to treatment development and approval, the most innovative approaches will never see the light of day or will be so constrained that they will be irrelevant to public health. Without lowering its standards for safety and efficacy, FDA could give notice that it will consider application of its fast track and expedited review authorities that have been so successful in jumpstarting the pipeline of medicines for treating AIDS and cancer. FDA could give notice that it will consider a broader range of science based indications and claims shown to be desired and helpful to tobacco users. In short, FDA has existing authorities that could unleash improvements in treatment appeal, diversity, and availability. It just needs to apply them appropriately and flexibly.

Federal efforts by CDC and NIH in particular have made a difference but could do much more. It is in the interest of the federal government to support greater access and appropriate use of treatments that are approved by the FDA as well as those that are not under FDA jurisdiction but have been found to be effective by the US Public Health Service, such as behavioral therapies and alternative medications to meet the diversity of needs. Such treatments are among the most cost-effective of all treatments in health care, especially when compared to the enormous costs of treatments for the consequences of smoking such as cancer chemotherapies.

More fundamentally, it is in the interest of striving toward a healthy and productive America in which preventing unnecessary disease by tobacco is valued as highly as preventing auto accidents, and bioterrorism. Remember the basic numbers: 4000-5000 new cigarette and smokeless tobacco users (most of whom are kids) and more than 1000 preventable tobacco deaths every day as far as the epidemiologic eye can see. Should freedom from this preventable cause of death and disease be any less valued than freedom from other causes of disease? Perhaps most important to consider is that this area of public health is one in which many core principles have been established, tested and found effective.

While we do not have all the answers, recent progress following the application of tobacco control policies nationally and even more intensively in states such as California and Massachusetts is more impressive than many of us had dared hope for. A recent set of recommendations developed by the Subcommittee on Cessation by the Interagency Committee on Smoking and Health outlines a plan that is predicted to prevent at least three million premature deaths in existing smokers, and help an additional five million Americans quit smoking within one year. I support full adoption of the recommendations of this special report to the Secretary Thompson. Furthermore, any progress towards the goals articulated in the report would be steps in the right direction.

Tobacco products that genuinely reduce risk merit serious consideration for inclusion in comprehensive tobacco control strategies but should be positioned so as to not undermine approaches that work. I have served on many committees in the US and for the World Health Organization that take seriously the concept that every effort should be made to reduce tobacco toxin exposures to those who continue to use tobacco. It is evident that tobacco products are made more deadly than is technically and commercially feasible and that performance standards could be developed to establish maximum allowable levels of various toxins.

It is also recognized that effective regulation is critical. Without it, such an approach could do more harm than good. This is because how a product is used is as important how it is made when it comes to health effects. Regulation can guide how it is made, marketed, and used and provide a mechanism for corrective actions so that we never again need wait for several million deaths as we did from light cigarettes before recognizing unintended consequences. Regulation of tobacco and medications to treat dependence must be a coordinated process. Otherwise we will perpetuate the situation in which snake oil is increasingly at the doorstep in ever more attractive iterations, while proven safe and effective treatments and strategies that could save lives die in development.

Dr. Koop's advice: ***Be appropriate and flexible.*** In conclusion, I urge the Committee to consider the wisdom of former Surgeon General C. Everett Koop whose testimony in support of over the counter marketing of nicotine gum and patches I paraphrase: *It is easy to get the disease and hard to get treatment, as a nation we must work to reverse this. Over-the-counter marketing is a step in the right direction.* Remarkably and presciently, FDA granted this approval in the same year that it issued its rule to regulate tobacco products and restrict tobacco product marketing. Time has proved that FDA was on target from the perspective of science and health. We need to get back on track. We need FDA to be appropriate and flexible; we need it to be engaged. We need it to be supported by equally engaged CDC and NIH efforts to provide the science and surveillance to assure that we are on the path to better health in America.

Thank you for the opportunity to testify. I will be pleased to contribute to this important process in any way.

Chairman TOM DAVIS. Dr. Kozlowski.

Dr. KOZLOWSKI. Thank you for this opportunity to testify. It's an honor to be here.

I'm professor and head of the Department of Biobehavioral Health at Penn State. My opinions are my own and not necessarily those of Penn State.

Strong, pharmaceutical-type governmental regulation of all tobacco products is urgently needed. Such regulation will provide grounds for commercial claims, help reduce product risks, and help prevent continued abuses of consumers.

Some prominent governmental public health information on smokeless tobacco already makes health claims, is fundamentally misleading, and is not supported by science. Let me repeat that. Some prominent governmental public health information on smokeless tobacco already makes health claims, is fundamentally misleading, and is not supported by science.

If I were drafting a Web page for youth on smokeless tobacco and cigarettes, I might begin: "you are dumb to use smokeless tobacco and you are way dumber to smoke."

Contrast the National Center for Drug Information, a government Web site, Tips for Teens: The Truth About Tobacco. Question: Isn't smokeless tobacco safer to use than cigarettes? No. There is no safe form of tobacco.

As generally available in the United States, smokeless tobacco is doubtless safer than cigarettes to individual users. For example, smokeless tobacco is not a significant cause of lung cancer or other respiratory disease, which together account for about 60 percent of death from cigarettes.

Individuals have rights to honest health information. Disinformation should not be used to discourage tobacco use. Making a smokeless tobacco user of any age think that smokeless is just as dangerous as cigarettes could actually foster a switch to cigarettes.

But doesn't smokeless tobacco cause cigarette smoking?

The terms "Gateway" and "Starter product" are ambiguous. They confuse the correlational effects and causative effects. Concern about product switching should arise mainly if smokeless tobacco as a significant cause of subsequent smoking, but there is little evidence of causation. Rather, it is more likely due to other factors—for example, risk taking—making some individuals more likely to experiment with both tobacco products and make other individuals less likely to experiment with any tobacco products.

The large majority of male smokeless tobacco users in the United States appear to either have used smokeless tobacco only—and to have never smoked—or started smoking before using smokeless. Therefore, neither group began to smoke as a result of smokeless tobacco use. Research on smokeless tobacco should also explore the extent to which smokeless could prevent smoking in high-risk youth.

I have been asked to talk about the risk/use equilibrium briefly. Some have expressed concern that more individuals using a reduced-risk product could lead to an overall public health loss. The risk/use equilibrium offers a sense of scale to this truism. Basically the equilibrium plots, for increasing levels of risk reduction, how

much increase in use is needed for no change in public health cost to result from a new reduced-risk product. With only a small reduction in risks, as perhaps from a novel cigarette product, even a small increase in the percentage of users of this product could eliminate any public health benefit. For products that reduce risks dramatically, such as medicinal nicotine products, the likely risk reduction is so large that the chances for a net public health loss are vanishingly small, if not impossible. For low-nitrosamine moist snuff, the risk reduction is probably so large that an increased number of users would also be unlikely to reach the level of producing a net public health loss.

It will be challenging and may take years to do the needed research to confirm the likely small risks from novel smoke products. However, current toxicological and epidemiological research on smokeless tobacco in the United States and even more so from medicinal nicotine show that significant risk reduction is available in these products.

In closing, the current regulatory vacuum should not keep us from saying: To use smokeless is dumb and to smoke is dumber—much dumber. That there is a promise of harm reduction from smokeless tobacco and medicinal nicotine should add to the urgency of objective governmental regulation. Without such strong regulation, this promise could easily be wasted.

Thank you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Kozlowski follows:]

Potential Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Health Impact and Regulatory Challenges

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

Statement of Lynn T. Kozlowski, June 3, 2003

Thank you for this opportunity to testify. It is an honor to be here.

Since 1975, I have conducted and published research on tobacco use and been involved with tobacco policy. Since 1990, I have worked at Penn State, where I am currently Professor and Head of the Department of Biobehavioral Health in the College of Health and Human Development. My opinions here today are my own and not necessarily those of Penn State. I do not have funding from the tobacco industry, but I currently am or recently have been funded by the Robert Wood Johnson Foundation, the National Cancer Institute, and the Centers for Disease Control through the Association of Teachers of Preventive Medicine. I have on occasion provided consultation supported by the pharmaceutical industry. I have also testified in lawsuits against the cigarette industry.

Strong, pharmaceutical-style governmental regulation of all tobacco/nicotine products is urgently needed.

Such regulation would provide grounds for commercial claims, help reduce product risks, and help prevent continued abuses of consumers.

Some prominent governmental public health information on smokeless tobacco already makes health claims, is fundamentally misleading, and is not supported by science.

If I were drafting a web-page for youth on smokeless tobacco and cigarettes, I might begin:

> **You are dumb to use smokeless tobacco**
> **and way dumber to smoke!**

Contrast the National Center for Drug Information web-site at
http://www.health.org/govpubs/phd633i/ (accessed May 29, 2003)

Tips for Teens: The Truth About Tobacco. . . .

Q. Isn't smokeless tobacco safer to use than cigarettes?
A. No. There is no safe form of tobacco. Smokeless tobacco can cause mouth, cheek, throat, and stomach cancer. Smokeless tobacco users are 50 times more likely to get oral cancer than non-users. Those smokeless tobacco users who don't develop some type of cancer are still likely to have signs of use, like stained teeth, bad breath, and mouth sores.

As generally available in the United States, smokeless tobacco is clearly safer than cigarettes. For example, there is evidence that smokeless is not a significant cause of lung cancer or other respiratory disease, which accounts for about 60 percent of the deaths from cigarettes. This alone is grounds for calling smokeless *safer* than cigarettes. I can't be sure of the scientific basis of the claim that "smokeless tobacco users are 50 times more likely to get cancer than non-users," but wouldn't the more pertinent numbers, given the question of relatively safety, compare the oral cancer risks of smokeless tobacco with the oral cancer risks of cigarettes. The numbers I have seen indicate that smoking is a greater risk of oral cancer than is smokeless tobacco.

Individuals have rights to honest health information. Disinformation should not be used to discourage tobacco use. Making a smokeless user of any age think that smokeless is just as dangerous as cigarettes could actually foster a switch to cigarettes.

But doesn't smokeless tobacco cause cigarette smoking?

The terms "Gateway" and "Starter product" are ambiguous. Concern about product switching should arise mainly if smokeless tobacco is a significant cause of subsequent smoking. But there is little evidence of causation; rather it is more likely that other factors (for example, risk-taking) make some individuals more likely to experiment with both tobacco products and make other individuals less likely to experiment with any tobacco products.

The large majority of male smokeless tobacco users in the United States appear to have either used smokeless tobacco only (and to have never smoked) or started smoking before using smokeless. Therefore, neither group began to smoke as a result of smokeless tobacco use. Research on smokeless tobacco should also explore the extent to which smokeless could prevent smoking in high-risk youth.

The Risk/Use Equilibrium.

Some have expressed concern that more individuals using a reduced-risk product could lead to an overall public health loss. The Risk/Use Equilibrium offers a sense of scale to this truism. Basically the equilibrium plots, for increasing levels of risk reduction, how much increase in use is needed for no change in public health costs to result from a new reduced-risk product. With only a small reduction in risks, as perhaps from a novel cigarette product, even a small increase in the percentage of users of this product could eliminate any public health benefit. For products that reduce risk dramatically, such as medicinal nicotine products, the likely risk reduction is so large that chances for a net public health loss are vanishingly small, if not impossible. For low-nitrosamine moist snuff, the risk reduction is probably so large that an increased number of users would also be unlikely to reach the level of producing a net public health loss..

It will be challenging and may take years to do the needed research to confirm the likely small risk reductions from novel smoked products. However, current toxicological and epidemiological research on smokeless tobacco in the United States and even more so for medicinal nicotine show that significant risk reduction is available from these products.

In closing

The current regulatory vacuum should not keep us from saying: "To use smokeless is dumb and to smoke is dumber--much dumber."

That there is a promise of harm reduction from smokeless tobacco and medicinal nicotine should add to the urgency of objective, governmental regulation. Without such strong regulation, this promise could easily be wasted.

Several papers are appended that provide elaboration of my statement.

Running Head: Non-Gateway SLT-Cigarette Relationships

Most smokeless tobacco use is not a causal gateway to cigarettes:

Using order of product use to evaluate causation in a national U.S. sample

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Most smokeless tobacco use is not a causal gateway to cigarettes: Using order of product use to evaluate causation in a national U.S. sample

Lynn T. Kozlowski, Richard J. O'Connor, Beth Quinio Edwards, and Brian P. Flaherty

Abstract

Aims- To evaluate non-causal and causal patterns of smokeless tobacco (SLT) and cigarette use; to assess the prevalence of "non-gateway" and possible "gateway" patterns of SLT use.

Design & Setting- Data from the Cancer Control Supplement to the 1987 National Health Interview Survey, a representative survey of non-institutionalized adults in the United States. From reported age at first use, participants were categorized by type and sequence of tobacco product use. SUDAAN 8.0.1 (Research Triangle Institute, 2002) was used for statistical analyses.

Participants- Males aged 18-34 (N = 3,454), weighted to provide estimates of the U.S. population. A subsample of males aged 23-34 (N = 2,614) was analyzed to minimize the possibility of future product switching.

Measurements- Smoking status, smokeless tobacco (snuff, chewing tobacco, both) use status. age at regular use of cigarettes, age at first use of smokeless tobacco.

Findings- Of those 23-34 year-olds who had ever used SLT with or without cigarettes, 77.2% (95% CI: 71.3, 83.3) were classifiable as non-gateway users in that 35.0% (95% CI: 29.9, 40.1) had only used SLT and 42.2% (95% CI: 36.8, 47.7) had used cigarettes first. Cigarette use in younger cohorts was less common, despite increased SLT use. Those who used cigarettes before moist snuff were 2.1 times more likely to have quit smoking (95% C.I.: 1.21,6.39) than cigarette-only users.

Conclusions- The large majority of SLT users are non-gateway users. Causal gateway effects should be of minor concern for policy. SLT may be more likely to prevent smoking than cause it.

Key Words: gateway, smokeless tobacco, smoking, risk factors

Most smokeless tobacco use is not a causal gateway to cigarettes:

Using order of product use to evaluate causation in a national U.S. sample of adults

Much contemporary policy on smokeless tobacco (SLT) in the United States and Europe is influenced by concern that smokeless tobacco acts as a causal "gateway" to a more unhealthy nicotine-delivery system--cigarettes (e.g., National Cancer Institute, 1992; Stratton, Shetty, Wallace, & Bondurant, 2001; Ferrence, Slade, Room, & Pope, 2001; Tomar, 2002, in press; Haddock, van der Weg, De Bon, *et al.*, 2001; McNeill, 1990; Nordgren & Ramström, 1990). The causal gateway argument holds that prior use of SLT causes an increased probability of subsequent use of cigarettes. For SLT to be judged a causal gateway to cigarette smoking in any individual, it is important to know which product was used first. This simple priority principle (e.g., Davis, 1985), so critical in establishing that cigarette smoking causes disease (USDHEW, 1964), has been sometimes neglected in research on SLT as a causal gateway to cigarettes.

Several authors have pointed out deficiencies of causal gateway models (e.g., Baumrind, 1983; Kandel and Jessor, 2002). A detailed review (Kandel and Jessor, 2002) has found: "There is no compelling evidence that the use of a drug earlier in the sequence, *in and of itself* [emphasis added] causes the use of . . . any other drug. . ." (p. 366). Nevertheless, the causal gateway hypothesis remains prominent in ostensibly science-based policy. (Of course, the SLT/cigarette gateway is special in that it does not involve transitions to different types of drugs, but rather transitions between two forms of one drug--nicotine). A correlation between SLT use and smoking is not adequate to establish a causal link. Some of the correlation among the use of drugs of abuse is due to the association of non-use as well as use (Miller, 1994). In other words, persons who are very unlikely to ever try drug "A" can also be very unlikely to ever try any other

drug of abuse (Miller, 1994; Kozlowski & Harford, 1976). With the diminishment of the issue that some smokeless products (Swedish snus) cause cancer (Lewin, Norell, Johansson *et al.*, 1998; see also, Accortt, Waterbor, Beall *et al.*, 2002), the causal gateway issue has become even more influential in guiding tobacco and harm-reduction policy.

Although some experts apply the gateway model only in a non-causal, associative sense (see Kandel & Jessor, 2002), our evaluation is directed to the causal gateway model, because this causal model has clearer implications for policy (i.e., promoting SLT use for harm reduction could cause an increase in smoking; or, stopping SLT use could act to stop cigarette smoking). The causal gateway argument holds that prior use of SLT increases the probability of subsequent use of cigarettes. This argument does not require one to think that cigarette smoking occurs if and only if there has been prior use of SLT, but that some smoking would not have occurred if not for prior use of SLT.

Prior evidence supporting a dominant causal SLT gateway effects is weak

Prior to 1999, there were several longitudinal studies in the U.S. on SLT as a possible causal gateway to cigarettes. The review done in the 1994 U.S. Surgeon General's Report (USDHHS, 1994) describes the results as mixed, with some studies showing that SLT use predicted smoking (e.g., Peterson, Marek, & Mann, 1989) and others showing that smoking predicted SLT use (e.g., Murray *et al.*, 1988). Among recent studies, Griffin and associates (1999) and Hatsukami and associates (1999) found no association between SLT use and later cigarette smoking, while Cohen-Smith & Severson (1999) found that smoking predicted later SLT use.

Recent attention has focused on two large longitudinal studies. Haddock and colleagues (2001) studied military recruits who were non-smokers at the beginning of basic training and

evaluated whether SLT use predicted subsequent smoking. Past and current SLT users (at baseline) were each about 2.3 times more likely to have begun smoking at followup (Haddock *et al.*, 2001). This study is limited in two major ways. First, male military recruits (who have not started smoking by age 18) are likely unrepresentative of males in the general population. Second, the definition of smoking changed from baseline to follow-up. At baseline, smokers were defined as having smoked at least one cigarette per day [timeframe is not specified, but we assume the past 7 days, consistent with their other definitions], while at follow-up smoking was defined as having even *a single puff* on a cigarette in the preceding seven days. Tomar (in press) used the longitudinal component of Teenage Attitudes and Practices Survey to evaluate progression to smoking 4 years later in 12-18 year olds who were never smokers at Time 1. His analyses found that SLT use at Time 1 predicted onset of smoking by Time 2. However, two major limitations of this study were that (1) the never smokers at Time 1, especially for older adolescents, comprise a complexly biased sample, and (2) available psychosocial predictor variables were not included in the model. Longitudinal studies (Tomar, in press, Haddock, *et al.* 2001) do have advantages over cross-sectional studies, but they do not necessarily provide adequate analyses of causal effects. They remain fundamentally correlational, not experimental studies.

Tomar has also analyzed cross-sectional adult data from the 1998 National Health Interview Survey in the United States (Tomar, 2002), but this survey did not ask about age at first use of smokeless products, so no analyses were possible on sequence of product use. He reported that males were 2.5 times more likely to be former snuff users who currently smoked than to be former smokers who currently used snuff (2.5% vs. 1%). He proposed that SLT "may be a "gateway" form of nicotine dosing . . . that may lead to subsequent smoking" (Tomar, 2002,

p. 147), a phrasing that implies a causal function, especially that in a paper that discusses harm reduction themes.

Our Approach

There is a fundamental asymmetry in causal analysis that employs the order of first use of SLT and cigarettes. If cigarette use *follows* SLT use, it is *possible, but not certain* that SLT use has caused smoking in smoke individuals. On the other hand, for SLT users who have used SLT but never go on to cigarettes, it is *certain* that SLT has not *caused* smoking in any of these individuals (provided one uses old enough samples, such that recruitment to smoking is over). Similarly, for those who first smoked cigarettes, it is *illogical* to think that SLT use *caused* smoking in these individuals. Together the two categories of sole SLT use and prior cigarette use constitute a broad class of SLT users for whom SLT use is *not a causal gateway* to cigarettes. Estimating the prevalence of such *non-gateway* use of SLT provides way to estimate an upper limit on how large a public health problem a causal SLT gateway might be. In other words, if one-third of SLT users might be victims of a causal gateway, one can be confident that *at least* 67% of SLT users are *not* examples of a causal gateway. And, unless one makes the unreasonable assumption that 100% of prior SLT users have had their smoking caused by SLT use (i.e., they would not have smoked otherwise), one should view that, logically, "non-gateway" users provide a conservative estimate of the overall non-gateway patterns of use. This analytical framework is different than the more traditional scheme of estimating if use of SLT is more associated with smoking than is non-use of SLT, because it arises from a special, logic-based analysis of what interpretations are sensible from specific patterns of use.

Ramström (1990, 2001) has reported data on 18-34 year-old males from a survey in Sweden (1987-1988) that asked a direct question on whether cigarettes or SLT were used first.

SLT in this study was Swedish snus, a low nitrosamine, oral moist snuff that is placed in the upper front of the mouth between the lip and gums. He found substantial numbers of respondents who used snus solely or after they started smoking cigarettes, but he did not put forward the same logical analysis of the interpretations arising from the different patterns of use.

The National Health Interview Survey, 1987, (USDHHS, 1987) asked about age of using cigarettes, snuff, and chewing tobacco. By comparing age at use of these products, we tried to replicate the patterns found in Sweden and to evaluate what can be learned from a consideration of priority of use, under the assumption that sole users of SLT or prior users of cigarettes are "non-gateway" users and prior users of SLT who went on to cigarettes should be considered "possible gateway" users.

Methods

Data

Data for this study were obtained from the Cancer Control Supplement to the 1987 National Health Interview Survey (NHIS) (Centers for Disease Control, 1987), a representative survey of non-institutionalized adults in the United States. The NHIS is a continuous, nationwide, household survey of the civilian population. In 1987, 22,043 individuals completed the Cancer Control supplement (a response rate of 86%) (Schoenborn & Boyd, 1989). Public use data is available on CD-ROM from the National Center of Health Statistics. Complete details about the complex survey design and procedures are available elsewhere (see Schoenborn & Boyd, 1989, Appendix I).

Subjects

We initially limited our sample to males aged 18-34 to provide an exact replication of Ramström (1990, 2001); this provided a sample size of 3,454. At a second stage, to be

conservative in estimating those who were users of smokeless tobacco only (i.e., those who never use cigarettes), we limited the sample to 23-34 year olds (N= 2,614). We selected the age of 23 as the lower cutoff, because no one in this sample who first used snuff and then used cigarettes regularly had started smoking after age 22. This provided a category of SLT only users who would be very unlikely to include those who might still recruit to smoking. Note that sample sizes reported in tables will be smaller due to missing data.

Creating tobacco use categories.

Figure 1 depicts the process for determining six tobacco use categories using a series of questions from the survey. The final six categories are SLT only, Cigarettes first, SLT first, same time, cigarettes only, and never users of tobacco. In order to reach the final six categories, we first determined lifetime tobacco product use for cigarettes, snuff, chewing tobacco, and combined snuff and chewing tobacco use (referred to as combined SLT use) followed by an analysis of order of tobacco product use. Lifetime cigarette use was determined by asking whether 100 cigarettes had been smoked. Participants were categorized as Never (smoked 0-99 cigarettes), or Ever (100 or more cigarettes) smokers. Lifetime snuff use was assessed by asking whether snuff had been used 20 times. Participants were characterized as Never (used 0-19 times) or Ever (used 20 or more times) snuff users. Analyses of snuff use were limited to moist snuff users, removing individuals who reported any dry snuff use. This was done because of the very small number of dry snuff users, potential differences between dry and moist snuff users, and because moist snuff is the U.S. product most comparable to Swedish snus. A similar scheme was used to assess chewing tobacco use. Finally, a combined smokeless tobacco (SLT) use variable was created, combining those who had used moist snuff, chew, or both into a single variable. Participants were characterized as Never (used neither snuff nor chew) or Ever (used

snuff, chew, or both). Ever users of snuff, chew, SLT, and cigarettes were further divided into former (no use in past 30 days) and current users (used at least once in past 30 days).

Those who could be classified as 'Never' for cigarettes, snuff, and chewing tobacco were called 'Never-users.' Those who reported snuff and/or chewing tobacco use but no cigarette use formed a second category ('SLT Only'). Similarly, those who reported cigarette use but no snuff and/or chewing tobacco use formed a third category ('Cigarette Only').

Order of tobacco product use was determined as follows. For those participants who could be classed as 'Ever' for cigarettes and SLT, the age at which they started using cigarettes regularly, and the age at which they first used snuff/chewing tobacco was next considered. These different questions were used because parallel age questions for cigarettes and smokeless were not asked. For the combined SLT variable, age at first use was determined by the lower age of the two SLT products (for those with combined use) or by the age at first use of whichever SLT product was used (for those who used only one product). To determine which tobacco use came first, age at first snuff use, age at first chewing tobacco use, and age at first SLT use were each subtracted from age at regular cigarette smoking. If age at regular cigarette smoking was less than age at first snuff use, then cigarettes were judged to have been used first ('Cigarettes First'). Similarly, if age at first snuff use was less than age at first cigarette use, then snuff was judged to have come first ('Snuff First'). Some participants reported using both cigarettes and SLT at the same age – hence a separate category was created for those with no age difference ('Same Time').

Insert Figure 1 About Here

We believe our classification method provides an upper-bound estimate of gateway effects, as the snuff first group is likely overestimated (because age at regular snuff use is not available), and the cigarettes first group likely underestimated (because age at regular use, rather than first use is employed). Three different smokeless tobacco use classifications were used: Snuff, Chewing Tobacco, and Combined SLT. For the snuff and chewing tobacco variables, users of the other smokeless products were not excluded. Hence, someone categorized as 'snuff only' may have also used chewing tobacco, but did not smoke. Someone who is designated 'neither' did not use snuff or cigarettes, but may have used chew.

Analyses. Descriptive statistics on tobacco use categories were computed with SUDAAN 8.0.1 (Research Triangle Institute, 2002) in order to accommodate the complex NHIS sample design. Statistical inferences were performed through the use of 95% confidence intervals (CI) around percentages (see Altman *et al.*, 2000). If CI's overlapped, then two groups were not significantly different at the alpha=.05 level; if CI's did not overlap, then the groups were different at the alpha less than .05 level. We also compared our computed values to those reported by Ramström (1990, 2001), again using 95% CI's to assess significant differences. A chi-square test was used to test for significant differences in the distribution of tobacco use categories by age cohort. All logistic regression models were nonsequential and controlled for age, education, and region of the US (Northeast, North-central, South, West). Odds ratios and confidence intervals were used to indicate effect sizes and statistical significance.

Results

Results are arranged as follows. First, a replication of the Ramström (1990) study is presented using the 18-34 year old sample. Second, the sample is narrowed to those aged 23-34. Third, we divide the sample into three age cohorts and reanalyze patterns of tobacco use. Fourth,

analyses similar to previous evaluations of gateway effects are presented, along with the consequences of considering order of use. Finally, we present analyses of smoking cessation behavior in mixed cigarette-SLT users and exclusive cigarette users, by order of use.

Comparing patterns of non-gateway and possible gateway snuff use in Sweden and the U.S around 1987.

Moist snuff is the product in the United States most similar to Swedish snuff (snus). Table 1 shows the pattern of snuff use and smoking in six mutually exclusive categories for the U.S. and five mutually exclusive categories for Sweden for males aged 18-34. Levels of snuff use were much higher in Sweden than the U.S (all ps < .05). The Swedish values come from Ramström (1990). Figure 2 shows non-gateway and possible gateway use as a percentage of ever use of SLT. Patterns of use for those who had ever used snuff with or without cigarettes were very similar. The large majority of snuff users in Sweden (83%) and the U.S. (77.2%) appear to be "non-gateway users" in that their snuff use did not lead to smoking or their smoking preceded snuff use. Only 17.5% of Swedish users and 22.9% of U.S. users used SLT before smoking and therefore are possibly gateway users, a small difference in percentage points, but statistically significant ($p < .05$).

Insert Table 1 and Figure 2 about here

Patterns of non-gateway and possible gateway tobacco use in U.S. males aged 23-34

The remaining analyses do not include those aged 18-22. Individuals in this excluded group still carry significant risk of becoming cigarette smokers. By limiting the sample to those 23 or older, we have much greater confidence that very few, if any, of those in the SLT Only

group might still become members of the SLT First group. On average, SLT was used 4.0 years (SEM = 0.30) before cigarettes by those who had used SLT before cigarettes; cigarettes were used 5.6 (SEM = 0.38) years before SLT by those who used cigarettes first. These numbers indicate that there was, on average, a substantial time lag from using one product to switching products or adding another.

Table 2 shows the patterns of snuff, chew, and combined SLT use as a function of the six mutually exclusive categories of use among U.S. males aged 23-34. Only a small percentage of users (less than one percent) started using both products in the same year. Figure 2 shows the non-gateway and possible gateway use as a percentage of all those who had ever used snuff or chew. (The same values can be calculated from Table 2 for SLT.)

Insert Table 2 here

Cohort effects

To investigate age-related patterns of tobacco use, we cross-tabulated age (categorized as 23-26, 27-30, and 31-34) with tobacco use category (see Table 3). Chi-square analysis showed significant differences in the distribution of tobacco use by age [$\chi^2(10)=46.79$, $p<.0001$]. While 'cigarettes only' use was 9.3 percentage points lower in the youngest age group than the oldest group, 'SLT-only' use was 5.1 percentage points higher. Use of SLT before cigarettes was 1.7 percentage points higher in the youngest group than the oldest group, while Cigarettes-before-SLT use was 2.4 percentage points lower.

Combining values in Table 3, we find that ever smoking [middle 4 categories of Table 3] was 10.3 percentage points lower in the youngest age group [46.6% (95% CI: 42.5,50.7) vs. 57.0% (95% CI: 53.3,60.7)] compared to the oldest group [$\chi^2(2)=16.2$, p=.0007]. Ever SLT use [first 4 categories] was 4.1 percentage points higher [17.0% (95% CI: 14.1,19.9) vs. 12.9% (95% CI: 10.4,15.4)] over the same comparison [$\chi^2(2)=4.9$, p=.096]. That is, there were 32% more ever SLT users among the youngest group compared to the oldest group, while ever smoking decreased by 18%. Logistic regression showed that the youngest age group was 0.58 times as likely to be ever smokers (versus never smokers) (95% CI: 0.46,0.74) as the oldest age group. At the same time, the youngest age group was 1.4 times more likely to be an ever SLT user (versus never SLT users) (95% CI: 1.01,1.84). This pattern of results does not indicate that increased use of SLT was associated with increased smoking; on the contrary it shows a negative relationship between SLT and cigarette use.

Insert Table 3 about here

Analyses using more traditional methods to evaluate gateway effects

As others have reported, we found a positive relationship between SLT use and cigarette smoking when use of both was dichotomized as ever/never [$\chi^2(1)=40.8$, p<.0001; Relative Risk = 1.4, (95% CI: 1.3,1.5); phi = .13]. When smoking and SLT were designated as Non, Former, Current, we find that there were more current smokers who were former SLT users [4.5% (95% CI: 3.5,5.5) of the sample] than there were current SLT users who were former smokers [1.4% (95% CI: 0.8,2.0) of the sample] (see Tomar, 2002). In a logistic regression model, ever-use of SLT was a significant predictor of current smoking (OR=1.35, 95% CI: 1.05, 1.74). However, if

we remove those who used cigarettes before they used SLT (i.e., those in whom SLT could not logically have caused smoking, but could contribute to an association), the results change. Ever-use of SLT is no longer a significant predictor of current smoking (OR=0.79; 95% CI: 0.56, 1.11). These results argue strongly for consideration of order of use.

Quitting Smoking

Ramström (2000) reports increased smoking cessation in ever snus users who first used cigarettes. We also looked at quitting behavior of smokers by snuff use category. Multiple logistic regression showed that those who used cigarettes before snuff were 2.1 times more likely to have quit smoking (95% C.I.: 1.21,3.45) than were cigarette-only users. No significant effect on quitting was seen for those who used snuff first compared to cigarette-only users (OR=1.21, 95% CI: 0.64,2.26). No significant effect on quitting was seen for chewing tobacco use, either before (OR=1.51, 95% CI: 0.83,2.78) or after (OR=1.36, 95% CI: 0.87,2.13) cigarette use, compared to cigarette-only users. When the two forms of SLT were combined, no significant effect on quitting was found, either for SLT use before (OR=1.28, 95% CI: 0.76,2.16) or after (OR=1.45, 95% CI: 0.96,2.20) cigarettes compared to cigarette-only use.

Discussion

A possible causal gateway effect of SLT use on cigarette smoking is of understandable concern to policy makers, and some authorities have acted as if there is an established gateway effect (e.g., Haddock *et al.*, 2001; Tomar, 2002, in press; Stratton *et al.*, 2001; Ferrence, *et al.*, 2001), but it is crucial to consider the extent of the problem. If only a small subset of youth fall victim to a causal gateway (i.e., would not started smoking if not for prior use of SLT), the policy implications may be relatively minor. The large majority of SLT use (77%) appears <u>not</u>

to be a causal gateway to cigarettes, and, further, policymakers seem to have ignored the counter-valing prospect that some users of SLT might be prevented from smoking because of SLT. Given the pattern of results (i.e., non-gateway uses much more common than gateway uses), it is possible that SLT has greater smoking preventive than smoking causative effects. To focus only on putative gateway effects neglects possible benefits of SLT for individuals at highest risk of taking up smoking. We think that both proponents and opponents of SLT for harm reduction would benefit from the analytical exercise of thinking of alternative explanations for either SLT as causing smoking or SLT as preventing smoking based solely on the sequence of product use (or lack thereof). Although sequence of use alone cannot establish causation or prevention, the analyses we have presented can help rule out causation.

Our results support those of Ramström (1990, 2001), despite large differences in base-rates of use. Subsequent to our analyses, we located a marketing study done by Philip Morris in the early 1980s (Miller, 1984). Interviewers asked 236 18-34-year old SLT users in Houston, Atlanta, and Florida whether they had ever smoked and, if so, which product they had used first. Overall, 53% (N=125) used SLT only, 26% (N=61) used cigarettes before SLT, for a total of 79% non-causal gateway use, and 21% (N=50) used SLT before cigarettes (Miller, 1984). This represents another basic replication of the finding of a majority non-gateway effect for SLT.

Tomar's analysis of adult NHIS data from 1998 (Tomar, 2002), found that males were 2.5 times more likely to be former snuff users who currently smoked than to be former smokers who currently used snuff (2.5% vs. 1%). We found a similar pattern (2.2% vs 0.8%) in the NHIS data from 1987 (ages 18-98). At the same time, the data reported on order of first use allows a more refined, process-oriented look at the phenomena in question and does not support a strong gateway effect from SLT to cigarettes.

The age cohort effects do not support the "gateway" fear that increased SLT use leads to increased smoking. Although there was an increase in SLT use in younger cohorts, this increase is associated with a decrease in smoking, not an increase. This was true having eliminated the young people who might reasonably still move from SLT-only use to SLT-first use. The cohort finding also raises doubt that increases in use of smokeless tobacco will generally lead to increases in cigarette smoking. Rather, they lend support to the idea that SLT may be preventing some would-be smokers from smoking.

Levels of snuff and chewing tobacco use were similar. Our logistic regression analyses of smoking cessation showed effects only for those snuff users who used cigarettes first; no effect was seen when a combined SLT use variable was used. It may be premature to focus on just snuff or to collapse snuff and chewing tobacco into one category in surveys, as was the case in the Teenage Attitudes and Practices Survey (TAPS) (Moss, Allen, Giovino, *et al.*, 1992).

There are limitations to our study beyond those already noted. Recalled age of first use or even regular use of a tobacco product may have limited reliability or validity. Complex patterns of early starting and stopping could not be assessed. For example, it is possible that the age at daily or heavy use of SLT or cigarettes is not directly related to age at first use or even age at "regular" use. If one can be sure that the prior use of cigarettes was long-standing and heavy, one could be confident that SLT did not cause cigarette smoking; however, if the prior use of cigarettes was minimal, followed by heavy use of SLT that then led to smoking, it would be wrong to rule out a possible SLT gateway effect. Direct questions were never asked about what the individual thought about his or her transitions in tobacco use. How many of those who used SLT first switched to cigarettes to try to achieve greater pharmacological satisfaction or because of greater convenience of use? How many who switched to cigarettes were unaware that they

were substantially increasing risks of disease and death? No information is available from this dataset on these important questions.

Another important question is how many of those who switched from cigarettes to SLT were intentionally using SLT to substitute for cigarettes. A cigarette company conducted in-store interviews (Miller, 1984) of former smokers (96/180) in Texas, Georgia, and Florida, and found that 53% said "Yes" to the question, "Did you start smokeless/chewing tobacco as a replacement for cigarettes, that is, when you stopped smoking cigarettes, or not?" (Miller, 1984). Similarly, Cohen-Smith and Severson (1999) found that 58.8% of men in their study reported using SLT as a replacement for cigarettes when they were quitting smoking. Asking such direct questions as part of the NHIS survey would provide direct means for policy makers to assess the use of SLT for smoking cessation. To evaluate smoking preventive effects of SLT, it would be helpful to know if users thought they might use cigarettes if SLT were not available.

The gateway hypothesis seems to be supported by the pharmacological principle that faster-acting drug forms are preferred to slower-acting drug forms (USDHHS, 1988; Russell & Feyerabend, 1978). But the present finding that many smokeless users do not progress to cigarettes encourages a closer look at this prevailing belief. Context also contributes to drug preferences (Kozlowski, 1982). Public health concern about public spitting may have contributed as much to the decline of smokeless and the rise of the cigarette in the early 20th Century, as did the more rapid pharmacokinetics of inhaled cigarette smoke. We were surprised to learn from a report in the tobacco documents that 62% of respondents who used both smokeless and cigarettes reported that smokeless/chewing tobacco was "more enjoyable" than cigarettes (Miller, 1984).

Remember also that these are historical patterns of use. For policy, it is important to realize that various interventions might influence rates of use. For example, health organizations can emphasize the greater dangers of cigarettes in comparison to smokeless (Kozlowski and O'Connor, in press). Governments can tax products differentially, with greater taxes on more dangerous products, providing an economic incentive for harm reduction. Any gateway effects are likely to be influenced by such interventions, and could be minimized with proper policy implementation.

Overall, our findings argue for a reduced emphasis on causal gateway effects for smokeless tobacco on cigarette smoking. Science-based policy makers should also consider that SLT use can actively prevent smoking in some high-risk users, and such a potential harm-reducing effect needs to be weighed against those individuals who might become smokers because of prior use of SLT.

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Table 1. Prevalence of ever use of moist snuff[a] and cigarettes as a function of order of product use, solitary product use, and never use in U.S. males aged 18-34, NHIS 1987 and Swedish males 18-34, 1986-1987.

	Tobacco Use Status						
	Non-Gateway		**Potential Gateway**				
	Snuff only	***Cigarettes First***	**Snuff First**	Snuff & Cigarettes in same year	Cigarettes only	Neither Snuff nor Cigarettes	Total
Sweden							
% Ever Use	18	15	7		21	39	100
(95% C.I.)	(16.7,19.3)	(13.8,16.2)	(6.1,7.9)	N/A	(19.6,22.4)	(37.3,40.7)	[N = 824]
United States							
% Ever Use	4.3	3.1	2.2	0.5	39.7	50.1	100
(95% C.I.)	(3.6,5.0)	(2.4,3.8)	(1.7,2.7)	(0.23,0.77)	(37.7,41.7)	(49.0,52.2)	[N=3297]

a. In Sweden, moist snuff is *snus*.

Table 2. Prevalence of ever use of smokeless tobacco (Moist snuff, Chewing Tobacco, and Combined Smokeless) and cigarettes as a function of order of tobacco product use, single tobacco product use, and never use in males aged 23-34, NHIS 1987. Percentages are weighted to the U.S. population.

	Tobacco Use Status						
	Non-Gateway		**Potential Gateway**				
	SLT Product only	***Cigarettes First***	**SLT Product First**	SLT Product & Cigarettes in same year	Cigarettes only	Neither SLT Product nor Cigarettes	Total
Moist Snuff							
%	3.0	3.8	1.9	0.5	44.9	45.9	100
(95% CI)	(2.3,3.7)	(2.9,4.7)	(1.3,2.5)	(0.2,0.8)	(42.6,47.2)	(43.5,48.3)	[N=2498]
Chewing Tobacco							
%	3.6	4.1	2.2	0.6	44.1	45.5	100
(95% CI)	(2.9,4.3)	(3.3,4.9)	(1.6,2.8)	(0.3,0.9)	(41.7,46.5)	(43.2,47.8)	[N=2497]
Combined SLT							
%	5.0	6.0	3.2	0.7	41.0	44.0	100
(95% CI)	(4.2,5.8)	(4.9, 7.1)	(2.5,3.9)	(0.4,1.1)	(38.6,43.4)	(41.7,46.3)	[N=2492]

Table 3. Distribution of tobacco product use categories as a function order of using these products, sole use, and never use, males aged 23-34, by four-year age cohort, NHIS 1987. Percentages are weighted to the U.S. population.

	Tobacco Use Status						
	Non-Gateway		**Potential Gateway**				
	SLT Product only	***Cigarettes First***	**SLT Product First**	SLT Product & Cigarettes in same year	Cigarettes only	Neither SLT Product nor Cigarettes	Total
23-26							
%	8.0	4.4	4.0	0.57	37.7	45.4	100
(95% CI)	(6.0,10.0)	(2.9,5.9)	(2.6,5.4)	(0.0,1.1)	(33.7,41.7)	(41.1,49.7)	[N=801]
27-30							
%	4.0	6.8	3.4	0.75	38.6	46.5	100
(95% CI)	(2.6,5.4)	(4.8,8.8)	(2.0,4.8)	(0.10,1.4)	(34.9,42.3)	(42.8,50.2)	[N=852]
31-34							
%	2.9	6.8	2.3	0.88	47.0	40.1	100
(95% CI)	(1.8,4.0)	(5.1,8.5)	(1.3,3.3)	(0.21,1.6)	(43.1,50.9)	(36.4,43.8)	[N=839]

Figure 1. Derivation of tobacco use categories, NHIS 1987.

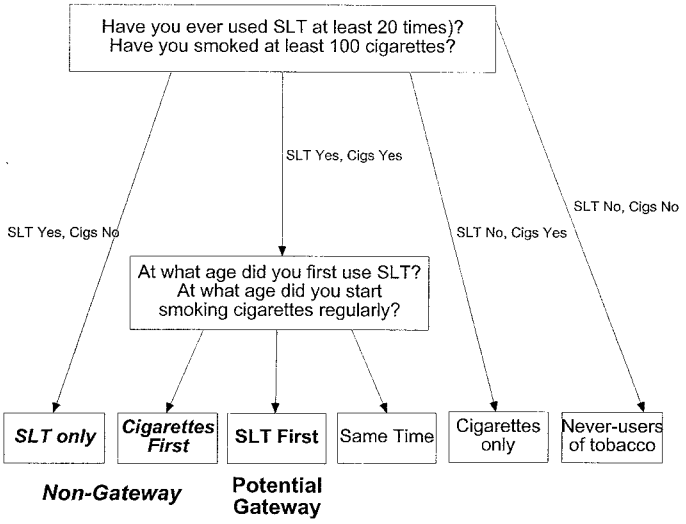
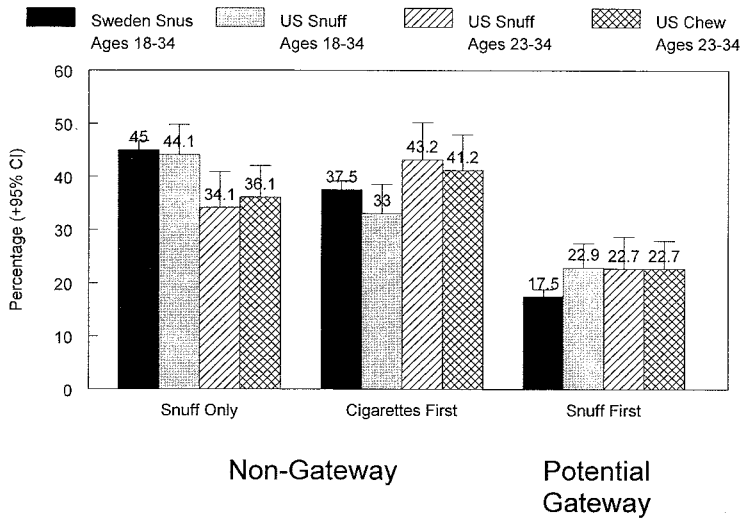


Figure 2. Distribution of non-gateway and potential gateway users of smokeless tobacco, Sweden 1987-88 and U.S. NHIS 1987. U.S. snuff data plotted both for 18-34 cohort and 23-34 cohort. Chewing tobacco data plotted for 23-34 cohort only. Error bars show 95% CI.


Sweden Snus Ages 18-34
US Snuff Ages 18-34
US Snuff Ages 23-34
US Chew Ages 23-34
Percentage (+95% CI)
60
50
40
30
20
10
0
45
44.1
34.1
36.1
37.5
33
43.2
41.2
17.5
22.9
22.7
22.7
Snuff Only
Cigarettes First
Snuff First
Non-Gateway
Potential Gateway

VIEWPOINT

Apply Federal Research Rules on Deception to Misleading Health Information: An Example on Smokeless Tobacco and Cigarettes

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Two respected agencies of the U.S. Department of Health and Human Services (DHHS)—the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA)—have maintained websites which have erroneously reported that smokeless tobacco is not safer than cigarettes.[1,2] This claim is not supported by science and acts unethically to mislead readers of these websites.[3-10] Although others have examined ethical issues in health communication,[11-15] we think these scholars did not go far enough. We think that the explicit ethical standards embodied in current federal regulations for deception in research should be applied to judge deceptive or misleading information in health communication interventions.[16] The term *deception* usually refers to intended acts of deception; regardless of intention, however, erroneous information can cause the recipient to be deceived about the true state of affairs. The misleading health information on smokeless tobacco fails to meet the government criteria against deception in research. First, the misleading information may have adverse effects on some individuals (e.g., those who switch to cigarettes or fail to switch from cigarettes because they think they are not more dangerous than smokeless). Second, individuals have a right to know about the dramatically different dangers of smokeless tobacco and cigarettes. Third, there are alternative communication strategies that could be employed to inform people of the risks of both products. And, finally, such misleading information would be unallowable because it is not linked to debriefing. This article reviews the misleading information on the governmental websites, shows how modern ethical rules against deception can be applied to health information, and argues that providing information about the comparative risks of cigarettes and smokeless tobacco is the least evasive and most ethical course of action.

DISINFORMATION

Up until June 2002, the CDC web page for the Surgeon General's Report (SGR) for Kids about Smoking asked the question: "Is smokeless tobacco safer than cigarettes?"—and answered, "NO WAY!"[1] As the result of our broaching

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the issue of deception with them, they revised the web page to ask, "Is smokeless tobacco safe?" and they answer, "NO WAY!" We will discuss issues related to the revised page below, but think it fair to note that for many months this prominent governmental source was offering inaccurate comparative information on smokeless tobacco and cigarettes.

The web page of SAMHSA's National Clearinghouse for Alcohol and Drug Information contains this passage in a section called, "Tips for Teens: the Truth about Tobacco":

> Question: Isn't smokeless tobacco safer to use than cigarettes?
>
> Answer: No. There is no safe form of tobacco. Smokeless tobacco can cause mouth, cheek, throat, and stomach cancer. Smokeless tobacco users are 50 times more likely to get oral cancer than non-users. Those smokeless tobacco users who don't develop some type of cancer are still likely to have signs of use, like stained teeth, bad breath, and mouth sores.[1]

Wherein lies the error or possible deception in asserting that smokeless tobacco and cigarettes are equally dangerous? First, there is no scientific doubt that smokeless tobacco is substantially safer than cigarettes.[8-10] (The Institute of Medicine [IOM] report provides a thorough review, indicating that smokeless tobacco is safer than cigarettes, particularly as used in Sweden and North America, rather than as used in India.)[8] Smokeless tobacco does not cause respiratory disease or lung cancer, meaning that there would be at least 60% fewer deaths from smokeless than from cigarettes.[17] In fact, epidemiological analyses estimate that smokeless tobacco has only 2% of the risk of cigarettes.[7] The account on the SAMHSA web page also employs a logical non sequitur. The question posed was, "Isn't smokeless safer?" and yet the question answered was, "Isn't it safe?"

Note also, SAMHSA doesn't compare the oral cancer effects of smokeless to cigarettes (which would address the "safer" question), but rather to the risks in non-users of tobacco. The predominant health risk linked to smokeless tobacco is oral cancer, but cigarettes seem to be even more strongly linked to oral cancer than is smokeless tobacco. Figures reported by Rodu show that cigarettes cause 2.28 times more oral cancer than does smokeless tobacco.[8] In other words, smokers would achieve a significant 43% reduced risk of oral cancer by switching to smokeless.[7] The only possible scientific source we know for the SAMHSA claim that smokeless tobacco users are 50 times more likely to get oral cancer than are non-users is from one cell of the Winn et al. study of female users of a form of dry snuff, where this number applies only to those who have used the product for 50 years.[18] The overall figure from this study is 4.2 times greater risk of oral cancer for white, female dry snuff users in rural North Carolina. A recent review of epidemiological research finds that moist snuff users have 1.1 times relative risk of oral cancer than non-smokers, while chewing tobacco users have 0.6 times relative risk, and, for general users of smokeless tobacco, the risk was 2.8 times relative risk of that for non-users.[19] This review concludes: "The use of moist snuff and chewing tobacco imposes minimal risks for cancers of the oral cavity and other upper respiratory sites, with relative risks ranging from 0.6 to 1.7."[19]

The U.S. authorities are not alone in making misleading errors. The Government of Saskatchewan (Canada) is explicitly wrong in the assertion: "Smokeless (spit) tobacco is not safer than smoking. In fact, smokeless (spit) tobacco is just as dangerous to your health as cigarette smoking."[20]

It is difficult to know whether these websites represent mistakes or conscious misrepresentations. The desire to do everything possible (including denying the truth and evading questions) to discourage the use of addictive smokeless tobacco could arise for several reasons. There is understandable reluctance to do anything that might encourage the use of addictive substances that carry health risks (i.e., are not safe). Moreover, there is widespread concern that smokeless could act as a stepping-stone or gateway product to use of the much more dangerous cigarette.[21-23] The IOM report on tobacco harm reduction, for example, indicates that one of the population-level risks of smokeless tobacco is "adolescent use of smokeless tobacco as a gateway to cigarette smoking."[8]

But we do not think, as will be explained below, that such concerns justify disinformation or deception in health communication. Several scholars have reviewed ethical issues in health promotion.[11-13] Guttman in particular has called for the systematic consideration of ethical implications of all health campaigns.[12] Attempts to persuade can involve rhetorical maneuvering that, in the course of wordsmithing, can serve to mislead. Similarly, messages that appeal to fears or prejudices can be coercive.[12] There will always be a gray area between truthful persuasiveness and outright deception. But these smokeless tobacco messages clearly cross the line and actively mislead individuals.

It is critical to understand that this article focuses on the issues of deception and misleading information in health communication and health campaigns, not on other ethical issues in public health interventions. Gostin has provided a valuable review of public health law, and we agree that there are circumstances in which the health needs of society should prevail over the needs and rights of the individual (e.g., required vaccinations, quarantines for certain infectious diseases, and so forth).[24] But these public health measures are not carried out deceptively—they are done in the service of evidence and principles that can be publicly assessed. These measures openly confront the abrogation of autonomy for the good of society. We propose that governmental ethics guidelines[11] already in existence for human subjects research provide an appropriate system for assessing potentially misleading health messages.

ETHICAL REGULATIONS FOR DECEPTION IN RESEARCH SHOULD BE APPLIED TO PUBLIC HEALTH INFORMATION

Deception in public health messages should be as controlled as deception in human subjects research. *The Belmont Report*[27] was influential in the formation of federal regulations concerning informed consent.[28] Of the three ethical principles outlined as most relevant to research involving humans, autonomy (respect for persons) is arguably most relevant for our analysis. Specifically, the *Report* states:

> An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or *to withhold information necessary to make a considered judgment*, when there are no compelling reasons to do so.[27] [emphasis added]

Clearly, autonomy is the principle most violated by deceptive communications. Berg and colleagues note that deception is anathema to informed consent because it serves the aims of the researcher (or communicator in our case) while "demeaning human dignity."[29]

We do not think that well intended, paternalistic health communications should be exempted from ethical rules against deception. Title 45, Part 46, of the Code of Federal Regulations (Title 45 CFR Part 46), the current law governing human subjects research, lists specifically the types of research to which these rules do not apply: (*a*) educational research involving evaluation of accepted curricula, procedures, or tests; (*b*) research involving publicly available data or specimen sources where identification of subjects is impossible; (*c*) research designed to evaluate public services; and (*d*) taste and food quality evaluation, where the ingredients are generally recognized as safe.[30] Deception in health communication does not fall under any of these exemptions.

We think that federal rules concerning deception in research can and should be applied to health communication.[16] Research is done, essentially, to answer questions to which the answers are unknown or uncertain. Similarly, public health institutions often use messages based on hypothesized, rather than proven, effects. In essence, health communication frequently represents a large-scale uncontrolled research study with a subject pool in the millions. The regulations do allow for suspension of informed consent (i.e., deception), provided four conditions are met: (1) the research involves no more than minimal risk; (2) the rights or welfare of subjects is not adversely affected; (3) the research can be done no other way; and (4) when debriefing can occur after the study.[16] Disinformation in health communications on smokeless tobacco in comparison to cigarettes strikingly fails to meet any of these requirements.

Requirement 1: no more than minimal risk

Bok observed that deception often has effects beyond those initially intended,[31] and Guttman has argued that even well intended messages can have inadvertent harms.[12] Title 45 CFR Part 46 puts forth a specific definition of minimal risk.[30] It states, "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life. . . ."[30] That is, the risk of the activity is minimal if the subject is placed at the same level of risk whether or not they take part.

Although disinformation may keep some individuals from using smokeless tobacco, and it may also contribute to some individuals not smoking cigarettes, it presents significant risks to the children and adults already experimenting with or using cigarettes or smokeless. One of the most unfortunate consequences would be convincing adolescents or adults to smoke rather than use smokeless tobacco, since trustworthy authorities report them to be equally dangerous. In other words, individuals might be influenced to use cigarettes because they think they are not more dangerous than smokeless tobacco. This message represents greater than minimal risk—as in the absence of the message some consumers might not use cigarettes, but rather smokeless. The reality that most recruitment to tobacco use takes place before the age of 18 requires

communications that honestly describe the risks and decisions faced by young adults. Honest communication allows for more informed decision-making.[25]

Requirement 2: no adverse effects on rights or welfare

The prior argument indicates that the welfare of some individuals may be adversely affected by deceptive health messages. Moreover, the deceptive information is a clear violation of an individual's right to honest information related to one's health. The right to health-related information (as opposed to ownership of one's own medical information, a separate right) is now recognized as an important human right to be respected by those in public health.[32,33] Since information about effective reduced risk products can have dramatic effects on individual health risks, the individual has a right to this information.[5]

Some may argue that individual rights are outweighed by the potential benefit of the deception for public health. A product that reduced risk to the individual could harm public health overall, if more people use the less risky product. This argument can be seen in the IOM report, "Clearing the smoke."[3] Kozlowski and colleagues have shown that at high levels of risk reduction (e.g., greater than 90%), increases in use that could result in net public health harm become practically impossible.[34] To justify violations of individual rights by deception, the public health harm from presenting the truth must be clear, not speculative or remote.[32]

Requirement 3: no alternative

If the intent of the information is to prevent both smokeless tobacco use and cigarette smoking, deception is certainly not the only way to achieve these goals. Honest messages against smokeless and cigarettes, which could describe some risks from smokeless and much greater risks for cigarettes, may be no less effective than the deceptive message. It is unknown whether the disinformation is effective in discouraging either smokeless tobacco use or cigarette smoking, let alone whether it discourages both.

A quick browse through the CDC's website reveals two documents that outline effective tobacco control strategies: *Best Practices for Comprehensive Tobacco Control Programs*,[35] and *Program and Funding Guidelines for Comprehensive Local Tobacco Control Programs*.[36] These documents list seven strategies for effective tobacco control: (1) community programs; (2) school programs; (3) counter marketing; (4) cessation; (5) enforcement; (6) administration and management; and (7) surveillance and evaluation. The CDC recommends that these factors be integrated into local programs to change social norms around tobacco, discourage youth use, encourage cessation, and enforce anti-tobacco laws. Under these strategies, disinformation is not a necessary means to achieve these ends. Undoubtedly, disinformation is not the only way to discourage cigarette and smokeless tobacco use. There are alternatives that may be more effective.

Requirement 4: debriefing possible

In clinical research, debriefing requires that subjects (*a*) be informed that they were deceived; (*b*) be told why deception was necessary; and (*c*) be told the true purpose of the study.[16] Debriefing is likely not practical for most health communication interventions. Requiring debriefing may be an unrealistic, essentially impossible, rule for health communications via mass media. A case could be made that the requirement for debriefing be ignored on practicability grounds. We do not think, however, that this requirement should be made optional. Nonetheless, even if we disregard the requirement to debrief, the current messages still fail the deception test on the three other levels.

Professional integrity and credibility

Just as the right of personal autonomy is linked to the obligation to employ informed consent,[5] the right to honest information is linked to the obligation to have professional integrity in providing information. Using disinformation when other means of persuasion are available not only violates the rights of the individual, it also harms the credibility of the organization producing the message. Callahan argues that those in health promotion should take a long-term view, using approaches that both achieve their aims and preserve credibility.[15] He warns that, once the public becomes aware of deception, a backlash against health promotion could occur wherein even truthful messages would be rejected by the public.

Professional organizations have explicitly called for integrity and honesty. The American Public Health Association (APHA) holds that: "Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances, in accordance with internationally recognized standards."[37] Similarly, the Health Education Code of Ethics (from the Society of Public Health Education) states that ". . . health educators must consider all issues and give priority to those that promote wellness and quality of living through principles of self-determination and freedom of choice *for the individual*."[38] [emphasis added] The Code of Conduct for Psychologists (from the American Psychological Association) states that, "Psychologists seek to promote integrity in the science, teaching, and practice of psychology. . . . In describing or reporting . . . research, or teaching, they do not make statements that are false, misleading, or deceptive. . . ."[39] Clearly, these organizations' codes would not tolerate deception in health communications.

CONCLUSIONS

The Federal Trade Commission's required warning on smokeless tobacco products and advertisements states, "This product is not a safe alternative to cigarettes." This warning, thus, engages the issue of the relative dangers of these products. Consumers probably do have an interest in knowing if one tobacco product is less dangerous than another—even if they accept that no tobacco product is safe. The revised CDC web page avoids answering the comparative question, which previously had been the featured leading question of their site. We think that health communicators need to develop ways to answer the question, "Is smokeless tobacco safer than cigarettes?" For example, one might write, "Yes, smokeless is safer than cigarettes, but smokeless is not safe and there are a host of reasons to not use smokeless—especially if you have not used any tobacco products in the past." (This and the examples below are broad suggestions for content—obviously, health communicators would face a number of important issues related to optimum wording, reading-level, information-processing, and age considerations.) Or perhaps it would be useful to answer, "Smokeless tobacco may cause disease, including oral cancer, but cigarettes cause oral cancer, lung cancer, chronic obstructive pulmonary disease, cardiovascular disease, fires, and expose others to secondhand smoke." We are not aware of evidence that messages along these lines would be less effective in discouraging smokeless use overall than are the ones used above. Following are some questions and answers, which appear scientifically supportable, and are perhaps useful to also consider:

Question: Is smokeless less addictive than cigarettes?
Answer: No.
Question: Is it hard to quit smokeless?
Answer: Yes.
Question: Does smokeless cause dental disease?
Answer: Yes.
Question: Is smokeless a safe alternative to cigarettes?
Answer: No, particularly if you don't smoke now. However, smokeless is much less risky to current smokers than is smoking.

We anticipate that some public health advocates and researchers will be distressed by our conclusions. We suggest they direct their critiques to whether the four ethical research principles can and should be properly applied to public health communications;[16,30] and whether our explanation of how the four principles should be applied to smokeless tobacco and cigarettes is appropriate.

Health communicators should observe the sound ethical principles that oppose deception. Federal research regulations should be applied to public health information. Public health needs can sometimes override individual needs and rights;[16] this should happen, though, only under well defined circumstances. Disinformation should not, however, be employed unless the standards for research ethics can be met. In practice, this will almost certainly mean that deception has no ethical place in the public health toolkit.[16]

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Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options

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Public health policy needs to be assessed for effects on human rights as well as public health. Although promoting harm reduction products to cigarette smokers might lead to greater total public health harm, if the products become too popular, human rights issues also need to be considered. Avoiding, or objecting to, the fair presentation of information on effective harm reduction products to smokers to allow them to make an informed choice to reduce health risk can represent a violation of a human right – the right to information. The necessary conditions are not met for protecting public health by restricting information on certain risk reduction products. As examples, based on current evidence, smokers have a right to information on snus (Swedish moist snuff) and medicinal nicotine as harm reduction options that would reduce substantially the risk of death to individuals. Smokers also have a right to truthful information about lower-tar cigarettes that have been erroneously promoted as risk reducing.

Introduction

Two recent, major publications have helped shape consideration of pharmaceutical or tobacco products for reducing harm to cigarette smokers who are unwilling to cease nicotine use completely. The first book resulted from an international workshop funded by the Robert Wood Johnson Foundation, the American Society of Addiction Medicine, and the Addiction Research Foundation (Ferrence, Slade, Room, & Pope, 2000), and the second book was the result of an expert committee convened by the prestigious Institute of Medicine of the National Academy of Sciences and partially funded by the U.S. Food and Drug Administration (Stratton, Shetty, Wallace, & Bondurant, 2001). In nicotine-related public health policy, there has been a desire to avoid promotion of harm reduction products that, while reducing toxicity to individual users, might increase public health harm because of increased numbers of users.

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Ferrence et al. (2000) noted one of the important questions: 'Would there be a net benefit to society if novel products reduced risk but increased use?' Later in the book, Henningfield and Fant (2000) indicated that, in evaluating a harm reduction product, it is important to include 'the potential immediate and long-term health effects at the population level' (p. 240). A later chapter urged that a key question in evaluating harm reduction products is whether the product 'ends up reducing harm for the population as a whole' (Reuter, 2000, p. 337). The Institute of Medicine report (Stratton et al., 2001) assessed the science base for tobacco harm reduction. Before endorsing any product, the committee wanted to see evidence on increase in harm 'to the population from encouraging initiation or continuation of smoking'. The Executive Summary had as its final conclusion, 'Conclusion 6. *The public health impact of PREPs [Potential Reduced Exposure Products] is unknown. They are potentially beneficial, but the net impact on public health could, in fact, be negative*' (p. 6).

The principle of protecting the health of the public has been offered, then, as one guiding principle in the development of harm reduction products; but these major works (Ferrence et al., 2000; Stratton et al., 2001) offer no consideration of another established principle: the

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human right of individuals to receive information relevant to their health and their health choices. The right to information derives from the principle of respect for autonomy. (The principle of autonomy is also the source of the requirement for informed consent for individuals who take part in research.) If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health (Freedman, 1999). In a tradition deriving from the Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948), the American Public Health Association concluded, 'Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances, in accordance with internationally recognized standards' (Bird, 2001). Assessments need to be made if a public health goal justifies restrictions on human rights (Gostin & Mann, 1999).

The present commentary asserts that (a) snus (Swedish moist snuff) and medicinal nicotine, based on present evidence, make dramatic reductions in health risks to individual smokers; (b) there is an established right to information that affects health; and (c) the potential public health harm is not clear and convincing enough to justify suspension of advice about reduced risks to individuals from these products. Other possible issues involved with reluctance to promote known harm reduction products will be discussed briefly. These include (a) concern that addicts are impaired in making free choices, (b) belief that no harm reduction products of any kind are warranted, (c) refusal to advise at all in the absence of strong governmental regulation, and (d) preference to let the industry solely promote their own products.

Two significant harm reduction products for individuals who smoke cigarettes

This commentary is not the place for a detailed review of harm reduction products; for that, see the Institute of Medicine report (Stratton et al., 2001). The Institute of Medicine report avoided recommendations about harm reduction products, declared every product as a 'potential' harm reduction product, and proposed an elaborate, extensive scheme for assessment (based on toxicology, epidemiology, as well as proper governmental regulation). Though such assessment is desirable, the feasibility or practicability of the Institute of Medicine report is far from clear. It is sufficient in this commentary to establish that a product lowers risks substantially to individuals. While further research is needed, the toxicology and epidemiology of smokeless products and medicinal nicotine are well enough understood at present to be confident that these products are substantially less dangerous than cigarettes. For purposes of this argument, it is unnecessary to establish a precise estimate of risk and unnecessary to show that the product is absolutely 'safe.' This commentary focuses on two types of products to illustrate, snus and medicinal nicotine.

Snus reduces tobacco harm dramatically in comparison to cigarettes (Ramström, 2000; Henningfield & Fagerström, 2001). Rodu and Cole (1994, 1999) have presented evidence for substantial harm reduction from smokeless tobacco in general. Since about half of cigarette deaths arise from lung cancer and respiratory disease (English et al. 1995; Peto, Lopez, Boreham, Thun, & Heath, 1994) and since smokeless products are not otherwise more dangerous than cigarettes, smokeless tobacco products can be estimated to reduce mortality by at least half, because they do not cause lung cancer or respiratory disease. Snus is lower than other moist snuffs in known toxins (N-nitrosamines and polynuclear aromatic hydrocarbons) (see Ramström, 2000). There has been concern about smokeless tobacco and oral cancer. Noting the high rate of snus use in Sweden and citing five studies, the Institute of Medicine report stated, '[T]he use of snus in Sweden has generally not been associated with oral cavity cancer' (p. 428). The Institute of Medicine report also indicated, 'In a large population-based study looking at risk factors for squamous cancer of the head and neck, Lewin et al. (1998) found no increased risk with the use of Swedish snuff' (p. 301). There also are no secondhand smoke or fire risks from snus. The findings are mixed on whether snus contributes to cardiovascular disease (Ramström, 2000; Henningfield & Fagerström, 2001; Rodu & Cole, 1999). Snus is not safe, but, on the basis of toxicological principles (no smoke toxins from smoke exposure to the lungs) and current epidemiological knowledge, snus is significantly less dangerous to individual users than cigarettes.

Medicinal nicotine products (nicotine replacement therapies) such as gum, patch, nasal spray, and inhaler also are likely to be much less dangerous than cigarettes (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). They deliver no smoke or tobacco toxins (except nicotine) to the user. Medicinal nicotine products have been judged to be so low in risk that some of the varieties are available as non-prescription pharmaceuticals in many countries around the world, including Australia, Austria, Brazil, Canada, Denmark, France, Spain, Sweden, Taiwan, and the United States (Corrao, Guindon, Sharma, & Shokoohi, 2000). On current epidemiological evidence, these products appear to reduce risk in comparison with cigarettes by close to 100% (Kozlowski, Strasser, Giovino et al., 2001). They have been demonstrated to carry little to no excess cardiovascular risk (Kimmel et al., 2001; Benowitz, & Gourlay, 1997), even in heart patients (Rennard, Daughton, & Windle, 1998), and no risks of oral cancer, lung cancer, or respiratory disease (Greenland et al., 1998). As much as five years use of medicinal nicotine in the Lung Health Study (Murray & Daniels, 1998) was unrelated to cardiovascular disease or other serious health effects. While greater, longer-term use of medicinal nicotine might reveal some increased to risk to health, it is not plausible to expect that such risks would ever come close to the dangers of cigarettes.

The Institute of Medicine report itself shows guarded support for this position: 'The committee also concludes that for persons addicted to nicotine, a nicotine-containing drug product is preferable to a cigarette or other tobacco-containing product as a chronic source of nicotine' (p. 227). The very next sentence in the report goes on, not to encourage such use, but rather to encourage that the Food and Drug Administration look into the matter: 'The FDA should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy, again, if supported by valid clinical data' (p. 227).

Snus and medicinal nicotine are not safe or completely without risk. Both snus and medicinal nicotine may cause reproductive health problems and should be avoided during pregnancy, but these problems should still likely be less than for cigarettes (Benowitz, 1998; Stratton et al., 2001). Medicinal nicotine probably is somewhat less dangerous than snus, because medicinal nicotine lacks some of the tobacco toxins still present in snus, and because medicinal nicotine gives clearer evidence of low cardiovascular risk. However, for the present argument, it is not important to compare snus with medicinal nicotine, but it is critical to establish each as significantly less dangerous than cigarettes.

There are supposed harm reduction products that have been proved to not reduce harm to individuals. The lower-tar cigarette appears to not reduce toxic smoke delivered to smokers (Jarvis et al., 2001; Kozlowski & O'Connor, 2000; Kozlowski, O'Connor, & Sweeney, in press; National Cancer Institute, 1996; Benowitz et al. 1983) or mortality (Burns, Major, Shanks, & Thun, 2001). Newer cigarette-like products (Eclipse and Accord) at best make smaller changes in the product (smaller than snus or medicinal nicotine in comparison to cigarettes), and likely make concomitantly small changes, if any, in risk. Careful testing such as prescribed by the Institute of Medicine report would be needed to establish the magnitude, if any, of risk reduction from the products.

The human right to health relevant information

Several ethical traditions (legal, medical, and public health) lead to a view that there is a human right to fair information relevant to health care. All traditions depend upon the principle of individual autonomy. Beauchamp and Childress (1994) argue that both Emmanuel Kant and John Stuart Mill helped establish the philosophical basis for valuing an individual's self worth and the individual's rights to determine goals. The Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948) acknowledge a basic human right of autonomy. Legal traditions have also helped shape expectations about patient autonomy and patient rights to be informed of and consent to medical treatment (Wear, 1998). McCullough and Wear (1985) described a 'new ethos of patient autonomy' that has arisen in the face of benevolent but paternalistic ('doctor knows best') practices. Increasing governmental regulations on formal informed consent procedures and research have influenced the modern context in which patients deal with health care (Wear, 1998).

Public health ethics overlap with biomedical ethics but also have some distinctive emphases (Mann, 1999). Working in the public health field of family planning information, which can involve both one-on-one clinical encounters as well as diverse social sources of information, Freedman (1999) argued that censorship of information about reproductive and sexual health violates individual human rights. Freedman wrote: 'Women need and want reproductive health services because they want – and have – a fundamental human right to live lives that are free from unnecessary physical and mental suffering, and that permit the exercise of fundamental freedoms' (p. 147). Similarly, censoring information on genuine risk reductions to individual smokers restricts the ability of smokers to exercise their fundamental freedoms to make choices that can have dramatic effects on individual health risks.

In public health, benefit to the many can override the rights of the individual. Public health interests should prevail when there is low cost to the individual and high benefit to society (Annas, 1999). For an individual smoker who will not give up nicotine use, the benefits of snus or medicinal nicotine could be profound to the individual (and possibly to society), while the costs to society are far from clear and convincing.

Clear and convincing evidence needed

In law there are three standards of evidence, in order of increasing stringency: (1) the *preponderance* of the evidence, where a conclusion is 'more likely than not' to be true; (2) *clear and convincing* evidence, producing firm belief or conviction; and (3) evidence *beyond a reasonable doubt*. Clear and convincing evidence has been required in court cases involving issues like quarantine, where an individual's rights are suspended to protect the public from the risk of spreading a serious disease (Annas, 1999).

Two principles have been emphasized in determining whether public health interests should override individual health interests: proportionality and probability. The limitation of rights 'must be proportional to the public health interest and its objective.' (International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights 1999, p. 48); and 'The risks to the public must be probable, not merely speculative or remote.' (Gostin & Mann, 1999, p. 67).

The language of the prospects for adverse public health effects is decidedly tentative with little indication of adverse public health effects being either probable or proportional. The Institute of Medicine report (Stratton et al., 2001) notes: 'Both Pauly & colleagues (1995) and Hughes (1998) *raise the possibility* that the introduction of PREPs and their promotion as less harmful ways to

smoke *could* lead to increased initiation.' (Stratton et al., 2001, p. 73); and 'The major concern for public health is that tobacco users who might have otherwise quit will use PREPs instead, or others may initiate smoking, feeling that PREPs are safe. That will lead to less harm reduction for a population (as well as less risk reduction for that individual) than would occur without the PREP, and *possibly* to an adverse effect on the population' (Stratton et al., 2001, pp. 8–4; italics added.)

When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001). The risk to individuals from medicinal nicotine seems to be so low that it is not possible for use to increase enough to cause a net public health loss: If risks from these often over-the-counter products are less than 0.1% (1 per 1000), then use would have to increase over 1000 times to cause an equal public health problem (Kozlowski, Strasser, Giovino, et al., 2001). For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.

Other issues that might prevent public health advice

Are addicts in a position to freely choose?

To hold that adult nicotine addicts are too impaired by their addiction to give informed choice is not in keeping with prevailing legal traditions on competency. Nearly every individual is assumed to be competent to choose, unless proved otherwise (Wear, 1998).

Are any harm reduction products warranted?

At least one distinguished public health scientist has raised doubts about whether harm reduction products are needed at all (Pierce, 2000, p. 227). He stated that prevention and cessation programs should possibly be the sole focus of controlling smoking-caused disease. This position can be seen as an extreme form of neglecting the right of smokers to make informed choices. If complete abstinence is *not* the only way for an individual smoker to significantly reduce health risks from nicotine addiction, then the rights of smokers to be informed of this is still in opposition to an exclusive emphasis on prevention and cessation.

Should we provide advice in the absence of proper governmental regulation?

The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.

Shouldn't manufacturers do their own promotion?

I have also heard colleagues say that manufacturers of these products don't need our help to promote their products. But that should not be justification for avoiding any positive comment or support for information that might reduce for individual smokers the harm from smoking. Note that the public health community has not similarly left all advice or encouragement about products–vaccines or seat belts or condoms (another harm reduction product).

Public health approaches to informing smokers of harm reduction options

I am not primarily calling on the medical profession to talk with their noncompliant smoking patients about harm reduction. A broad-based model for public health interventions can be found in work on reproductive health. In the area of reproductive health and the right to information, it is argued that *comprehensive programming is needed to inform individuals* (Cohen, 1994). Such programs should include mass media advertising, message placements in TV programs, and systematic training of health professionals to discuss the needed information (Freedman, 1995).

Public health policies should be assessed for their affect of human rights

The late Jonathan Mann was a leader in calling for formal assessments of the impact of public health policies on human rights (Gostin & Mann, 1999; Mann et al., 1999). Figure 1 is derived from some of his work (Mann et al., 1999). The best policies are those that protect human rights as well as promote public health. Mann noted that it was a violation of human rights on the part of governments to not provide honest information

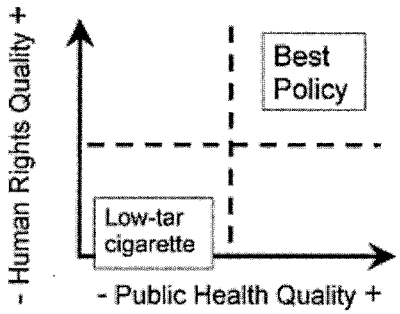

Figure 1. Schematic showing the interactive relationship between public health policy and human rights. The best policies are those that are consistent with human rights. Low-tar cigarettes are both poor public health policy and in violation of human rights to information.

about the dangers of cigarettes (Mann et al., 1999). Low-tar cigarettes are designed to reassure smokers and keep them smoking (Kozlowski & Sweeney, 1997) but do not reduce health risks to smokers (Burns et al., in press). This is both a violation of the human right to know and a counterproductive public health measure.

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 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.

Declaration of Competing Interests

Lynn T. Kozlowski received research funding nine years ago from a manufacturer of medicinal nicotine and has consulted with Pinney Associates, who provide consultative services to manufacturers of medicinal nicotine.

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TOBACCO CONTROL
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Editorial

Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction

Both the recent Institute of Medicine (IOM) report[1] and the article by Henningfield and Fagerstrom[2] in this issue of *Tobacco Control* consider the value of adding harm reduction products to the main public health strategies for dealing with tobacco use—prevention, cessation, and protection of non-smokers from tobacco smoke pollution.[3 4] Harm reducing products are those that lower total tobacco caused morbidity and mortality, even though these products might involve continued exposure to one or more tobacco related toxicants. The IOM committee developed a testing strategy to assess which products (tobacco or pharmaceutical) are truly harm reducing, along with surveillance and regulatory principles for the protection of public health. Henningfield and Fagerstrom[2] discussed the possible benefits from an uncontrolled harm reduction "intervention" in Sweden involving Snus (Swedish moist snuff) and to some extent nicotine replacement pharmaceuticals or medicinal nicotine (MN).

It will take years, if ever, before any battery of IOM-type tests will be in place. Given the probability of legal and political battles, the final form of testing and regulation may be far from adequate, leading to further decades of the promotion of ostensibly reduced risk products falsely reassuring tobacco users. Cigarette smoking remains the single leading preventable cause of death in most developed countries[5] and a major cause of current and future deaths in developing countries.[6] For health, non-smokers should never start smoking, and current smokers should become former smokers as soon as possible. Harm reduction, if done well, offers additional promise. Once it was hoped that lower tar cigarettes would have harm reducing properties and be good for the public's health,[7] but, on current evidence, they have been a public health disaster.[8-11]

Strongly prefer harm reduction products with the largest effects to those with small effects

One harm reduction strategy is to alter cigarettes to try to reduce or eliminate toxic ingredients. Such altered cigarettes are of obvious interest to the cigarette industry. But there are serious practical challenges to assessing the impact of small changes. Scientifically, smaller effects are harder to identify than are larger effects. Reliably finding smaller effects requires more reliable measures and larger samples.[12] In other words, more expensive, longer term studies will be needed to determine, for example, if a product change has caused a 5% reduction in risk than an 80% reduction. The proposed IOM testing methods need to be applied to these new tobacco products before any recommendations can be made about novel, small change, reduced risk products; therefore, it will be years before it will be possible to assess with confidence the health risks of changes in cigarette formulations or other burned/heated tobacco products (for example, Eclipse, Accord, Advance).

Our strategy is to start with the least risky nicotine delivery products and try to judge if it is reasonable at the present time to recommend that smokers use them for harm reduction. We have concluded that: (1) smokers who cannot or will not stop using nicotine in cigarettes should be encouraged to use MN as their only source of nicotine; and (2) never smokers should not be encouraged to use nicotine in any form. We are not advocating the mixing of cigarettes and MN.

From the point of view of someone treating an individual with a health problem, risks and benefits are weighed, and decisions are made on the basis of current evidence—often flawed and inconclusive. For the individual smoker, there is no doubt that MN, in the form of pharmaceutically tested products such as gum, patch, nasal spray, is less dangerous than continuing smoking. We concur with the IOM report "that for persons addicted to nicotine, a nicotine containing drug product is preferable to a cigarette or other tobacco containing product as a chronic source of nicotine"(pages 7–20).[1] Henningfield and Fagerstrom[2] also suggest that medicinal nicotine may be preferred to Snus as a less dangerous product.

The case for the individual smoker is clear, but the case for public health has been questioned. In discussions of harm reduction products for cigarettes, we have often heard participants (including some of us) argue that a less dangerous product might encourage use so much that the reduced risk for individuals sums to greater risk for the entire population. What if more people use MN?

Applying the risk/use equilibrium

To evaluate the possible problems caused by increased use of a less dangerous product, it is helpful to consider what might be called *the risk/use equilibrium*—an equilibrium achieved by increasing use as risk decreases. Maintaining this equilibrium constitutes a public health stalemate. To the extent use rises faster than risk is decreased, public health will be increasingly disadvantaged. To the extent risk is decreased faster than use rises, public health will be advantaged. Figure 1 shows a plot of the relation between level of risk and the increase in the number of users (as a multiplier) needed to achieve an equilibrium, or, in other words, no increased population level risks.

MORTALITY RISKS FROM MEDICINAL NICOTINE

A carcinogen-free, unburned nicotine source, free of all other smoke toxins, is not widely expected to cause cancer,

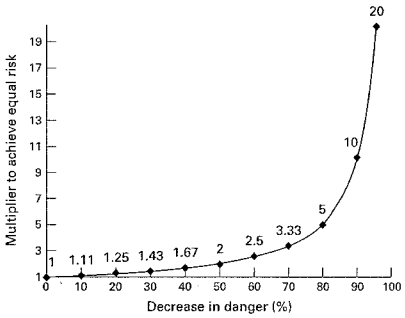

Figure 1 The risk/use equilibrium. Each point on this curve indicates the multiplier needed to achieve a constant level of population risk, given specific levels of decreased danger per user. For example, if 100 individuals used a product with full danger (for example, killing 100% of users), 10 times that number (1000 individuals) would need to use a product that had 90% decreased danger, to achieve an equal health problem (100 dead in each instance). The formula is Y = 100/100−X, where Y = multiplier and X = decrease in danger, expressed in percentages. If danger is 0.1%, use would have to increase by 1000 times to produce a problem of the same magnitude as the full risk product (not plotted on figure). For a given risk on the curve, use that is increased by a smaller multiplier represents a public health benefit, and use that is increased by a larger multiplier represents a public health (population level) cost. (See text for more details.)

chronic obstructive lung disease, or fires—all causes of tobacco attributable mortality.[13-15] (Nicotine should be avoided during pregnancy, but cigarettes cause greater problems for reproductive health.[1 16]) Most concerns about mortality effects in users of MN focus on possible effects on cardiovascular disease,[1 16] so we will take a closer look at MN and cardiovascular disease.

The toxicological literature is mixed on the relative dangers of nicotine alone versus cigarette smoke for cardiovascular disease. Although nicotine can increase heart rate, blood pressure, and cardiac contractility, MN does not seem to produce many of the cardiovascular risks of cigarette smoke.[1 16] Unlike cigarettes, MN does not appear to promote platelet aggregation.[17 18] MN has no carbon monoxide. MN (gum) was shown to not have adverse effects on coronary circulation.[19] MN (nasal spray) was found to not have adverse effects on blood lipids (for example, high density:low density lipoprotein cholesterol ratio).[20]

Epidemiological research provides a better estimate of actual cardiovascular risks from MN. Although there were some early media reports of cardiovascular problems caused by MN (in particular, the nicotine patch),[21] subsequent research supports that MN has very low cardiovascular risk. Up to five years of nicotine gum use in the Lung Health Study was unrelated to cardiovascular diseases or other serious side effects.[22 23] Other research has found no excess risk of myocardial infarction from the nicotine patch in the general population[24] or even in patients with cardiovascular disease.[25] A meta-analysis of 35 clinical trials (5501 active patch, 3752 controls) found no evidence of cardiovascular or other life threatening adverse effects caused by MN, and noted that: "The results of this meta-analysis indicate that very large studies would be needed to assess the effect of the patch, if any, on serious, rare outcomes."[26] Based on current epidemiological evidence (which might change with more data on longer term use), MN has small to negligible effects on cardiovascular disease in former smokers. Some may say that it cannot be established that MN is "safe" (without any excess risk). This may be true, but it is fatuous to treat such a statement as an argument, in and of itself, against the use of this low risk product for both individual and public health care. We think the risk/use equilibrium needs to be considered.

HOW MANY PEOPLE WOULD USE MEDICINAL NICOTINE?

MN use by never smokers is likely to be rare. In a study of nicotine replacement therapies in the UK and Sweden, Ramstrom[27] found no cases where Nicorette gum was being used by someone who had not used tobacco previously. Note that over-the-counter (OTC) MN has been available for several years in the USA, and there is no evidence of emergence of a MN abuse problem in never smokers.[28] We find it hard to expect that more that 10% of former smokers might start using MN—but many of them might be spared from returning to cigarettes by using MN. Fifty per cent use of cigarettes by adults (males and females combined) appears to be close to a maximum use levels for cigarettes world wide,[29] but it would be unlikely that MN would ever be used by more half of smokers. Summing the projected use of MN by current and former smokers, we would expect a lower limit on use of about 10% and an upper limit of about 35% of adults.

POPULATION LEVEL RISK

We have not put an exact number on the mortality risks, if any, from MN, but our best estimate is that the risks of these often OTC medications are extremely small. For example, if the risk were less than 1/10 000, use would have to increase by over an impossible 10 000 times to cause an equivalent level of problems! On current knowledge, MN use could not increase to a degree that there would be a net public health loss.

The complete public health picture is, of course, somewhat more complicated. Except if MN prevented never smokers from becoming smokers, never smokers who started using MN would be increasing risk somewhat, not decreasing it. As noted above, however, increased use by never smokers and ex-smokers is an unlikely outcome unless the MN industry were to embark on marketing efforts designed to encourage never smokers and ex-smokers to take up MN. On current knowledge, we would not recommend that smokers use MN to reduce cigarette intake. Mixed use of cigarettes and MN will occur, despite recommendations to the contrary. A much more complex and complete model of use and risk is being developed[30] that will estimate risks of different patterns of starting, continuing, and quitting product use. Such a model may be important for judging the value of harm reduction products with less promising risk reducing effects than MN.

Use medicinal nicotine for harm reduction now

The public health community should send a strong message now that the best harm reduction strategy for current smokers, after abstinence, is MN. While others will be promoting tinkering with cigarettes to reduce tobacco risks, we think these modifications are unlikely to produce worthwhile changes in risk and will take years of research to evaluate their actual level of risk. Henningfield and Fagerstrom[2] show evidence that Swedish Snus offers harm reduction compared to cigarettes, but we would particularly support the use of MN as a more powerful harm reduction product carrying less public health risk. As has been pointed out by others,[31] the current regulatory system is upside down, with the more dangerous products (that is, tobacco products) receiving the least regulation and the least dangerous products (that is, MN) subject to the most stringent constraints. If tobacco companies are

unregulated or under regulated, they may well find ways to drown out the messages of medical and public health professionals regarding the least dangerous form of nicotine delivery. Medical and public health authorities should advocate for MN products that provide doses of nicotine in forms that are as affordable and reinforcing as the more toxic tobacco products. They should also advocate for the long term use of MN by those who need it, as has been advocated by Rodu and Cole.[32] Considerable work needs to be done to inform consumers that MN is the least toxic way to get nicotine. One anecdotal report, for example, suggests that some smokers believe that MN is more likely to cause heart attacks than traditional cigarettes.[33] Many adults may perceive MN as a sign of weakness, with tobacco use associated with freedom and the pursuit of pleasure (KM Cummings, personal communication, April 2000). Such an image needs to be changed. If empirical evidence related to MN changes, and making MN more reinforcing might lead to more adverse effects, advice may need to change. For now, we think it is urgent to promote complete substitution of medicinal nicotine for cigarettes for harm reduction in smokers.

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Lynn Kozlowski had some research funding nine years ago from a manufacturer of medicinal nicotine and has consulted with Pinney Associates who provides consultative services to manufacturers of medicinal nicotine. Gary Giovino has also provided consultative services to Pinney Associates. Pennifer Erickson has consulted widely for the pharmaceutical industry related to measures of quality of life.

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Chairman TOM DAVIS. Mr. Sweanor.

Mr. SWEANOR. Thank you very much. I'm also going to be speaking on my own behalf, rather than organizations that I work with.

My name is David Sweanor. I'm a lawyer based in Canada. I've spent just over 20 years now working full time on a whole range of tobacco-control policies in Canada and around the world, many of which I believe have been very successful and certainly had significant impacts in overall consumption; and issues of toxicity reduction is something that I'm very interested in.

I think, to put it all in perspective, what we're looking at by way of policy in tobacco control and public health goals, is we're trying to reduce death and disease as much as we possibly can; and there's really three ways we can do that: We can prevent the onset of tobacco use, we can encourage and facilitate cessation, and we can reduce toxicity for those people who don't quit.

This is an incredibly important task, given the size of the health problem; and you all have heard that from many people. I need not repeat it, but I think it's worth noting a few things about the lack of information smokers have.

Many smokers believe light cigarettes are significantly less hazardous. I think that is one of the most pernicious frauds that either of our countries currently face. They also believe that nicotine causes cancer and, as a result, they're less likely to use approved, effective nicotine medications to help them quit. If they do use them, they won't use as much as they should or for as long as they should. They also believe that smokeless tobacco causes cancer every bit as much as smoking, hence are less likely to use it.

Well, is there a way out of this mess? I think there is because at least theoretically, if we look at this, nicotine is the primary reason why people smoke, but combustion is the primary reason they're dying. Were we to introduce cleaner delivery systems at least in theory that makes a whole lot of sense, and if we're able to do this through some sort of regulated framework from a body that FDA would make available I think reduced toxicity could really complement what else we're doing on prevention of onset and cessation.

I don't think this is just theoretical. When we look at alternative products, we know, for instance, that medicinal nicotine products have been used by some people for long periods of time with no indication of adverse effects. We also know that many other countries have approved these medicinal products, things like patches and gum, etc., for uses that are not approved for here; that it can be used longer term; it can be used for smoking reduction; it can be used for temporary abstinence, relapse prevention.

In the case of smokeless tobacco, there is an absolutely fascinating example from Sweden where a market has been transformed from one that was dominated by combustion-based delivery to one now dominated by smokeless products, and the smokeless products simply don't have the same sort of health impact. The disease rates in Sweden follow the trends of smoking rates, not the trends of overall tobacco use.

So were we to move on this I think we do need to look at some sort of comprehensive oversight. It has to be something like FDA

and for various reasons, in terms of protecting public health, giving consumer protection and actually allowing the market to function.

We need to have answers to some questions such as just how much less risky is a product compared to cigarettes on a one-for-one basis. I think that's an easy determination to make with medicinal products. I think it's an easy determination to make for low-nitrosamine smokeless products. But what about the whole range of other products that people are bringing out? How do we make that determination? How do we look at what impact these products will have if they only replace some cigarettes? Where do we put these products on a range of the continuum of risk so that we can give people information about where they can be in terms of relative risk? How do we make sure these products aren't going to interfere with cessation or encourage uptake of smoking? And how do we communicate messages?

I think this is an absolutely critical issue now because even if tobacco companies were to give totally accurate information that could truly save people's lives, nobody will believe them. There has to be some way of giving information to the public that the public will actually understand and trust. These are very tough issues. I think we know where we need to be. There's a serious question of what do we do in the meantime and how do we get there.

I think certainly as a preliminary step we should be looking at the FDA and the FTC, using the regulatory authority they already have over medicinal products to liberalize that market, make these products more widely available for a wider range of indicated uses. That's a first step.

I think it should be fairly quick to move on issues like low-nitrosamine smokeless tobacco products, but I think we also need discussion, getting more dialog because, ultimately, we're in a situation now where there's no longer a question of whether there will be alternatives to cigarettes or whether consumers will get information, it's how do we evaluate these products and how would we make sure they get accurate communications?

Thank you.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Mr. Sweanor follows:]

David Sweanor Testimony for June 3rd, 2003

Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Health Impact and Regulatory Changes

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

Thank you very much for the opportunity to appear before this committee to talk about a truly critical issue for global public health.

My name is David Sweanor, and I am counsel to the Non-Smokers' Rights Association [NSRA] in Canada, an organization I have worked for for over 20 years. NSRA has been a primary driver for a very full range of public health policies aimed at reducing the toll from tobacco. These include health-oriented tobacco tax policies, restrictions on tobacco sales, comprehensive restrictions of tobacco advertising and promotion, detailed package-based heath information – including picture-based warnings covering 50% of packages and package inserts giving additional health information, comprehensive disclosure of additives and sales data, and regulatory authority over tobacco manufacturing standards. These policies have played a key role in very significant drops in Canadian tobacco consumption, which have outpaced US declines. Last year alone, and largely due to very significant cigarette tax increases, per capita consumption in Canada fell by 8%. I believe that this is two to three times the rate of decline in the US.

In addition to my work in Canada I have, for many years, been very involved in tobacco control issues in this country, and globally. It is because of my interest in global public health, my long-term interest in applying harm reduction principles to tobacco, and the strong policy interactions between Canada and the United States that I welcome the opportunity to speak to you today.

The public health goals for tobacco policy

It is possible to articulate a concise view of the public health goals of tobacco control activities. The ultimate goal is to reduce death and disease as much as is practically possible within the constraints of law and with respect for human rights. To achieve this goal there are essentially three broad areas of intervention. We must expand current efforts that aim to prevent smoking onset and that encourage and facilitate cessation but we must also reduce the toxicity for those who continue to use tobacco.

While many nations have done much to try to prevent onset of smoking, far fewer have made significant strides in promoting and facilitating cessation, and almost none have moved significantly on issues of toxicity reduction. This is a major concern to me since preventing the uptake of smoking, even when successful, will not have a significant impact on disease rates for another 20-30 years due to the lag between the onset of smoking and the development of the resulting diseases. To put this into an American perspective, the World Health Organization estimates that roughly 10 million Americans will die as a direct result of cigarette smoking in the next 20 to 25 years. All of these people are currently smokers, most say they'd rather not be smoking, and only cessation and toxicity reduction can impact on this unfolding tragedy.

In short, the status quo is horrible. Cigarettes dominate the market, and will kill roughly 50% of their long-term users. Most individuals who want or need nicotine on a long-term basis meet this need via cigarettes and far too few turn to FDA approved Nicotine Replacement Therapies such as the patch, oral inhaler, and lozenge. FDA approved products have slowly increased but consumers have far too few choices, the development of long term replacement products have been stymied by FDA regulatory roadblocks, and there has been no meaningful consideration of using these products for long term harm reduction.

There may be a way out of this mess.

Nicotine is the primary reason for tobacco use. It provides various pharmacological effects sought by many smokers. But it is also, especially when delivered through cigarette smoking, highly addictive. Yet nicotine itself is apparently responsible for only a very small part of the health damage caused by tobacco use. The reason smokers are dying in such great numbers is that they are obtaining their nicotine through the repeated inhalation of smoke. Nicotine provides the demand for tobacco, but it is combustion that is the principal reason for the morbidity and mortality.

Simply put, cigarettes are an exceedingly 'dirty' delivery system for the drug nicotine.

Reduced risk products for smokers are a viable concept and, properly regulated and marketed, can complement efforts to reduce smoking onset and assist overall cessation efforts. We should do far more to motivate and facilitate cessation. But for those not currently ready, willing and able to totally cease all forms of tobacco and nicotine, toxicity reduction is the only alternative to a continuation of the current epidemic of smoking-caused disease and death.

The ability to provide reduced-risk forms of nicotine is not merely theoretical. Several countries now permit medicinal nicotine products, such as the patch and gum, to be widely available and to be used in place of cigarettes for purposes such as smoking reduction, temporary abstinence and relapse prevention. Some consumers are also using these products for long-term avoidance of smoking and doing so with no apparent ill effects. Clearly, the risk of these products is miniscule compared to the risk of cigarettes.

In addition, Sweden has witnessed a truly fascinating transition from a market dominated by cigarettes to one where smokeless tobacco is now more commonly used. The smokeless tobacco in that country is manufactured according to standards designed to reduce toxicity, and recent studies from that country have failed to show this form of tobacco to be the cause of any cancer. Recently, the regulatory requirement for a cancer warning on these products was actually removed. Sweden has rates of tobacco use very similar to other Scandinavian countries, but has much lower tobacco-related death rates, and this difference can be largely explained by the fact that so many Swedes use smokeless tobacco rather than smoking cigarettes.

Sweden is an interesting case study for many reasons. Perhaps the key lesson is that it is possible to offer consumer-acceptable alternatives to cigarettes that have massively reduced risks compared to cigarettes. This does not necessarily mean that we should all simply encourage the use of 'snus', but we certainly should look in detail at the Swedish experience when considering the risks and benefits of offering less hazardous substitutes for cigarettes. In fact, given the wealth of experience and data that can be obtained from Sweden [not to mention very different opinions about this data from the Swedes themselves] it is surprising to me that detailed analysis of the Swedish experience has not been more of a priority.

Replacing 'dirtier' delivery systems with cleaner ones is an obvious measure to take in efforts to reduce toxicity for those who are going to continue using nicotine. Different nicotine delivery devices will have differing levels of risk. Theoretically we could place all these products on a spectrum and look at ways to give information and other incentives that would encourage consumers to move toward the lowest risk products that can still meet their needs. And one could also imagine a system of incentives that would encourage manufacturers to work to create products with lower and lower toxicity levels.

But, like most seemingly straightforward public policy solutions it gets rather complicated in the real world. If it were truly easy to prevent a half million deaths a year in this country I am sure these hearings would not even be necessary since the corrective measures would have been taken many years ago.

The complicating issues

We need to avoid making new mistakes and we need to avoid unnecessarily adding to the death and illness caused by past mistakes. Millions of smokers smoke 'light' and 'mild' cigarettes in the false believe that they are actually safer. It took years for independent scientists and governments to discover that these

products are actually part of a massive consumer deception on relative risk. An effective harm reduction strategy must begin with an end to all forms of deception on relative risk and comprehensive science based regulation of all tobacco products and the marketing for those products. There needs to be a governmental agency that knows the whole truth about the relative health risks of different products and that is in a position to insure that consumers are provided the whole truth in a non-misleading way that promotes the overall public health. Without comprehensive regulation both the government and consumers cannot be sure they have complete information or the tools to best protect the public health.

Regulation is only a first step, and is not an end in itself. It needs to be based on clear goals. Here, briefly, are some of the issues I think we need to consider when looking at potential reduced-risk products:

1) **What is the degree of certainty that we want to have that a product truly does reduce risk compared to standard cigarettes?** On a one-for-one basis this is not a difficulty when looking at medicinal nicotine products such as the patch and nicotine gum that are already fully regulated. It should also not be a difficulty with low nitrosamine smokeless tobacco, given the massive differences in potential disease risk compared to cigarettes, if there was a mechanism that could stipulate the actual level of nitrosamines and other harmful substances in these products. If all cigarette use were simply replaced by medicinal nicotine and low nitrosamine smokeless tobacco products the death rates would be massively lower. But there are many products, especially combustion-based products, where the degree of risk reduction is by no means understood. There needs to be some system in place that can credibly evaluate the relative risks of all tobacco products.

2) **What about the risk from a product that only replaces some cigarettes?** It is quite possible that a product could be far less hazardous than cigarettes, but replace so few of the cigarettes that someone smokes that it would have no appreciable impact on risk. Yet if smokers believe such a product to have significant health benefits they are, once again, being deceived. How can we develop guidance on issues of 'smoking reduction'?

3) **How can we effectively place various current and future products on a 'continuum of risk' so that we can communicate to users the information they need to make fully informed decisions?** Many smokers believe that 'light' cigarettes are significantly less hazardous than regular cigarettes, which is perhaps the greatest consumer deception of our time. Consumers also believe that the 'tar' and nicotine listed on ads is what they actually get from smoking various cigarettes. As shown in Appendix 1, many also believe that nicotine causes cancer and that using smokeless tobacco is as deadly as smoking. In addition most harbor misunderstandings about the workings and potential risks from medicinal nicotine that only serve to keep them from availing themselves of these proven safe and effective means of quitting smoking. This level of confusion about such a critical public health issue is truly alarming, and could possibly even worsen as new and unregulated products hit the market.

4) **How can we prevent efforts at toxicity reduction from undermining our efforts on cessation and prevention of uptake?** The main planks of good public policy should be complementary rather than adversarial. If the promise of toxicity reduction reduces quitting or encourages more people to enter [or re-enter] the market the unintended consequences could negate any potential health gains from the intervention. This is the reason that meaningful regulation of both claims and how potential harm reduction products are marketed is critical.

5) **Who should communicate messages to the public?** One of the realities of the present environment, and one borne out by the history of foods and drugs prior to the existence of the FDA, is that without strong government oversight those with a vested interest in selling products should not be trusted to communicate full and truthful information. With foods and pharmaceuticals there are now stronger grounds to believe claims due to the intervention of a credible, objective and expert third party. Such third party validation is as important to tobacco companies as it is to public health. Even a tobacco company that tried to tell the truth about a massively reduced-risk product would probably not be believed in today's environment. It is

critical that FDA be given effective authority over all tobacco products in order to ensure that consumers are not misled about the relative risks of different products, including reduced risk tobacco/nicotine products.

6) **How can we be assured that the messages conveyed to the public are being appropriately interpreted?** What if smokers believed that smokeless tobacco was something they could switch to after they developed a smoking related disease like lung cancer? What if they came to believe that all smokeless tobacco [including, say, that sold in Sudan or Central Asia] had the same risks? There appears to be a strong need for an institutionalized form of post-marketing surveillance, both to assess attitudes and behaviors.

7) **How do we stay on top of what could be a rapidly changing environment?** Approximately 45 million Americans spend roughly $80 billion a year buying a dirty drug delivery system that is killing over 400,000 of them – and tens of thousands of non-smokers – annually. If this market were subject to effective FDA regulation that actually promotes competition based on good science - and marketing that is not misleading - private enterprise and informed consumers would cause a marketplace revolution. Just as did the legal reforms on foods and drugs in 1906 and 1938.

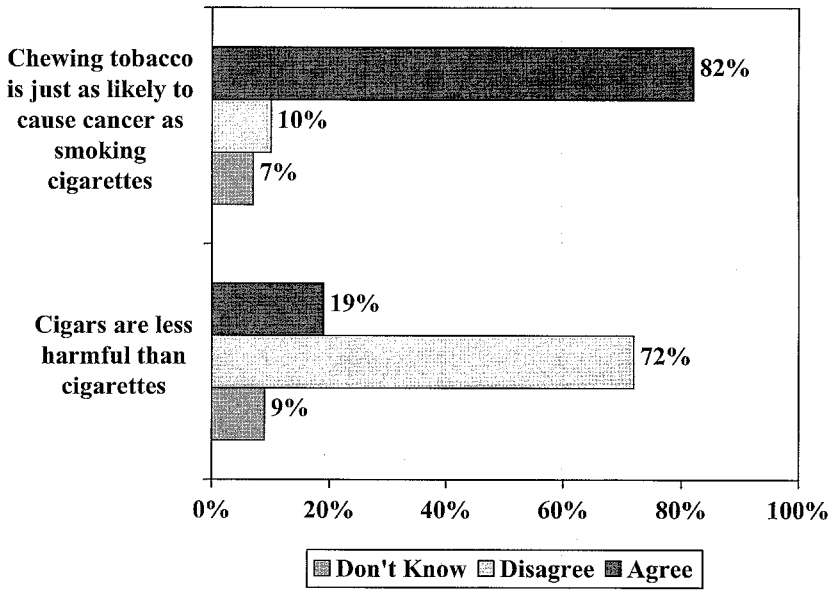
These are tough issues. But the need to address them is truly monumental. Your fellow citizens are dying from tobacco use, but they are also dying for want of truthful information on relative risks and from a lack of viable alternatives to cigarettes. There is a need for prompt action. The FDA and FTC already have authority over medicinal nicotine. I would hope that they would begin an immediate examination of how they might use their existing authority to expand the availability of these products and to explore their potential for harm reduction. Smokeless tobacco products could also be a key part of a harm reduction strategy if a federal agency were given the authority to regulate the content of these products and how they are advertised. I would hope that this, too, could be done quickly.

There are no easy answers. There is, instead, a need to balance potential risks and benefits. There is a need to assess the science behind products and the best way to communicate relevant information to consumers, and how best to regulate a market in order to give maximum protection for consumers. There is also a great need to stimulate discussion on how to proceed. It is no longer a question of whether there will be alternatives to cigarettes or whether truthful information on relative risks should be communicated to consumers. It is, instead, an issue of how to evaluate products and of how to communicate information in a way that complements public health goals and provides consumers with much needed information about the relative risks of alternative products.

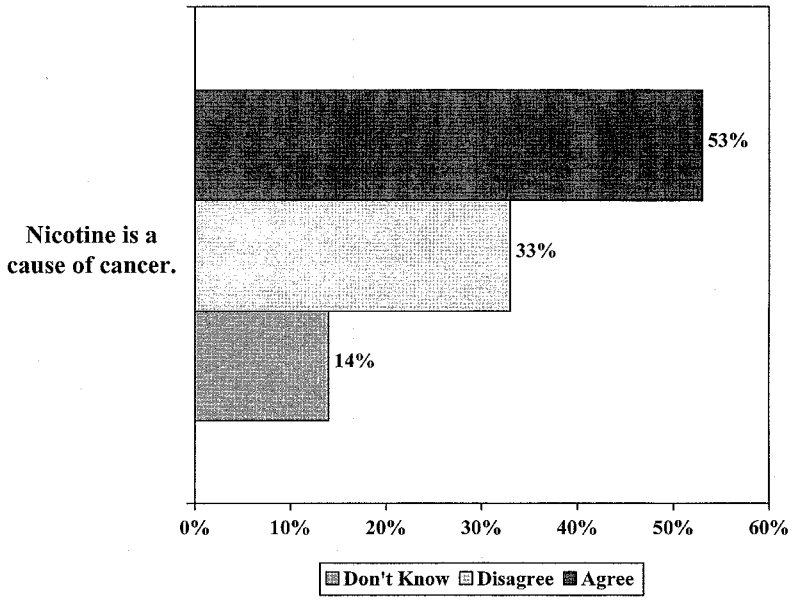
Thank you for your time,

APPENDIX 1

Data From: ***Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products***, K. Michael Cummings, PhD, MPH, Gary A. Giovino, PhD, Maansi A. Bansal, Andrew Hyland, PhD, Jan Hastrup, PhD, Berwood Yost, National Conference on Tobacco or Health *New Orleans, Louisiana, November 2001*



APPENDIX 1, page 2



Chairman TOM DAVIS. Dr. Burns.

Dr. BURNS. Thank you, Mr. Chairman and members of the committee. I'm delighted to be here in front of you.

I am David Burns. I'm a professor of medicine and professor of family and preventative medicine at UCSD School of Medicine. I was the editor of the monograph on low tar cigarettes for the National Cancer Institute. I chair a committee for the State of Massachusetts to advise them on the measurement of harm reduction, and I sit on the Scientific Advisory Committee on Tobacco for the World Health Organization which looks at regulatory issues. I have also testified in litigation against the tobacco industry. My opinions are my own and not any of those organizations.

I've been asked to address the issues of what lessons we've learned from our experience with low tar and nicotine cigarettes, and I think that there are several. The first of them is that no single test can be an adequate measure of the risk potential for these products. That is true not only because it is a complex issue. It is also true because the user interacts with the product, and design changes will lead people to use a product differently, and therefore a single test or a single protocol cannot reflect that diversity of actual use.

The second lesson we've learned is that external tests of the product are really not adequate. We need to have tests derived from the use of the product in people who actually use it. The complexity of transferring from chemical measurements to actual human exposure is formidable, and it is not possible from simple chemical measurements to understand the level of exposure that individuals will actually receive. We need to assess the exposure that occurs in the people who actually use the product, and we need to base that assessment on what their other choices might have been. A product that substantially lowers the toxicity of exposure will not be a harm reduction product if the people who use it would otherwise have quit smoking, and so the interpretation of data from these products needs to be done in the context of people who actually use it and what their other choices might have been. The claims that are made quite obviously need to be based on science, and we need to be sure that the claims made do not exceed the existing science that is available.

Last, as everyone has told you today, harm reduction can only be assessed in the context of adequate regulatory control by an agency that has sufficient scientific expertise to interpret the data presented to it. Absent that regulatory control, we cannot ensure that accurate information will be provided to the consumer.

I thank you for your attention.

Chairman TOM DAVIS. Thank you very much.

[The prepared statement of Dr. Burns follows:]

Extended Testimony of David M. Burns M.D.

U.S. House of Representatives
The Government Reform Committee
Hearing entitled "Potential Reduced Exposure/Reduced Risk Products: An Examination of the Possible Public Health Impact and Regulatory Challenges."
Rayburn Bldg. 2154 2:00 p.m. 6/3/03

My name is David Burns, and I am a medical doctor, professor of medicine and professor of family and preventive medicine at the University of California, San Diego School of Medicine. I was one of two scientific editors for the National Cancer Institute Smoking and Tobacco Control Monograph # 13 entitled "Risks associated with smoking cigarettes with low machine measured yields of tar and nicotine". I am also chair of the scientific advisory group for the Massachusetts Department of Health Services charged with examining the methods by which harm reduction can be evaluated, and I am on the Scientific Advisory Committee on Tobacco for the World Health Organization examining the regulation of new tobacco products. My Curriculum Vitae is attached to this testimony. My testimony today draws heavily on the deliberations of those groups and excerpts from their published reports (SACTob 2003), but I am speaking today as an individual and not as a representative of my university or of any group.

New tobacco products are being introduced for which reduced exposure, reduced toxicity, and reduced health risk claims are being made. These products include cigarettes made with modified tobacco from which established carcinogens were reduced/removed, products designed employing unconventional advanced technologies and a variety of oral tobacco products.

Evaluation of these newer products should be informed by our understanding of, and experience with, so called "light and ultralight cigarettes. Tobacco companies marketed products that claimed lower emissions (Pollay and Dewhirst 2002) but in fact, these cigarettes did not deliver reduced uptake of toxicants or lower risks to those who smoked them (Stratton et al. 2001; NCI Monograph # 13; SACTob 2002). There is no existing regulatory structure to evaluate the scientific validity of current claims for existing or modified tobacco products or to evaluate future claims (Stratton et al. 2001).

The lessons we have learned include:

1. **A simple standardized testing protocol cannot asses the exposure or risk likely to occur with different products.** Human smoking behavior changes when products with different design characteristics are smoked, whereas machines do not change their pattern of smoking in response to the changes in cigarette design. Our error in relying on tar measurement from a single protocol driven machine measurement is not that the parameters of the test were set wrong, but rather that the machine parameters that best mimic actual use are different for different styles of cigarettes. When smokers smoke ultra light cigarettes with larger more intense puffs than full flavor cigarettes, machine measurements using any single puff profile will not match the smoke delivered by these cigarettes as they are actually used by smokers.
2. **Smoke chemistry measurements may be useful to evaluate engineering changes in cigarettes or the characteristics of the smoke produced, but they are not adequate measures of actual human exposure.** Because smokers smoke different products in different ways and may respond to a given design change in an unanticipated manner, human exposure and risk can only be reliably assessed by measurements made in human smokers.
3. **Changes in risk must be evaluated for those smokers who actually use the product rather than being based simply on the characteristics of the product.** Low tar cigarettes were marketed to smokers who were thinking about quitting rather than to smokers who would not or could not quit. Even a product with real reduced toxicity in comparison to conventional cigarettes will not reduce the harm caused by smoking if it is used by those who would otherwise have quit or by those who had not previously smoked.
4. **Claims must be constrained by the data available to support them.** Because of the marketing advantages of reduced harm claims, there is great risk that the claims made will exceed the evidence to support them. For example, using evidence of changes in smoke chemistry to claim reduced exposure or reduced harm is an over statement of the actual evidence available to support the claim. The fact that it is difficult and time consuming to acquire the evidence to establish differences in exposure or reduced harm does not justify making claims for which the evidence to support them does not exist.
5. **Harm reduction cannot be adequately considered without examining the marketing messages used for the product.** Messages communicated to the consumer, the groups targeted by the marketing effort, and the proposed use of the product all define who will use a new tobacco product and how it will be used. Messages that promote initiation of tobacco use, interfere with

cessation or encourage use as a means of preserving and enhancing the level of addiction will cause harm even if the product itself is less harmful than conventional cigarettes.

6. **The meaning of a claim is defined by the understanding of the consumer not the manufacturer.** Marketing messages communicate to the consumer in a variety of ways including the words used, images presented and colors portrayed. It is the message received by the consumer from a harm reduction marketing effort that is important in determining what the consumer believes he or she is receiving when they purchase the produce and how they will use it. Methods exist to determine what consumers will comprehend from various marketing strategies and these methods should be used to prevent the delivery of marketing messages which communicate inaccurate or misleading information.
7. **Absent effective regulatory control of tobacco products, verification of manufacturer's harm reduction claims in time to prevent future consumer deception will be impossible.**

EXISTING SCIENTIFIC KNOWLEDGE

Evaluating the potential for newer tobacco products to cause/reduce harm is complex, even if real changes occur in the emission profile when they are used. Differences in human exposure and injury as well as the influence of the product on cessation and initiation all need to be included in an assessment of potential harm. Extensive reviews of the relative hazard of using existing cigarettes, and the changes in cigarettes over the past several decades, conclude that evidence does not support a difference in disease risks with the use of cigarettes with different levels of machine measured tar and nicotine yields or with product modifiers such as light or mild. (Stratton et al., 2001; NCI 2001; Canadian Expert Panel 2001; SACTob 2002). The evidence available for newer tobacco products is more limited and is largely based on chemical measurements and *in vitro* toxicity assays. The U.S. Institute of Medicine concluded that existing scientific evidence is not sufficient to allow definition of differences between newly engineered tobacco products and currently existing products for human uptake of toxicants, toxicity, or harm (Stratton et al., 2001). They also concluded that a scientific methodology to establish toxicity and harm differences for these products does not currently exist and that a structure for regulatory oversight would be essential to any scientific assessment of claims for reduced harm (Stratton et al., 2001). However, the report also concludes that emerging scientific understanding of disease mechanisms offers the promise of new and more specific methods of assessing tobacco toxicity and harm.

Product characteristics that are important in evaluating the potential for harm reduction include cigarette ingredients (particularly the type and blend of tobacco), design and engineering characteristics of the product, and elements of the manufacturing processes that may alter the ingredients used. Quantities of these ingredients by brand, and the design and manufacturing techniques used for the cigarette brand, are usually not provided by tobacco manufacturers, but they are essential for evaluation of toxicity; and they could be provided without any increased cost to the manufacturer. Patterns of actual use are also important determinants of toxicity, since they influence the delivery of toxicants to the smoker. Compensation leads smokers to use products differently based on the amount, rate and form in which nicotine is provided, making exposure extrapolation from chemical measurements even more difficult (Djordjevic et al., 1995, 2000; Kozlowski et al., 1994, 1998; Kozlowski and O'Connor 2002).

Assessment of differences in human exposure and harm is complicated by differences in the demographic characteristics and intensity of use of those who choose to use different products (Giovino et al1996; Haddock et al., 1999, NCI 2001); by the difficulty in extrapolating from forced switching studies to actual uses exposures (Benowitz 2001); by the reality that how products are marketed determines who uses the product; by what the alternatives are for the person switching to the product, and by the context in which the product is used (Ashley et al., 2001; Health Canada 2002a,b).

Harm To Non-Users/By-Standers

Many new products may claim reductions in environmental tobacco smoke generation and there is clear reduction when shifting from burned tobacco products to products that heat rather than burn tobacco, or to smokeless tobacco use. However, there may be an increase in secondhand smoke exposure if individual smoking duration increases or if new products result in an increase in toxicants present in either sidestream smoke or exhaled mainstream smoke. An additional concern is the reduction in smoke emissions may be used to justify delay or reversal of restrictions on smoking in indoor environments.

Harm To The Population

The harm to the population is the net effect of the changes in harm to the individual users and the changes in number of users who are exposed. A principal concern for all harm reduction products is that their presence on the market will offer alternatives to cessation for those who are interested in quitting. If the only users of a reduced harm product are those who would have quit in the absence of the product, or if the number of smokers whose cessation is delayed or aborted by use of the product exceed the number of those who would never have quit who are using the product, then it is likely that there would be a net increase in harm to the population. This would occur even from the introduction of a product that could actually reduce the harm for those individual smokers who would not otherwise quit. Conversely, it is possible that offering harm reduction products might induce some smokers who would not otherwise have quit to use the product and then begin a path that leads to successful long-term abstinence from tobacco. These products may also play a role in enhancing the cessation success of those who are having difficulty achieving abstinence. The potential benefits described here are theoretical, as no tobacco product has currently demonstrated such benefits.

Population harm, therefore, is the net of the combined effects that harm reduction products and their marketing have on the use of tobacco products and resultant population exposure to toxicants. This calculus involves consideration of who is using the newer products and why; what the users alternative behavior might have been; whether the availability of the new product increases the initiation of tobacco use with that product; and whether, once initiated, users then transition to products with a greater degree of toxicity. These concerns cannot be addressed without considering the marketing approaches and messages utilized for harm reduction products as they are introduced in the marketplace. The experience with so called "light" and "ultralight" cigarettes is not only that their marketing messages were misleading but also that their marketing target included those who were thinking about quitting smoking (Pollay and Dewherst 2002). The risk that marketing messages may be used to intercept smokers who are on the way to cessation, or to increase the initiation of tobacco use, must be part of any estimate of the net harm produced by newer tobacco products. Monitoring of the rates of initiation and cessation are critical elements of any post-market surveillance program.

Harm Due To Marketing Messages

Messages used to market purportedly less harmful tobacco products can create harm not measured by changes in rates of tobacco initiation, use and cessation. Creation of a false perception of safety alters population norms and beliefs about tobacco, may be used by young smokers to continue tobacco use since they can switch to a safer alternative in the future, and may alter the perceived need for regulatory control of products or of smoking behavior. In addition, the offer on the market of purportedly safer products may be used by the tobacco companies as a demonstration that they have changed their corporate behavior and are now acting responsibly, even if there is no meaningful effort to actually market the products. Harm to society may accrue if these marketing messages slow the changes in social norms and the development of regulatory controls that are effective in altering tobacco use.

A Framework For Evaluating New Products

No operational regulatory model exists to adequately address the evaluation of the harm reduction claims being made for products currently on the market or for products that are likely to be introduced in the near future. There is also no scientifically validated testing protocol that would allow comparison of the injury caused by modified (reduced toxicant) cigarettes with that of older more conventional cigarette brands (Stratton et al., 2001). However, WHO has provided a scientific framework of questions that would need to be answered in examining the claims made for newer products (SACTob 2003). The questions vary somewhat for the different types of products.

Modified (reduced carcinogen/toxicant) Cigarettes

The ideal evaluation of any purported harm reduction product would be based on measures of disease outcomes from human epidemiological studies of individuals followed before and after they switched to the new product. For most disease outcomes, such studies would require very large populations followed for long intervals and could therefore only provide information on changes that occurred many years in the past. More timely examination of new products is important for both regulatory oversight and for providing accurate public health advice to consumers. The data upon which this evaluation is made will, of necessity, be more limited than that which would be available from epidemiological and other observations made over long duration of use of the new product. Limitations of the data likely to be available make it useful to conceptualize the evaluation as a set of questions that can be answered in series and which allow a progressively more complete understanding of the actual benefits likely to be experienced by those who switch to a new product. Conceptually this sequence would involve five measures: measures of smoke emissions under conditions reflecting actual use, measures of smoke uptake in actual users of the product, measures of addiction potential of the product, measures of injury from use of the product, and measures of disease outcome.

Careful independent scientific review of existing data for each of these questions allow conclusions to be drawn (and claims to be validated) for each question independently at a point in time when the data are sufficient to support the claim. The separation of the questions, and of the data to support them, will also avoid confusion about the type of claim that can be made from the data presented. For example, data on the emissions generated by a cigarette might allow claims about differences in smoke composition but would not, without measures of injury, allow claims for reduced toxicity. Allowing measures of smoke emissions (machine measured tar and nicotine yields by the FTC/ISO method, or event the Massachusetts and Health Canada methods which prescribe more intense machine smoking parameters) to be extrapolated to enable claims of reduced uptake and reduced harm (light and mild brand designators) resulted in the consumer being misled (SACTob 2002), and this experience should not be repeated with new tobacco products. If claims are to be made by the manufacturer, it should be the responsibility of the manufacturer to provide evidence supporting the claim to an independent scientific review before the claim is made. The claims must be validated by the data presented, and claims that go beyond the data presented should not be allowed. Absence of evidence, or absence of scientific methods to measure toxicity or harm, are not legitimate scientific bases to allow claims of harm reduction from measures of smoke emissions.

The first logical step in examining a product having potential to reduce the harm produced by tobacco use is to examine the characteristics of the product. Consideration of the ingredients used, both quantitatively (type and amounts of ingredients, the blend of tobacco, reconstituted sheet tobacco) and qualitatively (toxicity of burned ingredients), defines likely areas of scientific concern as does a description of the engineering design and characteristics of the product. This information is currently available to the manufacturer and can be provided at no additional cost.

The next step is to examine emissions from the product, again both quantitatively and qualitatively. There are two dimensions to this question. The first is a comparison of the emissions of a product to other products under standardized conditions, and the second is the evaluation of the emissions under conditions of actual use. Smokers may vary in the way they use a single product (Djordjevic et al., 2000), and different products may be used differently by the same smoker, making machine measured values derived using a single set of smoking conditions misleading as an estimate of the smoke emissions actually arriving at the smokers mouth when the product is used (SACTob 2002). A companion concern is quantitative and qualitative measures of second hand smoke emissions.

Smoke uptake by the smoker, rather than smoke emissions, is the measure of intensity of exposure important for predicting disease risk. Measures of uptake with actual (rather than laboratory) use of the product are key to estimating uptake for populations of individuals who are likely to use a product. As they are developed and validated, measures of the biologically effective dose (levels of toxicants in critical target organs or tissues) may offer even more precise measures of smoke uptake for predicting smoke toxicity (Stratton et al., 2001). Additional keys to assessment of differences in uptake that result from differences in actual use of different products are understanding who is using the product and why. Measures of uptake derived from comparisons of groups of users may be misleading if a large fraction of those who switch to a new product are doing so in an effort to quit or cut down the amount that they smoke. Valid comparisons of the differences in uptake attributable to differences in the products used must ensure that the populations studied are using the products with similar intentions for maintaining the intensity of their smoking behavior.

Bioassays for injury related to cancer, lung disease, heart disease, reproduction and development, or neurobehavioral systems are essential to any examination or validation of claims of reduced toxicity. At present, the evidence linking existing biomarkers to ultimate disease outcomes remains incomplete, and no biomarkers have been validated for use in distinguishing the relative injury caused by different levels of cigarette smoke uptake (Stratton et al., 2001). The potential exists for evolving scientific techniques to make a meaningful contribution to the definition of early tobacco smoke related injury, but these approaches remain future rather than current solutions. The absence of existing validated biomarkers of injury from tobacco smoke is a scientific challenge to be overcome, but the absence of measurement tools should not be used to justify claims of reduced injury or reduced harm based on smoke emission or smoke exposure data.

One of the principal harms caused by tobacco use is addiction, and evaluation of the potential to create and sustain addiction is an important component of any consideration of the potential harm that can accrue from new and modified tobacco products.

Rates of disease outcomes following tobacco use are the ultimate measure of harm from tobacco use. The long time period required to generate this information for many of the diseases caused by smoking may preclude its use in making regulatory decisions surrounding the introduction of new tobacco products, but the importance of this information to understanding the harm caused by tobacco use makes collection of this information a scientific imperative. No claim for harm reduction should be allowed in the absence of evidence demonstrating reduced harm. The length of time required to generate such data is a reality that results from the biology of disease, and it is not a justification for allowing claims in the absence of evidence.

Once products are introduced into the market, there is a continuing need to monitor who is using the products and why, changes in the product design/ingredients or marketing approaches after the product is initially evaluated, and the impact of the product on rates of smoking initiation and cessation. Who the target populations are for the marketing messages, what those target populations actually understand those marketing messages to mean, and what the effect is for populations other than the target population, are concerns requiring ongoing monitoring. Many reduced toxicant products may have the potential to either increase or decrease harm depending on who uses them and what are the alternatives to their use. Absent monitoring of these phenomena, it will likely be impossible to determine whether use of reduced toxicant cigarettes by smokers provides a benefit or a cost to the population in terms of the damage and disease caused by smoking.

Products That Allegedly Heat Instead Of Burn Tobacco.

The issues to be examined for products that use processes other than tobacco combustion to deliver nicotine are similar to those for reduced toxicant cigarettes. However, much greater attention is necessary to the technology being employed and how it functions under a variety of smoking conditions. Assumptions that these new technologies will be smoked with the same pattern of puffing as conventional cigarettes, will continue to heat rather than burn the tobacco under all of the puffing conditions likely to be encountered by consumers, or will not contain new constituents with undefined risks are not warranted and must be tested. These products may also have different potential for creating of sustaining addiction than conventional cigarettes.

Oral Tobacco Products (including smokeless tobacco, but not including NRT products already regulated for a therapeutic purpose).

Differences in the process by which tobacco constituents are delivered to the user, sites of delivery and time course of uptake make comparisons of emissions from oral tobacco products and cigarettes difficult. Even comparisons of uptake of the same constituent (e.g. nicotine) can be difficult to interpret. However, the same general concerns described above for reduced toxicant cigarettes also apply for defining the harm reduction potential of oral tobacco products. However, there are some particular concern with oral tobacco products.

It remains to be demonstrated that large numbers of adult cigarette smokers who will not otherwise quit will switch to oral tobacco products. The rate at which adults are willing to switch is important for calculating the net effect for harm reduction of marketing oral tobacco products because of the likely effects of marketing on those not yet using any tobacco product. As a new product is introduced, or an existing tobacco product is marketed as offering less risk for the smoker who is unwilling to quit, the initiation of use of that product among adolescents may increase. Existing data on current use suggests that users of oral tobacco products are much more likely to transition to cigarette smoking than are cigarette smokers to transition to smokeless products (Tomar 2002). Initiation of oral tobacco use also occurs largely among the young raising further concerns about which age groups might be influenced most by marketing messages. A real concern is that a marketing message of lower risk might not change the behavior of adult smokers but might increase the rate of adolescent initiation of oral tobacco use, increasing rather than decreasing the fraction of the population using tobacco products.

A second issue is that the data available on the risks of using oral tobacco products are derived from populations of individuals who use only oral tobacco, and little is known about the magnitude and timing of any change in risk among those who switch from smoking cigarettes to use of oral tobacco. The fraction who switch who might otherwise quit, the fraction who relapse back to smoking, the fraction who continue dual use, and the impact of dual use on disease risks are all unanswered questions in the context of offering these products as vehicles for harm reduction.

A similar concern exists for existing oral tobacco users. Will harm reduction messages reduce cessation or delay cessation attempts?

Oral tobacco products are marketed as temporary alternatives to smoking that sustain nicotine addiction in those circumstances where smoking is prohibited. The potential for these products to sustain a high level of nicotine addiction, or to otherwise reduce the interest in quitting or success in achieving abstinence, are real concerns. These effects, if present, could cause a net harm to the population even if the products themselves have low levels of toxicity.

Conclusion

In conclusion, regulatory oversight of cigarette and cigarette like products should include examination of at least five separate aspects of the new products: physical chemical characteristics of tobacco and tobacco smoke, uptake of toxicants (both by smokers and by non-smokers), toxicity, addiction potential, and disease risk. Demonstration of reductions in smoke emissions or reduced uptake of toxicants alone is not sufficient to support claims or implications of reduced toxicity or harm. No claim should be permitted for any tobacco product absent adequate scientific data. Regulatory oversight, including post market surveillance, is necessary to assess and monitor changes in newly modified tobacco products

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Chairman TOM DAVIS. Mr. Verheij.

Mr. VERHEIJ. Mr. Chairman and members of the committee, good afternoon.

I am Richard Verheij, executive vice president, external affairs for U.S. Smokeless Tobacco Co. I would like to thank this committee for convening this hearing to examine the issue of tobacco harm reduction and the regulatory challenges.

We see this hearing as a significant step in the country's ongoing efforts to address the issues raised by the continued use of tobacco products by millions of Americans. Indeed, 50 million Americans smoke. The Institute of Medicine has predicted that a significant proportion of those individuals will continue to do so despite a multitude of approaches with the ultimate objective of total tobacco cessation. This prediction has prompted the public health community to consider new complementary strategies, including tobacco harm reduction.

As we proceed today, it's helpful to keep a couple of things in mind. First, this debate is not about whether smokeless tobacco is considered safe. Rather, it is about the increasing consensus in the public health community that smokeless tobacco is significantly less harmful than cigarettes.

Second, this debate is not about whether smoking cessation is the best public health strategy. Rather, it is about whether there are complementary strategies which public health advocates believe will save millions of lives.

We're here today because of the millions of adult smokers who do not quit and do not use medicinal nicotine products. Many in the public health community believe that a harm reduction strategy based on communicating to adult smokers truthful information about other options can have a significant impact on both those individual adult smokers and public health generally. Simply stated, many researchers have expressed the opinion that use of smokeless tobacco is significantly less harmful than cigarette smoking. Based on that judgment, these same researchers advocate that adult smokers who do not quit and do not use medicinal nicotine products switch completely to smokeless tobacco.

There is increasing consensus on this crucial issue among members of the public health community, some of whom are testifying before this committee today. However, despite this increasing consensus, it is documented that the vast majority of adult smokers are unaware of this information. One researcher has stated that, "until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain."

Our company, along with those public health advocates, believes that it is crucial that this information be made available to adult smokers. Such communication will help adult smokers make more informed decisions.

We look forward to discussing the real question, how best to communicate this important information. We know there are a variety of opinions on this topic. We welcome a serious and open dialog that brings to the table all the relevant parties to express their viewpoints and concerns. That is why we urge the Federal Trade Commission to initiate a forum that will bring together research-

ers, public health advocates, regulators, tobacco control experts, and tobacco product manufacturers to examine the most appropriate means for communicating this information to adult smokers.

Let me state clearly for the record that U.S. Smokeless Tobacco Co. is committed to restricting tobacco use to adults only. This commitment is not just rhetoric. It is backed by concrete action. In 1997, we were the only smokeless tobacco company to support the proposed tobacco resolution. When that proposal failed, we became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement with attorneys general of 45 States in various territories.

We are providing more than $100 million to the American Legacy Foundation for programs to reduce youth usage of tobacco. Our company is committed to proceeding in a responsible and deliberate manner that reflects the current state of the science and addresses the concerns of the public health community.

This debate presents a broad societal question: How should we collectively communicate information to adult smokers that many in the public health community believe will prolong and save lives? This is truly an unprecedented opportunity. Public health advocates, researchers, tobacco control advocates, and tobacco product manufacturers all agree on the fundamental principle that a harm reduction strategy could represent an important component of a comprehensive public health policy on tobacco. There may be disagreement on how best to implement this strategy. Nevertheless, given the stakes, this issue deserves serious consideration. We believe this hearing represents a significant step in this process.

May I ask that U.S. Smokeless Tobacco Co.'s written statement submitted to the committee on May 30 be incorporated in its entirety to the hearing after testimony today.

Chairman TOM DAVIS. Without objection, so ordered. Thank you very much.

[The prepared statement of Mr. Verheij follows:]

SUBMISSION OF U.S. SMOKELESS TOBACCO COMPANY

TO THE

HOUSE COMMITTEE ON GOVERNMENT REFORM

"REDUCED EXPOSURE/REDUCED RISK TOBACCO PRODUCTS: AN EXAMINATION OF THE POTENTIAL PUBLIC HEALTH IMPACT AND REGULATORY CHALLENGES"

JUNE 3, 2003

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Summary

The issue of tobacco harm reduction and the potential role of smokeless tobacco products in that effort is at a crossroads. The debate is no longer about whether smokeless tobacco is considered by the scientific community to be a significantly reduced risk alternative compared to cigarette smoking. The question now is whether that information should be communicated to adult cigarette smokers or whether it should be suppressed.

Adult cigarette smokers in the United States have a serious misperception about the comparative health risks of cigarette smoking and smokeless tobacco use. That fact is evidenced by the results of a 2001 survey reporting that 82 percent of the adult cigarette smokers questioned believed that smokeless tobacco was just as likely to cause cancer as smoking cigarettes. Clearly, the level of disinformation in the marketplace is alarming, and there is a need to provide adult cigarette smokers with truthful information about the comparative health risks of tobacco products.

A workshop or other forum sponsored by the Federal Trade Commission might help form a consensus as to how we move forward on this important public health issue, and could provide guidelines to ensure that any comparative risk communication is directed at adult smokers to avoid any unintended consequences.

In light of the information vacuum that exists, U.S. Smokeless Tobacco Company must confront the question of whether it has a responsibility to step forward and communicate to adult cigarette smokers information regarding the comparative health risks of tobacco products.

BIOGRAPHY

RICHARD H. VERHEIJ

EXECUTIVE VICE PRESIDENT – EXTERNAL AFFAIRS
U.S. SMOKELESS TOBACCO COMPANY

Richard H. Verheij is executive vice president – external affairs for U.S. Smokeless Tobacco Company and has responsibility for corporate communications, government relations and legal affairs. Previously, Mr. Verheij served as senior vice president and general counsel, a position he has held since 1994.

Mr. Verheij joined the Company in November 1986 as a corporate attorney. In October 1988, Mr. Verheij was named senior corporate counsel, and in 1991, he was elected assistant general counsel. In 1992, he was named a vice president and associate general counsel.

Before joining the Company, Mr. Verheij was an associate with a New York-based law firm, specializing in product liability litigation.

Mr. Verheij received his bachelor of arts degree from Case Western Reserve University in 1980, and his JD degree from the University's School of Law in 1983.

Mr. Verheij resides in Darien, Connecticut.

Committee on Government Reform

Witness Disclosure

"Truth in Testimony"

Required by House Rule XI, Clause 2(g)

I am not testifying on behalf of a Federal, State or Local Government entity. I am testifying on behalf of U.S. Smokeless Tobacco Company, a corporation that is not a government entity.

I have received no federal grants or contracts (including subgrants or subcontracts) at any time.

I am Executive Vice President – External Affairs of U.S. Smokeless Tobacco Company and appear before this Committee as a representative of that Company.

U.S. Smokeless Tobacco Company does have a parent organization, subsidiaries or partnerships for whom I do not represent before this Committee.

There were no federal grants or contracts (including subgrants and subcontracts) which were received by U.S. Smokeless Tobacco Company since October 1, 1999, which exceed 10% of the Company's revenue in the year received including the source and amount of each grant or contract.

Dated: May 29, 2003

Richard Verheij

Richard H. Verheij
Executive Vice President – External Affairs
U.S. Smokeless Tobacco Company

Statement of U.S. Smokeless Tobacco Company

Before the

House Committee on Government Reform

"Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Public Health Impact and Regulatory Challenges."

June 3, 2003

U.S. Smokeless Tobacco Company ("USSTC") welcomes the opportunity to participate in this hearing regarding tobacco harm reduction. This issue is of immense importance to the 50 million adult tobacco consumers in the United States, to the public health community, to medical practitioners and to tobacco manufacturers.

For decades, the public health community in the United States has asserted that cigarette smoking is the most deadly epidemic of modern times. For almost as long, the message of the public health community to cigarette smokers has been monolithic: stop all use of tobacco. Over the past several years, however, an increasing number of public health advocates have voiced doubts about what some have called the "quit or die" approach to smoking cessation.

Rather than rely entirely on programs intended to achieve total cessation of tobacco use, this segment of the public health community is urging that a more pragmatic goal be adopted – that of tobacco "harm reduction." One method of achieving tobacco harm reduction, according to a growing number of researchers, is to encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products. This strategy, however, is complicated by the fact that the vast majority of adult cigarette smokers in the United States – despite the generally accepted scientific view to the contrary – believe that cigarette smoking and smokeless tobacco use involve the same risk of adverse health effects.

The issue of tobacco harm reduction and the potential role of smokeless tobacco products in that effort is at a crossroads. The debate is no longer about whether smokeless tobacco is considered by the scientific community to be a significantly reduced risk alternative compared to cigarette smoking. The question now is whether that information should be communicated to adult cigarette smokers or whether it should be suppressed.

Set forth below is a brief description of USSTC and its smokeless tobacco products, followed by a review of some of the more significant issues relating to smokeless tobacco in the context of tobacco harm reduction.

I. USSTC

USSTC is the leading U.S. producer and marketer of moist smokeless tobacco or moist snuff. Copenhagen and Skoal -- two of USSTC's brands -- are America's best-selling moist snuff products. Two other brands -- Rooster and Red Seal -- were introduced within the last five years, and hold established positions in the marketplace. A new pouch product -- Revel -- has been test marketed. USSTC maintains manufacturing and processing facilities in Franklin Park, Illinois; Hopkinsville, Kentucky; and Nashville, Tennessee.

In 1997, USSTC was the only smokeless tobacco company to support the proposed tobacco resolution. When the proposal failed to pass the Congress, USSTC became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement ("STMSA") with Attorneys General of various states and U.S. territories. Pursuant to the STMSA, USSTC is providing up to $100 million (plus an inflation adjustment), over a 10-year period, to the American Legacy Foundation for programs to reduce youth usage of tobacco and

combat youth substance abuse, and for enforcement purposes.[1] Moreover, USSTC agreed to limitations on its advertising and marketing efforts, even though this put USSTC at a competitive disadvantage with other smokeless tobacco manufacturers.[2]

As these facts and the remainder of this statement will make clear, USSTC is truly a "distinctly different" tobacco company. Annexed as Attachment A to this statement are copies of excerpts from UST Inc.'s (USSTC's parent company) annual reports for 2000, 2001 and 2002 that discuss the ways in which USSTC is a "distinctly different" tobacco company.

II. Smokeless Tobacco in the Context of Tobacco Harm Reduction

A. Introduction

Since the Surgeon General's Report in 1964[3], there has been substantial public health discussion about the potential health effects of tobacco use. Various public health organizations have identified the risks of cigarette smoking as including cancer (*e.g.*, lung, oral cavity, esophagus, larynx, pancreas, bladder, kidney), chronic obstructive pulmonary disease, myocardial infarction, and stroke.[4] The Centers for Disease Control and Prevention ("CDC")

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[1] Youth usage of smokeless tobacco, as reported in surveys conducted by various federal government agencies and by the University of Michigan, has declined substantially in recent years. For example, in 2001 the authors of the report on the University of Michigan's Monitoring the Future national survey noted that "[t]he use of smokeless tobacco by teens has been decreasing gradually from recent peak levels in the mid-'90s, and the overall declines have been substantial." Johnston LD, O'Malley PM, Bachman JG. (2001) *Monitoring the Future national results on adolescent drug use: Overview of key findings 2000.* (NIH Publication No. 01-4923). Bethesda, MD: National Institute of Drug Abuse, at p. 34. More recently, these same authors reaffirmed their earlier findings, noting that the overall declines in teen use of smokeless tobacco have been "substantial" and that "teen use of smokeless tobacco is down by about one-half from the peak levels reached in the mid-1990s." Johnston LD, O'Malley PM, Bachman JG. (2003). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2002.* (NIH Publication No. 03-5374). Bethesda, MD: National Institute on Drug Abuse, at p. 34.

[2] These restrictions include, among other things, eliminating outdoor advertising of smokeless tobacco products, such as billboards and signs in arenas, stadiums, shopping malls, video-game arcades, and on public transit. In addition, USSTC voluntarily limited itself to one brand-name sponsorship in any 12-month period, and agreed to discontinue distribution to the public of non-tobacco merchandise, such as caps and T-shirts, bearing the brand name, logo, or trademark of any smokeless tobacco product.

[3] U.S. Department of Health, Education and Welfare. *Smoking and Health. Report of the Advisory Committee to the Surgeon General of the Public Health Service.* 1964.

[4] Stratton K, Sherry 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, at pp. 367-68.

estimates that cigarette smoking caused approximately 442,000 premature deaths in the United States in 1999.[5] The Surgeon General has indicated that the ideal way to avoid such health risks is to abstain from cigarette smoking.[6] Nonetheless, 47 to 50 million adults in the U.S. continue to smoke cigarettes. This number represents approximately 25 percent of all U.S. adults.[7]

The Surgeon General reached a judgment in 1986 that use of smokeless tobacco products "can cause cancer."[8] Federally-mandated rotating warnings on smokeless tobacco product packaging and advertising state:

> WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER
>
> WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS
>
> WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.[9]

Numerous methods have been suggested by public health advocates for achieving tobacco harm reduction, including urging cigarette smokers to smoke fewer cigarettes, developing "less hazardous" cigarettes and creating alternative sources of nicotine, such as nicotine inhalers. A growing number of tobacco harm reduction proponents, however, are arguing for an additional method for achieving their goal. Based on the generally accepted view

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[5] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs — United States, 1995–1999. *MMWR* 2002; **51**: 300-303.

[6] U.S. Department of Health & Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (1994); *see also Smoking As A Health Hazard*, American College of Cardiology Position Statement, available at http://www.acc.org/clinical/position/72565.pdf.

[7] The National Center For Chronic Disease Prevention and Health Promotion estimates that 47 million adults in the United States smoke cigarettes. *Targeting Tobacco Use: The Nation's Leading Cause of Death*, Tobacco Information and Prevention Source (2001). The U.S. Department of Health and Human Services estimates that more than 57 million Americans currently smoke cigarettes. *Preventing Death and Disease From Tobacco Use*, Fact Sheet (Jan. 8, 2001). Other reports suggest that the number of smokers in the United States is between 46.5 and 50 million. *Cigarette Smoking Among Adults - United States, 1999, MMWR Highlights* (Oct. 12, 2001) Vol. 50, No. 40; *Treating Tobacco Use and Dependence*, U.S. Public Health Service, Fact Sheet (June 2000).

[8] U.S. Department of Health & Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986).

[9] Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408.

in the scientific community that smokeless tobacco use involves significantly less risk of adverse health effects than cigarette smoking, they would encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products.

B. The IOM Report

A logical starting point for discussion of smokeless tobacco in the context of tobacco harm reduction is the 600 page report issued in 2001 by the Institute of Medicine ("IOM") entitled: *Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction* ("IOM Report"). The IOM was established in 1970 by the National Academy of Sciences to examine policy matters pertaining to public health, and acts under the Academy's congressional charter to be an advisor to the federal government and to assess issues relating to medical care, research and education. The IOM tobacco harm reduction project was undertaken at the request of, and was supported by, the U.S. Food and Drug Administration. The IOM Report explains the need for a tobacco harm reduction strategy as follows:

> Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. This is why many public health leaders believe that what has come to be called "harm reduction" must be included as a subsidiary component of a comprehensive public health policy toward tobacco.[10]

Tobacco "harm reduction" is defined in the IOM Report as follows:

> *For the purposes of this report, a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco related toxicants.* Many different policy strategies may contribute to harm reduction. However, this report focuses on tobacco products that may be less harmful

[10] Stratton K, et al. (2001) at p. 201.

> or on pharmaceutical preparations that may be used alone or concomitantly with decreased use of conventional tobacco. (Original emphasis). [11]

It is clear from this definition of "harm reduction" that, in the view of the IOM, it is not necessary to demonstrate that a product is "safe" or "harmless" in order for that product to play a role in tobacco harm reduction.

The IOM Report had the following to say with respect to smokeless tobacco products:

> Smokeless tobacco products are associated with oral cavity cancers, and a dose-response relationship exists. However, the overall risk is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk. It may be considered that such products could be used as a PREP [Potential Reduced-Exposure Product] for persons addicted to nicotine, but these products must undergo testing as PREPs using the guidelines and research agenda contained herein.[12]

There has been criticism of the IOM Report's recommendation that all products proposed for use in the context of a tobacco harm reduction strategy require substantial and elaborate scientific testing to demonstrate their harm reduction benefits. For example, Clive Bates, former Director of the United Kingdom's Action on Smoking and Health, has made the following comments:

> The report places very substantial evidential requirement on those seeking to bring PREPs to the market with a health related claim. The easiest approach for the public health and regulatory community is to demand near complete certainty before approving the marketing of any PREPs. At first sight this appears prudent, but it is actually a *transfer* of risk from the regulator to the smoker. With insurmountable evidential hurdles in place, the regulator may sleep easy in a cocoon of professional skepticism.[13]

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[11] *Id.* at p. 2.
[12] *Id.* at p. 434.
[13] Bates C. Clearing the smoke or muddying the water? (Editorial) *Tobacco Control* 2001; **10**: 87-88.

The IOM Report's focus on the need for further research and demonstration of harm reduction benefits may be understandable in the context of new or novel tobacco products or so-called "safer" cigarettes. When it comes to smokeless tobacco, however, there is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

As Professor Lynn Kozlowski, Head of the Pennsylvania State University Department of Biobehavioral Health, has stated in a commentary published last year in the journal *Nicotine and Tobacco Research*:

> The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. *Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.* (Emphasis supplied).[14]

C. There is General Agreement in the Scientific Community Regarding the Comparative Health Risks of Cigarette Smoking and Smokeless Tobacco Use

USSTC's February 5, 2002 Request to the Federal Trade Commission ("FTC") for an

[14] Kozlowski LT. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Res* 2002; **4 Suppl 2**: 55-60 at p. 58.

advisory opinion[15], which is discussed below, contains excerpts from 50 scientific publications, many of which were peer-reviewed, that assert or support the proposition that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. Additional scientific information and publications that became available subsequent to February 5, 2002 is reviewed in USSTC's May 9, 2003 submission to the FTC, which is also discussed below. Two of the publications referenced in that supplemental submission reflect the generally held view in the public health community regarding the comparative health risks of cigarette smoking and smokeless tobacco use. Those publications can be expected to have a significant impact on the tobacco harm reduction debate, and therefore merit some discussion.

i. Royal College of Physicians Report

In December 2002, the Royal College of Physicians ("RCP") issued a landmark report entitled *Protecting Smokers, Saving Lives*,[16] which assessed various issues relating to future tobacco regulation in the United Kingdom. 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.

The 2002 RCP Report recognized that tobacco harm reduction must be an essential element of any tobacco regulation program:

> A tobacco and nicotine regulatory authority should have a clear objective: *...to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users."* (Original emphasis)[17]

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[15] Throughout this statement reference will be made to USSTC's February 5, 2002 and May 9, 2003 submissions to the Federal Trade Commission and attachments thereto. Those documents and their attachments can be found at: http://www.ftc.gov/os/otherpubliccomments.htm and http://www.ussmokeless.com. Hereafter, documents that are part of these submissions will be indicated as follows: "See Website."

[16] Tobacco Advisory Group of the Royal College of Physicians. *Protecting smokers, saving lives*. Royal College of Physicians of London, 2002. See Website.

[17] *Id* at p. 24.

The 2002 RCP Report also recognized that smokeless tobacco would be a key component of any tobacco harm reduction strategy:

> Smokeless Tobacco:
>
> As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.[18]

The issuance of the RCP's 2002 Report is not the first time that the RCP has led the way on tobacco and health issues. In March 1962, the RCP issued a report on smoking and health which concluded that cigarette smoking caused lung cancer. Shortly after the issuance of that report, the U.S. Surgeon General, Dr. Luther L. Terry, established the Surgeon General's Advisory Committee on Smoking and Health to produce a similar report for the United States. That report was released in January 1964 and is generally referred to as the 1964 Surgeon General's Report. Its conclusions were similar to those of the 1962 RCP Report.

ii. White Paper on European Union Smokeless Tobacco Policy

In February 2003, a group of tobacco and health researchers and public health advocates from the United Kingdom, Sweden and Austria published a white paper entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.*[19] The authors recommend that the current European Union ban of smokeless tobacco be replaced with a regulatory program based on the recognition that smokeless tobacco is substantially less harmful than cigarette smoking and could play a significant role in tobacco

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[18] *Id.* at p. 5.

[19] Bates C, Fagerstrom K, Jarvis M, Kunze M, McNeill A, Ramstrom L. *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.* February 2003. See Website.

harm reduction. The group summarized the "public health case" favoring smokeless tobacco as follows:

> We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of *all* smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe. We think it is wrong to deny other Europeans this option for risk-reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco – the alternative being to 'quit or die' … and many die. (Original emphasis)[20]

Among other points made in the white paper are the following:

> [F]or oral tobacco to play a role in harm reduction it is not necessary to show that it does not cause cancer – it just needs to be substantially less hazardous than smoking. Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos – *are a very substantially less dangerous way to use tobacco than cigarettes.* Smokeless tobaccos are not associated with major lung diseases, including COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the public health community has a moral obligation to explore this strategy. It is likewise ethically wrong to actively *deny* users the option to reduce their risk in this way.[21]
>
> * * *
>
> The risk to the user arising from use of a smokeless tobacco product varies by product and is to some extent uncertain – notably in the area of heart disease (though at *worst* the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base suggests that it is reasonable to formulate the overall

[20] *Id.* at p. 2.
[21] *Id.* at p. 3.

> relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking.* In a spectrum of risk, snus is *much* closer to NRT [nicotine replacement therapy] than it is to cigarette smoking. (Original emphasis)[22]

D. Individual Risk Versus Population Risk

One concern raised by some in the public health community with respect to "reduced risk" tobacco products is that, while a product might reduce the health risk to an individual, the aggregate public health impact on the population might be negative. Thus, for example, it is argued that if a "safer" cigarette reduced the health risks associated with cigarette smoking by 10 percent, but resulted in a 20 percent increase in cigarette use (either through new smokers or by causing some smokers who otherwise would have quit to continue smoking), the aggregate public health impact would be negative. Professor Kenneth E. Warner of the University of Michigan gives the following example:

> [C]onsider the implications of Star Enterprise's advertising that its new cigarette, Advance, yields fewer nitrosamines than conventional cigarettes. Informed that most cigarette smoke contains nitrosamines and that nitrosamines are carcinogenic, would smokers preparing to quit flock to the new cigarette instead, believing that it would greatly reduce their risk of smoking-induced lung cancer? The net health consequences are unclear: for those smokers who would have continued smoking anyway, switching to Advance might well reduce risk. For smokers who would have quit, or former smokers induced to start smoking again by the availability of this purportedly 'safer' product, the active marketing of a low-nitrosamine cigarette clearly would *increase* risk. The net impact would depend on the unpredictable balance between such effects.[23]

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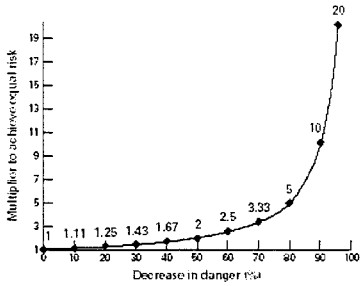
[22] *Id.* at pp. 3-4.

[23] Warner KE. Reducing harm to smokers: Methods, their effectiveness and the role of policy. In: Regulating Tobacco. Rabin RL, Sugarman SD (eds.) Oxford University Press, Oxford. 2001. Chapter 5, at pp. 133-134.

Professor Kozlowski has developed a "risk/use equilibrium" chart[24] to assess the issue of individual risk reduction versus aggregate population impact. The chart compares the "decrease in danger (%)" displayed on the horizontal axis to the "multiplier to achieve equal risk" on the vertical axis.



According to Professor Kozlowski's analysis, a tobacco product that reduces risk by only 10 percent raises a difficult public health issue because an 11 percent increase in use of the product would offset the risk reduction in the population as a whole, and an increase in excess of 11 percent would result in a negative public health impact on the population as a whole. On the other hand, a tobacco product that results in a reduced risk in excess of 90 percent presents a relatively easy public health issue since the increase in usage necessary to offset the reduction in risk is so substantial – more that 1,000 percent – that it is highly unlikely to occur.

Given the predominant view in the public health community that the risk of adverse health effects associated with smokeless tobacco products is slight compared to that of cigarette smoking, researchers believe it is highly unlikely the public health benefit of cigarette smokers switching to smokeless tobacco would ever be offset by increased usage of smokeless tobacco.

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[24] Kozlowski L, Strasser AA, Giovino GA, Erickson PA, Terza JV. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. (Editorial). *Tobacco Control* 2001; **10**: 201-203.

Professor Kozlowski expressed his agreement with this conclusion in a recent publication entitled *Harm Reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options*, in which he applied his "risk/use equilibrium" analysis to smokeless tobacco:

> When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001). . . . For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.[25]

E. The Swedish Experience

Proponents of encouraging "inveterate" cigarette smokers to switch to smokeless tobacco products point to the history of cigarette smoking and smokeless tobacco use in Sweden as support for their view. Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any Western country, and the daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes (18.2 percent daily smokeless tobacco users versus 17.1 percent daily cigarette smokers).[26] The following chart illustrates the changing pattern of tobacco use in Sweden during most of the past century, including the fact that smokeless tobacco use has overtaken cigarette smoking in recent years for the first time since World War II.[27]

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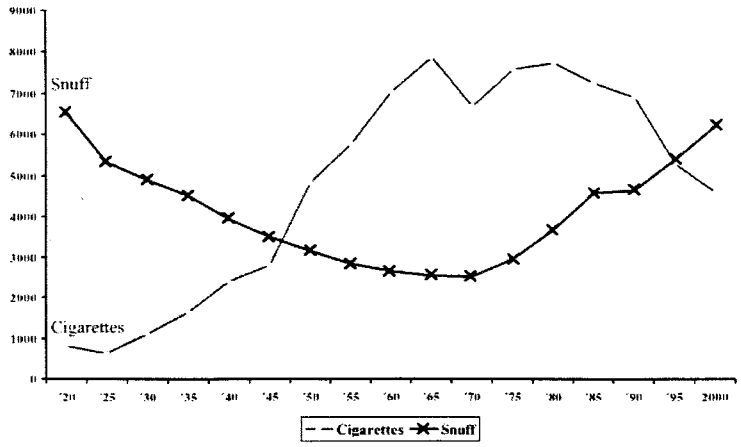
[25] Kozlowski LT (2002) at p. 58.

[26] Henningfield JE, Fagerström KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control* 2001; **10**: 253-257, at p. 254.

[27] Adapted from Swedish Match's Third Quarter Results, October 23, 2001, as posted on Company's web site. The figures cited reflect reported taxable shipments of snuff and cigarettes, measured in tons.



Tobacco and health researchers have linked Sweden's low rate of "tobacco-related mortality" to its high prevalence of smokeless tobacco use and low prevalence of cigarette smoking:

> Sweden, with a long tradition of smokeless tobacco use (16% of adult males use smokeless tobacco daily) and the highest penetration of NRT [nicotine replacement therapy] use, is the only European country that has reached (19%) the World Health Organization's target of 20% smokers in the adult population by the year 2000; about 35% of all nicotine consumed comes from nonsmoked deliver[y] forms. The tobacco-related mortality in Sweden is by far lower than in any other European or North American country, although nicotine consumption may not be lower than in other countries.[28]

In 2001, a *New Scientist* article summarized the Swedish experience in the context of tobacco harm reduction:

[28] Balfour DJK, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996; **72**: 51-81, at p. 71.

> [S]mokers [in Sweden] aren't faced with the quit-or-die dilemma. Instead of using a nicotine replacement therapy with the aim of quitting both smoking and ultimately nicotine, they can continue using tobacco as a recreational drug, safe in the knowledge that it probably won't kill them. It's all down to a product called 'snus,' a form of moist ground tobacco that you pop between your lip and gum.[29]
>
> * * *
>
> The 'Swedish experiment,' as it has come to be known, has inspired some health campaigners to press for a more enlightened approach to the smoking epidemic. It's a concept they call 'harm reduction.' 'If you look at Sweden, we have a living example of the concept in action,' says Clive Bates, director of ASH.[30]

Also of interest is Swedish survey data regarding the use of smokeless tobacco as a smoking cessation aid presented at two scientific conferences in late 2002. At the *3rd International Conference on Smokeless Tobacco: Advancing Science and Protecting Public Health,* held in Stockholm, Sweden in September 2002, Dr. Lars M. Ramström, Director of Stockholm's Institute for Tobacco Studies, reported on a recent nationwide survey of a representative sample 6,700 adults in Sweden sponsored by the Swedish National Institute of Public Health. Dr. Ramström reports the following in the press summary of his presentation:

> "Among males snus is the most commonly used and most effective smoking cessation aid." In support of this conclusion, Dr. Ramström cites survey data indicating that "76% of male Ever Daily Smokers have made at least one attempt to quit smoking. Around 40% of the 'triers' report that at their latest attempt they have used some kind of smoking cessation aid. 36% of these males have used nicotine gum, 20% nicotine patch and 55% have used snus as a smoking cessation aid. No other kind of cessation aid has been used by as much as 10%.[31] The proportion of those who have succeeded to quit smoking completely is 50% for gum users, 34% for patch users, 65% for snus users."[32]

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[29] Wilson C. My friend nicotine. *New Scientist* 2001; **10**: 28-31, at p. 29.
[30] *Id.* at p. 30.
[31] Dr. Ramström noted that the total exceeds 100% because some smokers used more than one aid.
[32] Ramstrom L. Press summary entitled: Snus as a substitution for smoking – the Swedish Experience. See Website.

At the *4th European Conference of the Society for Research on Nicotine and Tobacco: Improving Knowledge and Treatments of Nicotine Addiction*, held in Santander, Spain in October 2002, Clive Bates made a presentation entitled "Harm Reduction and Smokeless Tobacco." One of the points made was that "snus is an important factor in the low smoking prevalence in Sweden. It is used for cessation and as an alternative to smoking." He cited data from a 2001 survey commissioned by the Swedish Cancer Society reporting that, among 1,000 ex-smokers, 33% used snus as a smoking cessation aid, compared to 17% who used nicotine replacement therapies.[33]

The European Union white paper also points to smokeless tobacco as the explanation for Sweden's low rate of tobacco-related mortality:

> Evidence from Sweden suggests snus plays a positive public health role as a substitute for smoking and as an aid to smoking cessation. It is impossible to be definitive about this, because it is impossible to run a controlled trial on a whole nation.
>
> However, consider the following:
>
> - Sweden has the lowest levels of tobacco-related mortality in the developed world by some distance – approximately half the tobacco related mortality of the rest of the EU.
> - Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (c. 22%) prevalence.
> - However, it has comparable male *tobacco* prevalence and total consumption to neighbours Norway and Denmark - suggesting the big difference is in the *type* of tobacco used, rather than overall propensity to use tobacco or consume nicotine.
> - About half of tobacco in Sweden is now consumed as snus - this share has steadily grown since 1970s.
> - 33% of ex-smokers report use of snus - almost twice the number that report use of a pharmaceutical treatment (17%). Among males who

[33] Bates C. Presentation: Harm reduction and smokeless tobacco. See Website.

> have used a single aid to stop daily smoking, and succeeded to do so, some 70% had used snus and some 30% had used some kind of NRT.

Some have raised a question as to whether the Swedish experience is applicable to the United States, asserting that Swedish moist snuff products contain lower levels of so-called tobacco-specific nitrosamines (some of which have been reported to be laboratory carcinogens) than U.S. moist snuff products. For example, Professor Newell Johnson in an article published in 2001 entitled "Tobacco Use and Oral Cancer: A Global Perspective" conceded that "on present evidence, snuff habits as they exist in Scandinavia and probably in the United States carry lower risk of serious health hazards"[34] than cigarette smoking, but also made the following comment:

> In Scandinavia it is clear that local snuff is not a major risk factor: two recent case-control studies of oral cancer cases in Sweden have failed to show an association. This is because Swedish snus is not fermented and contains much lower nitrosamine levels than fermented tobaccos. The view that smokeless tobacco use may be associated with a lower risk of oral cancer in the United States has led to a movement to advocate the practice as a less dangerous alternative to smoking and an aid to nicotine withdrawal in those addicted to smoking.[35]

In fact, there is currently no significant difference in tobacco-specific nitrosamine (TSNA) levels in U.S. moist snuff products compared to Swedish moist snuff. Data reported in the scientific literature by researchers from the American Health Foundation, together with data

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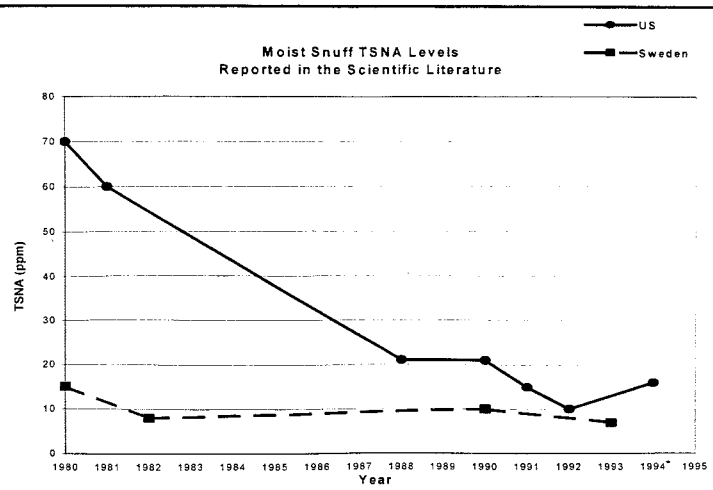
[34] Johnson N. Tobacco use and oral cancer: A global perspective. *J Dent Educ* 2001; **65**: 328–339, at p. 328.
[35] *Id.*, at pp. 332-333.

published by Swedish researchers,[36] show that the average levels of TSNAs in the major U.S. moist snuff products decreased 77% between 1980 and 1994 (the last time that data for both of these products was reported in the scientific literature), and that currently there is no significant difference between the levels of TSNAs in those products compared to Swedish moist snuff products. A chart depicting this data follows:

[36] Andersson G, Bjornberg G, Curvall M. Oral mucosal changes and nicotine disposition in users of Swedish smokeless tobacco products: A comparative study. *J Oral Pathol Med* 1994; 23: 161-167 (1993 Swedish data); Djordjevic MV, Brunnemann KD, Hoffmann D. The need for regulation of carcinogenic N-Nitrosamines in oral snuff. *Food Chem Toxicol* 1993; 31: 497-501 (1992 U.S. data and all earlier data); Hoffmann D, Djordjevic MV, Fan J, Zang E, Glynn T, Connolly GN. Five leading U.S. commercial brands of moist snuff in 1994: assessment of carcinogenic N-Nitrosamines. *J Natl Cancer Inst* 1995; 87: 1862-1869 (1994 U.S. data).



TSNA =Total of reported levels of NNN, NNK, NAT and NAB on dry weight basis in parts per million

US = Average of reported TSNA levels for leading American moist snuff products which, according to the researchers, "accounted for 84% of the snuff sales on the US market (Maxwell, 1992)," excluding anomalous data for 1986

Sweden = Average of reported TSNA levels for three unidentified Swedish moist snuff products

* No comparable data reported in the scientific literature for any period after 1994

This view is supported by a report issued in 1997 by the Swedish National Board of Health and Welfare, which concluded:

> Recent data suggest that the differences [in TSNA levels reported in American and Swedish moist snuff] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks -- at least where TSNA content is concerned.[37]

F. The Gateway Issue

One argument relied upon by those who oppose the use of smokeless tobacco as a component of a tobacco harm reduction strategy is that smokeless tobacco may be a causal "gateway" to cigarette smoking, that is, smokeless tobacco use may cause consumers to later take up cigarette smoking.

The authors of the EU white paper reject the notion of a causal "gateway" from smokeless tobacco to cigarette smoking based upon their assessment of empirical data from Sweden and their analysis of the studies relied upon by those who argue that there is a "causal" gateway effect. Indeed, the authors of the EU white paper conclude that the Swedish data suggest that smokeless tobacco prevents rather than promotes cigarette smoking:

> **Gateway effects.** There is concern that smokeless tobacco will function as a lead-in to smoking for people that would not otherwise smoke. Such 'gateway effects' are always contentious, and they are hard to demonstrate for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco - they may have simply moved straight to smoking. Gateways can act in the opposite direction too – they can be 'exits' rather than 'entrances'. Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the US and

[37] Ahlbom A, Olsson UA, Pershagen G. Health hazards of moist snuff. *SoS Report* 1997; 11:3-29, at p. 7.

Sweden, most smokeless tobacco use *cannot* be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes they may or may not have had their smoking caused by smokeless use.

Exit or entrance gateway? Understanding the order in which tobacco users take up different products is an important and necessary factor in establishing a gateway effect and whether the gateway is an exit from or entrance to smoking, but it is not in itself sufficient to establish a gateway from smokeless to cigarettes. The basic problem is that it is difficult to know whether those that start with smokeless tobacco would otherwise have started on cigarettes in the absence of smokeless tobacco. The data from Sweden suggest that the gateway is more likely to be an 'exit' from smoking than an 'entrance'. Among Swedish males with a primary use of snus no more than 20% ever started smoking, while 45% of other males did become smokers. In addition to this compelling evidence from the pattern of transitions, Sweden has the lowest rate of male smoking in Europe, combined with high levels of snus use. There is no other credible explanation for such low male smoking prevalence than the displacement and cessation of smoking through smokeless tobacco use. In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit. There have been studies in the United States that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users. However, these studies or related commentary have generally drawn causal inferences based on observation of transitions between often poorly defined categories of tobacco use, and sometimes from groups that are unrepresentative of the general population, such as the military. Psychosocial predictors of smoking initiation (school performance, parental smoking, risk taking etc.) can be used to assess which smokeless tobacco users might otherwise have been smokers. When these confounding factors are taken into account, the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker.

Additional data from Sweden contradicting the theory of a causal "gateway" from smokeless tobacco to cigarette smoking was recently published by Rodu et al. in a paper entitled *Evolving patterns of tobacco use in northern Sweden.*[38] The researchers report on their analysis of data from a prospective follow-up study of approximately 3,400 men and women in northern

[38] Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K. Evolving patterns of tobacco use in northern Sweden. *J Intern Med* 2003; **253**: 660-665.

Sweden, and describe the evolving patterns of tobacco use in this population over the period 1986 to 1999. While the researchers conclude that "the use of snus played a major role in the decline of smoking rates amongst men in northern Sweden,"[39] some of their data is of particular relevance to the "gateway" issue. They report that among men who used moist snuff but had never smoked at the beginning of the study, not a single person switched to cigarette smoking during the follow-up period of 5 to 13 years, and only 1 percent of these men used both moist snuff and cigarettes during the follow-up period.

G. Cigarette Smokers' Misperception that Smokeless Tobacco and Cigarettes Involve Equal Health Risks and Their Right to Accurate Information

At the November 2001 meeting of the National Conference on Tobacco or Health in New Orleans, Louisiana, Dr. K. Michael Cummings of New York's Roswell Park Cancer Institute, and his colleagues, presented results of a survey of a nationally representative sample of over 1,000 adult cigarette smokers regarding their beliefs about tobacco products. Of particular interest was the fact that 82% of adult cigarette smokers responded that they believed smokeless tobacco was just as likely to cause cancer as smoking cigarettes.[40]

Given these survey results, it was not surprising that in a 2002 publication, Dr. Cummings made the following comments regarding the comparative health risks of smokeless tobacco and cigarettes, and the need to provide adult cigarette smokers sufficient information to permit them to make informed choices regarding the tobacco products they choose to use:

> Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in

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[39] *Id.* at p. 660.

[40] Presentation by Dr. K. Michael Cummings at the National Conference on Tobacco or Health in November 2001.

> 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. (Emphasis supplied)[41]

Professor Kozlowski has also commented recently concerning the urgent need to provide cigarette smokers with information regarding risk reduction options and their right to receive such information:

> Cigarettes kill about half of those who smoke them . . . 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 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.[42]

H. USSTC's Request for FTC Guidance

On February 5, 2002, USSTC filed a request with the FTC seeking issuance of an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative as compared to cigarette smoking (See Website). USSTC noted in its request that issuance of an advisory

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[41] Cummings KM. Can capitalism advance the goals of tobacco control? Addiction 2002; 97: 957-958 at p. 957.
[42] Kozlowski LT. (2002) at p. 59.

opinion by the FTC would address an issue of significant public interest to adult tobacco consumers, USSTC, and other smokeless tobacco manufacturers. USSTC explained the rationale behind its request as follows:

> USSTC requests that the Commission issue an advisory opinion supporting the use of statements in advertising that provide the public with truthful and substantiated information about the harm reduction that a growing number of public health advocates believe can result from switching from cigarettes to smokeless tobacco products. The benefits of making such information available to consumers would be twofold: it would provide ready access to scientific opinion that otherwise would be difficult or costly to obtain, and it would help adult consumers make better educated choices about the tobacco products they use. As the federal agency with authority over tobacco advertising, the FTC should act affirmatively to provide guidance in this area.
>
> USSTC believes that the types of information it proposes to communicate in advertising are truthful, non-misleading and substantiated. At the same time, USSTC recognizes that cross-category (*i.e.*, smokeless tobacco advertisements directed at adult smokers) comparative advertising of reduced risk tobacco products raises issues which currently are the subject of ongoing public health debate. Providing USSTC with an advisory opinion would inform USSTC and other smokeless tobacco manufacturers of the criteria the FTC will apply when considering such statements. At a minimum, FTC consideration of these issues would advance the public debate on the issue of tobacco harm reduction, and increase the amount of information available to the public regarding reduced risk alternatives to cigarette smoking. Indeed, as part of its consideration of this request, the FTC may wish to hold a public workshop or similar forum to facilitate a full exchange of views on the issues involved.

USSTC's request made clear that any statement USSTC made would be truthful and non-deceptive, and gave an example of the type of statement contemplated:

> USSTC proposes to disseminate advertisements with the following or similar statements:
>
> > *The Surgeon General in 1986 concluded that smokeless tobacco "is not a safe substitute for smoking cigarettes." While not asserting that smokeless tobacco is "safe," many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking*

> *cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products.*

Following the submission of its request to the FTC, USSTC representatives met with FTC staff representatives on May 21, 2002 in order to present an overview of various issues relating to its request, as well as to answer any questions that might be raised by the FTC staff. Following the presentation and discussion, USSTC provided to the FTC staff additional information and documentation responsive to their requests. A similar meeting was held with representatives of Department of Health and Human Services public health agencies on May 30, 2002. Copies of the presentation materials relating to these meetings are annexed as Attachments B and C.

In the spring and summer of 2002, smokeless tobacco and tobacco harm reduction was the topic of discussion and debate at various scientific conferences and public policy forums in the United States and abroad. On May 16, the subject was discussed at a scientific conference in London entitled *Harm Reduction, Smoking and Smokeless Tobacco*; on May 29, the issue was the subject of a forum entitled *Marketing Highly Regulated Products* at Northwestern University in Chicago; on June 20 through 22, the issue was discussed at the *Third European Conference on Tobacco or Health* in Warsaw, Poland; on June 26, the issue was debated at a seminar sponsored by the American Council on Science and Health in New York City; and on July 16, the issue was the subject of debate at the CATO Institute in Washington, DC.

In the summer of 2002, USSTC became aware of the scheduling of two very important scientific conferences that would include a public debate directly relevant to USSTC's request. On September 22 through 25, 2002, the Centers for Disease Control, the National Cancer Institute, and the Stockholm Center of Public Health, Center For Tobacco Prevention, would

sponsor the *3rd International Conference on Smokeless Tobacco: Advancing Science & Protecting Public Health*, in Stockholm, Sweden. The conference would bring together leading experts on smokeless tobacco, and feature a session on tobacco harm reduction. Similarly, the *4th European Conference of the Society for Research on Nicotine and Tobacco* was to be held on October 3 through 5, 2002, in Santander, Spain. This conference would also include discussion and presentations of research findings on current scientific issues relating to smokeless tobacco, including harm reduction. In view of the pendency of these scientific conferences, on August 12, 2002, USSTC temporarily withdrew its request for an advisory opinion so that it would have the opportunity to provide for the FTC's consideration significant new information expected to be presented at these conferences.

On May 9, 2003, USSTC submitted to the FTC information regarding smokeless tobacco as a reduced risk alternative to cigarette smoking that had been presented or published subsequent to the August 2002 temporary withdrawal of its request for FTC guidance. As expected, the Stockholm and Santander conferences produced important new information relevant to USSTC's request. More significantly, however, two publications had appeared in late 2002 or early 2003 that will have a major impact on the public debate regarding smokeless tobacco in the context of tobacco harm reduction. Those publications, discussed above, are a report from London's Royal College of Physicians and a white paper prepared by a group of European tobacco and health researchers and public health advocates. In addition, several other scientific publications or documents had appeared that were relevant to USSTC's request for FTC guidance.

Significant new information from the above-referenced scientific conferences and publications was reviewed in USSTC's May 9, 2003 filing, submitted together with copies of the referenced materials (See Website).

USSTC suggested in its submission to the FTC that the Commission may wish to consider holding a workshop or other forum to address the appropriateness of conveying tobacco harm reduction information as part of smokeless tobacco advertising. USSTC continues to believe that such a workshop would afford all of the participants in this public health debate an opportunity to present their views in a constructive and productive manner. It might also help form a consensus as to how we move forward on this important public health issue, and could provide guidelines to ensure that any comparative risk communication is directed at adult smokers to avoid any unintended consequences.

I. USSTC Position on Proposed Federal Regulation

Proposals have been put forth for comprehensive federal regulation of tobacco products by the Food and Drug Administration or a new tobacco control agency. Some in the public health community argue that comparative risk statements in tobacco advertisements should not be approved until such a regulatory regime is in place. To date, USSTC has opposed such proposals because they fail completely to recognize that smokeless tobacco is distinctly different from cigarettes and thus preserve the status quo in favor of the manufacturers of conventional cigarettes. USSTC would consider supporting federal regulation of tobacco products if the proposed regulatory regime included the following components:

(i) a meaningful regulatory process whereby the agency would certify, based upon submissions by a manufacturer, that the use of

smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking;

(ii) a meaningful regulatory process whereby the agency could approve, based upon submission of a manufacturer, comparative risk communications to current adult users of tobacco products, e.g., cigarette smokers who do not quit and do not use medicinal nicotine products should switch completely to smokeless tobacco products; and

(iii) a meaningful regulatory process whereby the severity of any provisions regarding regulation of ingredients, constituents, advertising, promotion and availability could be reduced for products that were classified on a continuum as involving less risk (e.g. less restrictive regulations for products classified as significantly reduced risk, such as smokeless tobacco).[43]

Not surprisingly, some in the public heath community advocate a nicotine regulatory regime based on the comparative health risks of the regulated products. In late 2002, Dr. Cummings published an analysis entitled *Programs and policies to discourage the use of tobacco products*.[44] One conclusion reached by Dr. Cummings is that the regulation of "nicotine delivery products" on the basis of comparative health risks would lead to a rapid reduction in the health toll caused by cigarette smoking:

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[43] Annexed as Attachment D is an excerpt of UST Inc.'s Form 10-K for the fiscal year ended December 31, 2002 which addresses this issue.

[44] Cummings KM. Programs and policies to discourage the use of tobacco products. *Oncogene* 2002; **21**: 7349-7364.

> Up to now, government policies have actually hindered the development and marketing of less harmful alternatives to conventional cigarettes (Warner *et al.*, 1997; Jha *et al.*, 2000). If all nicotine products were regulated on the basis of their risk of causing health problems, nicotine medications would be the least regulated while cigarettes would be the most heavily regulated. Ironically, just the opposite has occurred with nicotine medications carefully regulated by governments while cigarettes have escaped regulatory control (Warner *et al.*, 1997; Sweanor, 2000; Stratton, *et al.*, 2001). Developing a rational basis for regulating nicotine delivery products on the basis of harm would appear to hold great promise for achieving a rapid reduction in the health toll caused by cigarettes (Kozlowski *et al.*, 2001).[45]

III. Conclusion

Some tobacco control activists have taken the position that USSTC should be prevented from communicating to adult cigarette smokers the prevailing view in the scientific community regarding the comparative health risks of tobacco products. Interestingly, they also believe that neither the federal government nor the public health community has any responsibility to undertake that task.

On the other hand, some in the public health community believe that communication of that vital information could have a significant positive impact on the lives of adult cigarette smokers. Indeed, some in the public health community believe that USSTC must confront the question of whether it has a responsibility to step forward and communicate this critical information to adult cigarette smokers in light of the vacuum created by the federal government and the tobacco control activists.

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[45] *Id.* at p. 7362.

SMOKELESS TOBACCO IS distinctly different

In previous annual reports, we highlighted the significant points of difference between our Company, as a manufacturer of smokeless tobacco products, and other segments of the American tobacco industry.

We focused primarily on the distinct tobacco litigation profile of smokeless tobacco as compared with cigarettes. As for cigarettes, approximately 2,400 smoking and health cases have been filed since 1954. Approximately 50 of those cases have been tried to a verdict, with approximately 10 adverse jury verdicts, including one for $146 billion. As for smokeless tobacco products, approximately 35 cases have been filed since 1954. Only one case has been tried to a verdict, resulting in a unanimous jury decision in favor of our Company.

However, a review of other aspects of the respective profiles of the two products confirms that smokeless tobacco products are distinctly different from cigarettes.

With respect to the health consequences of smoking cigarettes, some manufacturers have shifted from their historical positions and now concede that there is an "overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers" (cigarette manufacturer's website). At the same time, the recent scientific research with respect to smokeless tobacco has moved in the opposite direction. The overwhelming majority of the epidemiological studies published in the last ten years regarding smokeless tobacco and oral cancer has reported that there is no statistically significant association.

Although the Company's policy at this time is not to make comparative health claims, the shift by cigarette manufacturers on the issue of causation highlights a material difference between smokeless tobacco and cigarettes. This point of distinction is particularly significant in light of the emerging debate regarding the appropriate public policy for encouraging the development and sale of so-called "reduced risk" tobacco products. While this is not a new concept, currently no formal regulatory framework exists in the United States in which to make such claims for any tobacco product.

However, in Europe, in conjunction with the World Health Organization's (WHO) Framework Convention on Tobacco Control, a number of tobacco manufacturers are strongly advocating the establishment of a regulatory framework that would permit and guide the development, evaluation, approval, and sale of "reduced risk" tobacco products. Indeed, one Swedish manufacturer, in its submission, contended that smokeless tobacco could play "a valuable part in encouraging cigarette smokers to switch to a less harmful product" as part of WHO's overall harm-reduction strategy.

Here in the United States, one Philip Morris executive has publicly called for regulation of tobacco products by the Food and Drug Administration (FDA) as the "best way to establish appropriate standards for determining what is a 'reduced risk' cigarette." Concurrently, under the auspices of the Institute of Medicine of the National Academy of Sciences, a committee has been charged with assessing the scientific basis for harm-reduction strategies, with the goal of establishing "scientific standards by which to evaluate products with a potential indication to reduce harm from tobacco."

Notably, the committee's overall focus will include products for "the reduction, but not necessarily cessation, of traditional tobacco product use." A number of public health activists have begrudgingly acknowledged that the strategy of total cessation has not succeeded, and support is growing for the concept that "tobacco-related health risks may be reduced by switching existing smokers to less harmful nicotine-containing products." Some researchers have taken that concept one step further, concluding that smokeless tobacco is "far safer" than cigarettes and supporting harm-reduction programs and policies advocating that smokers switch to smokeless tobacco products.

The public debate regarding the appropriate regulatory framework for tobacco generally, and the promotion of the concept of "reduced risk" products specifically, will likely accelerate. Emerging from this debate is increasing recognition that smokeless tobacco products are distinctly different from cigarettes.

Antitrust Litigation

On March 29, 2000, a jury in Paducah, Kentucky, rendered a verdict against United States Tobacco Company, awarding $350 million in damages, subject to trebling, to Conwood Tobacco Company, L.P. for its claims under federal antitrust laws. The court upheld the verdict in August and rendered a judgment for $1.05 billion. The Company completed a $1 billion credit facility and posted the required bond of $500 million while the appeal is proceeding. We strongly believe the court misapplied the antitrust laws in our case and the trial record was insufficient to support the jury's findings. An amicus brief, filed by a Nobel Prize-winning economist, concluded that "[to] allow the damage award in this case to stand... would constitute a failure of justice." Therefore, we believe we will prevail on appeal.

Visit our website at *www.ustshareholder.com* to view the appellate brief.

SMOKELESS TOBACCO IS DISTINCTLY DIFFERENT

The name change of the Company's principal subsidiary to U.S. Smokeless Tobacco Company at the beginning of 2001 was another significant step in highlighting the fact that smokeless tobacco products are distinctly different from cigarettes.

More importantly, there is increasing recognition in the public health community as to one of those distinct differences in the context of the ongoing public debate regarding the appropriate regulatory framework for tobacco generally and the promotion by some tobacco manufacturers of "reduced risk" products specifically. That debate accelerated rapidly in 2001 with the publication of a 600-page report by the Institute of Medicine (IOM) entitled "Clearing the Smoke: Assessing the Science Base For Tobacco Harm Reduction," a project undertaken at the request of, and supported by, the U.S. Food and Drug Administration.

The IOM Report highlighted the debate regarding possible new strategies for public health policy toward tobacco:

> "Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. That is why many public health leaders believe that what has come to be called 'harm reduction' must be included as a subsidiary component of a comprehensive public health policy toward tobacco."

The IOM Report simultaneously cautioned that all products for use in the context of a tobacco harm reduction strategy require substantial and elaborate scientific testing, particularly in the context of new or novel tobacco products or so-called "safer" cigarettes.

However, when it comes to smokeless tobacco, there already is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. Moreover, a growing number of tobacco harm reduction proponents recommend that those cigarette smokers who do not quit should switch to smokeless tobacco products.

Those proponents point to the history of cigarette smoking and smokeless tobacco use in Sweden as support for their view. Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any western country, and the daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes. Indeed, Sweden is the only country to meet the World Health Organization's target of reducing smoking prevalence to 20 percent of the population, and some researchers have linked Sweden's low rate of "tobacco-related mortality" to its high prevalence of smokeless tobacco use. Many now believe that Sweden is a living example of the concept of tobacco harm reduction in action.

Here in the United States, tobacco manufacturers that launched novel products with perceived claims of "reduced risk" have been subject to intense criticism. A central concern is the contention that these products have been labeled as "reduced risk" absent any governmental oversight, and those in the public health community have been urged to publicly challenge those products.

Against this background, on February 5, 2002, in a historic step, U.S. Smokeless Tobacco Company requested the Federal Trade Commission (FTC) to issue an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative compared with cigarette smoking and that there is growing support in the public health community that cigarette smokers who do not quit should be encouraged to switch to smokeless tobacco products. The Company has encouraged the FTC to hold a workshop – involving medical and public health experts, public interest and advocacy groups, tobacco industry members and representatives from other federal and state agencies – to consider the appropriateness of communicating such information in tobacco advertising.

The Company believes it has the obligation on behalf of its stockholders to address this issue and participate in the ongoing debate. By voluntarily seeking guidance from the federal government before communicating comparative reduced risk statements regarding smokeless tobacco compared with cigarette smoking, the Company also believes it is conducting itself in a responsible manner. With the increasing recognition that smokeless tobacco products are distinctly different from cigarettes, it is conceivable over time that the Company and its smokeless tobacco products may eventually be viewed as part of the solution instead of being viewed as part of the problem.

Smokeless Tobacco Is Distinctly Different —The Evolving Debate

2002 was a landmark year with growing recognition — and acceptance — that smokeless tobacco is distinctly different from cigarettes.

The debate regarding tobacco harm reduction and the role of smokeless tobacco as part of a public health strategy to reduce cigarette smoking — as opposed to what has been characterized as the "quit or die" approach — has accelerated dramatically ever since the publication in 2001 of a 600-page report by the respected Institute of Medicine (IOM). In that report, entitled "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," the IOM concluded that "smokeless tobacco may be a valid substitute for cigarette smoking. . . ." In a sense, this conclusion was not surprising in light of the considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarettes.

In sharp contrast to the elaborate testing suggested for new or novel tobacco products or so-called "safer" cigarettes, tobacco harm reduction proponents point to Sweden as providing more than sufficient evidence that cigarette smokers who do not quit and do not use medicinal nicotine products should switch completely to smokeless tobacco products.

Sweden has the highest per-capita usage of smokeless tobacco of any country and the daily use of smokeless tobacco exceeds that of cigarettes. More importantly, from a public health perspective, Sweden is the only country to meet the World Health Organization's target of reducing smoking prevalence to below 20 percent of the population, with an accompanying drop in male lung cancer rates to the point that several media accounts have highlighted Sweden as a living example of the concept of tobacco harm reduction in action.

As reported in last year's annual report, confronted with these dramatic developments, U.S. Smokeless Tobacco Company requested that the Federal Trade Commission (FTC) issue an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered by many researchers in the public health community to be a significantly reduced risk alternative compared with cigarette smoking and that there is growing support in the public health community that cigarette smokers who do not quit outright and do not use medicinal nicotine products should be encouraged to switch to smokeless tobacco products.

Not surprisingly, the Company's FTC filing generated considerable debate. Notably, few took issue with the scientific evidence substantiating that smokeless tobacco is considered to be a significantly reduced risk alternative to cigarette smoking; much of the opposition focused on questioning whether that information should be permitted to be communicated to adult smokers.

The substance of our request to the FTC was the subject of intense discussion and debate at forums at Northwestern University in Chicago, the American Council on Science and Health in New York City, and the CATO Institute in Washington, D.C., in addition to public health conferences in London, Warsaw, Stockholm and Santander, Spain. In light of the papers expected to be generated by these conferences, the Company decided to temporarily withdraw its request to the FTC and is currently updating the submission with an eye to refiling with the FTC in 2003.

The Company's intention to refile was reinforced with the publication of a report in December 2002 that we believe will stand as a landmark in the history of tobacco regulatory policy. Britain's Royal College of Physicians, one of the world's most prestigious medical institutions, issued a report entitled "Protecting Smokers, Saving Lives." With a focus on recommendations for tobacco regulatory policy in the United Kingdom, including the role of smokeless tobacco, the report concluded that "the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product." More importantly, the report recognized that "some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community."

Additionally, in February 2003, leading members of the public health community in the United Kingdom, Sweden and Austria published a white paper entitled "European Union Policy on Smokeless Tobacco: A statement in favor of evidence-based regulation for public health." The white paper stated that "on average Scandinavian or American smokeless tobacco are at least 90 percent less hazardous than cigarette smoking."

The issue of tobacco harm reduction and the role of smokeless tobacco products is at a crossroads. The debate is no longer about whether smokeless tobacco is considered by the scientific community to be a significantly reduced risk alternative compared to cigarette smoking. The only question remaining is whether that information should be communicated to adult smokers or whether such information should be suppressed.

Some tobacco control activists have taken the position that the Company should be prevented from communicating such information to adult smokers. Interestingly, they also believe that neither the federal government nor the public health community has any obligation to undertake that responsibility. On the other hand, some in the public health community believe that suppression of that vital information could have a significant adverse impact on the lives of adult smokers.

Indeed, some in the public health community believe that the Company must confront the question as to whether it has an obligation to step forward and communicate this critical information to adult smokers in light of the vacuum created by the federal government and tobacco control activists.

More fundamentally, the real issue is whether the Company and its products will continue to be viewed as part of the problem, or ultimately will be viewed as part of the solution.

© UST 2002 Annual Report

U.S. Smokeless Tobacco Company

Presentation to
Federal Trade Commission

SMOKELESS TOBACCO AND TOBACCO HARM REDUCTION

May 21, 2002

TOPICS

I. There is competent and reliable scientific evidence to substantiate USSTC's proposed advertising statements

II. Issues raised regarding smokeless tobacco and harm reduction

III. Public comments regarding USSTC's February 5, 2002 Request

TOPIC I

There is competent and reliable scientific evidence to substantiate USSTC's proposed advertising statements

USSTC's EXEMPLAR STATEMENT

"The Surgeon General in 1986 concluded that smokeless tobacco 'is not a safe substitute for smoking cigarettes.' While not asserting that smokeless tobacco is 'safe,' many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products."

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- Exemplar Statement

  "The Surgeon General in 1986 concluded that smokeless tobacco 'is not a safe substitute for smoking cigarettes.'"

5

- Support

1986 Surgeon General's Report (p. vii)

"AFTER A CAREFUL EXAMINATION OF THE RELEVANT EPIDEMIOLOGIC, EXPERIMENTAL AND CLINICAL DATA, THE COMMITTEE CONCLUDES THAT THE ORAL USE OF SMOKELESS TOBACCO REPRESENTS A SIGNIFICANT HEALTH RISK. IT IS NOT A SAFE SUBSTITUTE FOR SMOKING CIGARETTES. IT CAN CAUSE CANCER AND A NUMBER OF NONCANCEROUS ORAL CONDITIONS AND CAN LEAD TO NICOTINE ADDICTION AND DEPENDENCE."

- Exemplar Statement

  "While not asserting that smokeless tobacco is 'safe,' many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes."

- Support
  - There is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.
  - Attached to USSTC's February 5, 2002 Submission is a compilation of excerpts from 50 publications in the scientific literature, many of which were peer-reviewed, which assert or support the proposition that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.
  - These publications were authored or co-authored by over 50 researchers or public health advocates and appeared in approximately 40 different scientific journals or books, most having been published over the past several years.

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CDC's ESTIMATES OF SMOKING ATTRIBUTABLE MORTALITY

	1990	1999
• Cancers:		
– Lip, oral cavity, pharynx	6,475	5,137
– Esophagus, larynx, kidney bladder, etc.	24,927	25,839
– Trachea, lung, bronchus	116,920	124,813
• Cardiovascular diseases	179,820	148,605
• Respiratory diseases	84,475	98,007
• Pediatric diseases	1,711	1,005
• Burns	1,362	966
• ETS	3,000	38,053
TOTAL	418,690 (8/27/93 MMWR)	442,425 (4/12/02 MMWR)

- Prof. Kozlowski's Analysis

Prof. Lynn T. Kozlowski, of the Department of Biobehavioral Health at Penn State University, made the following comments during a lecture presented at the Society for Research on Nicotine and Tobacco on February 23, 2002:

"Smokeless tobacco is safer than cigarettes, no lung cancer, no respiratory disease; add those up and you've got 50% less risk. Less cardiovascular disease probably, no second hand smoke, no fires."

- Dr. Rodu's Analysis
  - Dr. Brad Rodu, a Professor in the Department of Pathology at the University of Alabama at Birmingham and a Senior Scientist at the UAB Comprehensive Cancer Center, and several of his colleagues, are the most widely published researchers on the issue of smokeless tobacco and tobacco harm reduction.
  - Dr. Rodu maintains that smokeless tobacco is "98 percent less dangerous" than cigarette smoking.
  - Dr. Rodu calculates that if all 46 million cigarette smokers in the United States switched to smokeless tobacco there would be "at worst, 6,000 deaths from oral cancer" each year.

(Attachment A, Ref., Tab 37, pp. 181 & 131)

- Other Examples

"UST's argument that the use of chaw is safer than cigarette smoking is scientifically sound (though chaw has its own lesser risks)."

Dr. Elizabeth M. Whelan
President, American Council on Science & Health
February 14, 2002

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"[S]mokeless tobacco use, although definitely not without disease risks of its own, is unarguably less risky than smoking."

Prof. Kenneth E. Warner
University of Michigan, 2001
(Attachment A Ref., Tab 11, p. 119)

"My personal opinion is that we should not squander our forces. We should concentrate them on the fight against cigarettes – they are the overwhelming threat to people's health, snuff being only a mini-monster in comparison."

Dr. K. Asplund
Journal of Internal Medicine, 2001
(Attachment A, Ref., Tab 3, p. 460)

"While snuff use may entail some health risks, there is good evidence that these are substantially lower than those associated with smoking."

Dr. Lars Ramstrom
Director of the Institute for
Tobacco Studies in Sweden, 2000
(Attachment A, Ref., Tab 13, p. 172)

- Exemplar Statement

  "For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products."

- Support

  There is growing support in the public health community that, as part of an overall strategy to reduce harm from tobacco use, cigarette smokers who do not quit should be encouraged to switch to smokeless tobacco products.

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- A Few Examples

I urge physicians to encourage snuff and chewing tobacco as alternatives to cigarettes. No one disputes the role of snuff and similar products as the cause of oral leukoplakia, but there is a vast difference in the frequencies of oropharyngeal carcinoma and cigarette-induced lung cancer. If five new "dippers" are created to avert creation of one new cigarette smoker, then progress has been made."

Dr. LR Kirkland,
Emory University Hospital, 1980
(Attachment A, Ref., Tab 50, p. 165)

17

"Unlike tobacco smoking, use of wet snuff carries no risk of lung cancer, bronchitis, or emphysema, and no risk of cardiovascular disease has been demonstrated."

* * *

"If all smokers in Britain switched to [smokeless tobacco] sachets about 50 000 premature deaths per year might eventually be saved at an annual cost of less than 1000 deaths from mouth cancer."

Drs. MAH Russell, MJ Jarvis,
RJ West, C. Feyeravend,
The Lancet, 1985
(Attachment A, Ref., Tab 46, p. 1370)

While snuff use may entail some health risks, there is good evidence that these are substantially lower than those associated with smoking. Switching from smoking to snuff use would therefore represent a reduction in health risk.

Dr. Lars Ramstrom
Director of the Institute for
Tobacco Studies in Sweden, 2000
(Attachment A, Ref., Tab 13, p. 172)

It's very common to switch from smoking to snus. If they can't give up smoking then I suggest snus because it's much less dangerous than setting fire to tobacco. . . ."

Dr. Karl Fagerstrom
Fagerstrom Consulting AB,
Smokers Information Center, Sweden, 2001
(Attachment A, Ref., Tab 2, p. 30)

- Another View
  - There are some anti-tobacco advocates who object to encouraging cigarette smokers who do not quit to switch to smokeless tobacco products. One example is Dr. Gregory N. Connolly of the Massachusetts Department of Public Health.
  - Yet there is no real dispute in the public health community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

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- In 1998 testimony before a Committee of the U.S. Senate, Dr. Connolly stated that:

  "In all honesty, if you look at [smokeless tobacco] it's probably less harmful than cigarette smoking."

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TOPIC II

Issues raised regarding smokeless tobacco and harm reduction

A. The Nitrosamine Issue

B. Population Risk v. Individual Risk

THE NITROSAMINE ISSUE

- Dr. N. Johnson. Tobacco use and oral cancer: a global perspective. (2001)

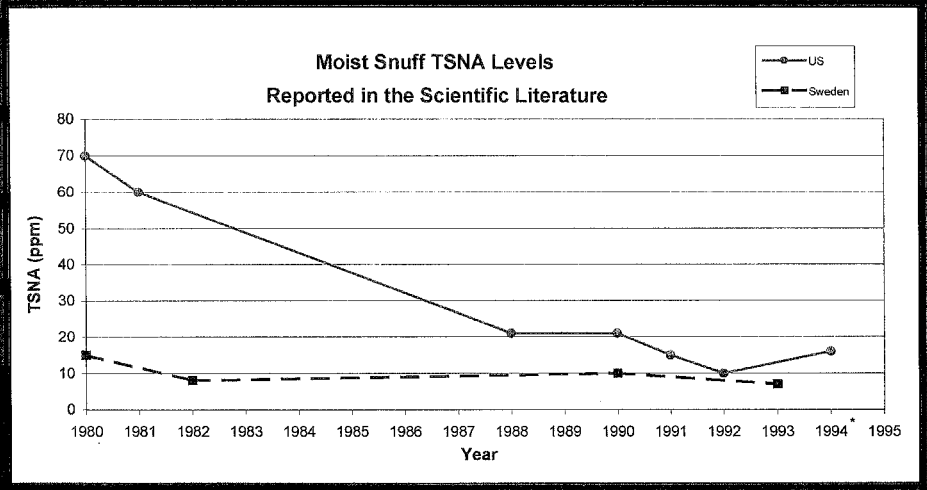
"In Scandinavia it is clear that local snuff is not a major risk factor: two recent case-control studies of oral cancer cases in Sweden have failed to show an association. This is because Swedish snus is not fermented and contains much lower nitrosamine levels than fermented tobaccos."

(Attachment A, Ref., Tab 9, p. 332)

NO "SHARP DISTINCTION" REGARDING NITROSAMINE LEVELS

- A 1997 Swedish government report concluded that "recent data suggest that the differences [in TSNA levels reported in American and Swedish moist snuff] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks --- at least where TSNA content is concerned."
  - Source: Ahlbom A, Olsson US, Pershagen G. Health hazards of moist snuff. SoS-Report 1997;11:3-29 at 7

SIGNIFICANT NITROSAMINE REDUCTION



TSNA =Total of reported levels of NNN, NNK, NAT and NAB on dry weight basis in parts per million

US = Average of reported TSNA levels for leading American moist snuff products which, according to the researchers, "accounted for 84% of the snuff sales on the US market (Maxwell, 1992)" (Ref. 1), excluding anomalous data for 1986

Sweden = Average of reported TSNA levels for three unidentified Swedish moist snuff products

* No comparable data reported for any period after 1994

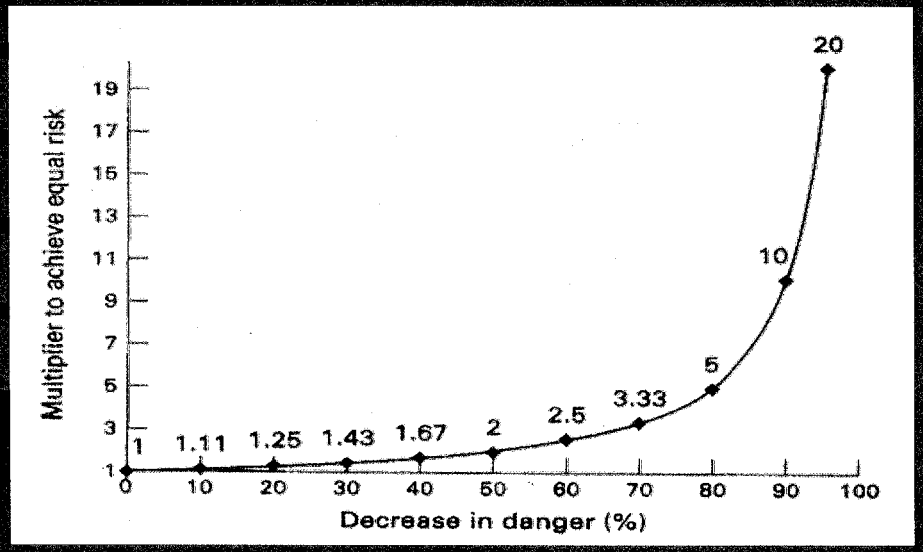
POPULATION RISK V. INDIVIDUAL RISK

- Clive Bates, M.S.C., Director, Action on Smoking and Health

  "If something reduces harm by 10 times then 10 times as many new users would be needed before the net harm was increased. If something reduces harm by 10% then only 11% more users causes greater harm. The risk/use equilibrium curve in the *Kozlowsky et al* article in the current Tobacco Control sets this out elegantly. This suggests different approaches to different harm reduction options. ie. tread very carefully with combustible tobacco - I share the concerns of others about this."

  (http://www.ash.org.uk/html/regulation/html/nscomments.html)

POPULATION RISK V. INDIVIDUAL RISK
RISK/USE EQUILIBRIUM



Kozlowski LT, et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tobacco Control* 2001; **10**: 201-203

TOPIC III

Public comments regarding USSTC's February 5, 2002 Request

A. Support

B. Criticism

C. Response

SUPPORT

- Elizabeth M. Whelan, Sc.D., M.P.H., President, American Council on Science & Health, February 14, 2002
  - "UST's argument that the use of chaw is safer than cigarette smoking is scientifically sound (though chaw has its own lesser risks)."
  - "While those of us in public health would like a tobacco-free society in our future, any improvement is welcome. If ads for chaw were specifically and exclusively aimed at current, adult cigarette smokers (in an imaginary world where smokers could be converted to chaw without turning non-smokers into chaw users), the FTC would be morally obligated to approve U.S. Tobacco's petition to claim that smokeless tobacco is safer than smoking cigarettes."

CRITICISM

1. Smokeless tobacco is not "safe"
2. Youth issue
3. Attempt to deceive the public
4. The FTC lacks authority

1. SMOKELESS TOBACCO IS NOT "SAFE"

- Dr. D. Gregory Chadwick, American Dental Association President, February 26, 2002

  "The U.S. Smokeless Tobacco Company is seeking permission from the government to make advertising claims that using their spit tobacco products is less of a health risk than smoking. Let's set aside for a moment the legitimate scientific and legal questions raised by this, and apply a little common sense. "We've seen the consequences when people - especially children - use these products. We know that spit tobacco is a carcinogen and a risk factor for oral cancer.

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- Dr. D. Gregory Chadwick (Cont.)

  "I suppose you could argue that shooting yourself in the leg poses less of a health risk than shooting yourself in the head. But do we really need to have that discussion? Tobacco use kills people, period. The ADA and its 141,000 member dentists oppose USSTC's proposal to make health claims about their spit tobacco products. It's simply a bad idea."

RESPONSE

The exemplar statement proposed by USSTC expressly communicates the views of many researchers in the public health community. It includes the fact that these researchers do not assert that smokeless tobacco products are "safe," and neither does USSTC. Rather, USSTC's exemplar statement makes clear that there is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

PROF. LYNN T. KOZLOWSKI
SRNT LECTURE, FEBRUARY 23, 2002

- "Smokeless tobacco is safer than cigarettes, no lung cancer, no respiratory disease; add those up and you've got 50% less risk. Less cardiovascular disease probably, no second hand smoke, no fires."
- "Smokeless is undoubtedly safer . . . . Smokers are not very wrong to think smokeless tobacco is safer. It's a non sequitur to say the truth is that smokeless tobacco is connected with all sorts of problems. To charge a safer product is not safe evades the question. The question is, how much safer is it?"

- Prof. Lynn T. Kozlowski (Cont.)

  "Avoiding, or objecting to, the fair presentation of information on effective harm reduction products to smokers to allow them to make an informed choice to reduce health risk can represent a violation of a human right -- the right to information . . . smokers have a right to information on snus and medicinal nicotine as harm reduction options that would substantially reduce the risk of death to individuals."

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2. YOUTH ISSUE

- Dr. Dileep G. Bal, Chief, Cancer Control Branch, California Department of Health

  "While USSTC claims that this health advisory is meant to claim harm reduction for the benefit of addicted adults, it would allow USSTC and other companies to market their products with this claim to young, non-tobacco users as well."

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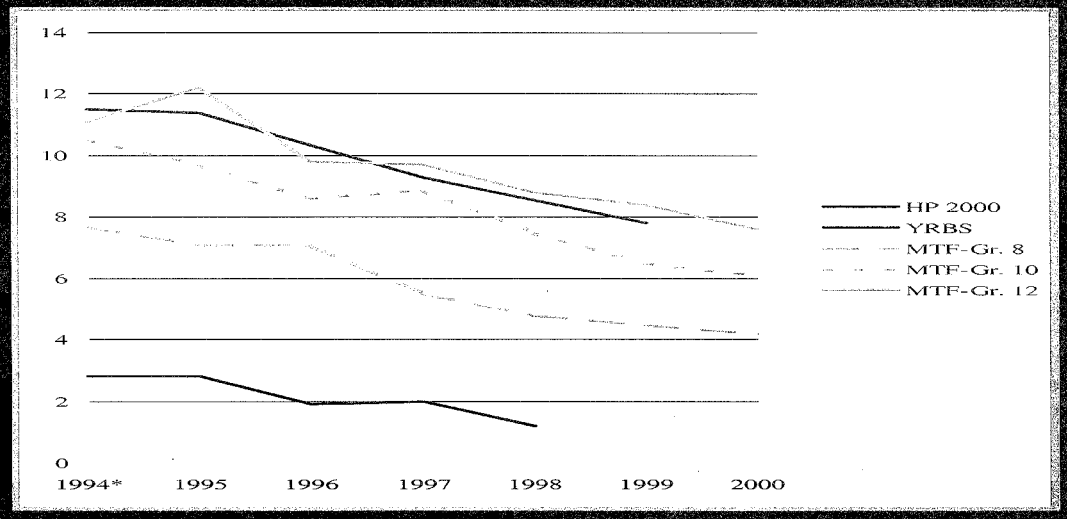
RESPONSE

- The proposed statements are clearly directed to adult smokers. They are matter-of-fact descriptions of the views of many public health researchers. They do not glamorize tobacco product use, nor contain any message targeted to minors.

- USSTC is committed to the principle that tobacco products should be sold to and used only by adults, and has demonstrated that commitment by agreeing to the Smokeless Tobacco Master Settlement Agreement.

- Youth usage of smokeless tobacco, as reported in surveys conducted by various federal government agencies and by the University of Michigan, has declined substantially in recent years. For example, the authors of last year's report on the University of Michigan's Monitoring the Future national survey noted that "[t]he use of smokeless tobacco by teens has been decreasing gradually from recent peak levels in the mid-'90s, and the overall declines have been substantial."

REPORTED YOUTH USE OF SMOKELESS TOBACCO PERCENT REPORTING ANY USE IN PAST MONTH MALES AND FEMALES



National Household Survey on Drug Abuse. Conducted annually by the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services. It is a national, household-based survey of household members aged 12 and over.

YRBS: Youth Risk Behavior Surveillance Survey. Conducted biennially by the Centers for Disease Control of the U.S. Department of Health and Human Services. * 1993 Data (No survey conducted in 1996 and 1998.)

MTF: Monitoring the Future Study. Conducted annually by the University of Michigan's Institute for Social Research. It is a national survey that covers segments of the population to age 32. The data stratum displayed above is 8th, 10th, and 12th grade students.

3. ATTEMPT TO DECEIVE THE PUBLIC

- Dr. Dileep G. Bal, Chief, Cancer Control Branch, California Department of Health

"We believe this is another attempt by the Tobacco Industry to manipulate and deceive the public, and that to release such an advisory would undermine the health of the populace of our nation."

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RESPONSE

Just the opposite is true. Encouraging publication of such information advances consumer knowledge and, therefore, consumer sovereignty. An advisory opinion that addresses parameters for reduced risk statements in advertising will encourage the publication of accurate information about the comparative risks associated with use of the various forms of tobacco and will help adult consumers make more informed choices about the tobacco products they use.

4. FTC LACKS AUTHORITY

- Matthew L. Myers, President, Campaign for Tobacco-Free Kids

  "[T]he the scientific judgments that USSTC is asking the FTC to make are more appropriately made by federal agencies charged with protecting the public health that also possess the expertise for and experience with evaluating all of the evidence of the health effects of smokeless tobacco products."

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RESPONSE

- [T]he FTC has clear statutory authority over this smokeless tobacco advertising issue, as Chairman Muris made clear before the Commerce, Trade and Consumer Protection Subcommittee of the House Energy and Commerce Committee on November 7, 2001. There, he stated that the Commission has the "authority now" to address reduced risk claims by tobacco manufacturers.
- Furthermore, as USSTC pointed out in its request, the Commission can and -- as it has in numerous other situations involving technical, scientific claims in advertising – may well consult with appropriate DHHS agencies in formulating its response.

CONCLUSION

- USSTC's proposed statements in advertising are truthful and substantiated
- Staff should recommend the issuance of an advisory opinion approving such statements
- Public Workshop may assist the Commission in considering the views of the public health community and interested government agencies regarding tobacco harm reduction and cross-category comparative reduced risk statements in advertising

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Chairman TOM DAVIS. I want to thank all of you.

This is actually a historic occasion, Mr. Szymanczyck, hearing your testimony here today, contrasting with—as you go over the past years what we've heard from other executives.

Let me ask a question to you and to Mr. Verheij. How can the public be sure that the products you want to market as reduced risk really are reduced risk, won't be harmful to public health, won't be marketed to children, aren't just an attempt to increase market share?

Mr. SZYMANCZYCK. Well, Congressman—Mr. Chairman, I——

Chairman TOM DAVIS. I like "Mr. Chairman" better.

Mr. SZYMANCZYCK. I believe that the public shouldn't have to trust the tobacco company in that regard. I believe that there needs to be a process for them to trust and that there needs to be someone in charge of that process that they can trust and that's why I'm supporting FDA regulation and supporting a process outlined by the Institute of Medicine to deal with a particular issue within FDA regulation and that's the development of reduced exposure so-called reduced harm products.

I think that they have to have some sort of an external process, and when you look at a piece of legislation like H.R. 140 what you see is that it spells out regulatory authority for the FDA, in particular, over these reduced harm products as well as all other tobacco products, and it also gives the FDA authority to make decisions about communication so as to make sure that, for example, kids aren't induced to smoke or other unintended consequences like people who were former smokers starting to smoke or situations where people who might be quitting might make a decision to continue to smoke. So I don't think that it's the tobacco company they should trust. I think it's the process, and I think that process needs to be driven by the FDA.

Chairman TOM DAVIS. There is considerable risk for your company in doing that. They may decide your ultra lights don't meet their criteria or something under those circumstances, right?

Mr. SZYMANCZYCK. Absolutely. I think that is correct, But I think that is what we have to do.

Chairman TOM DAVIS. Let me ask you, Mr. Verheij. I understand you like the FTC as opposed to the FDA on this. Is that correct?

Mr. VERHEIJ. Let me start with the underlying premise. Unlike claims associated with new reduced-risk products, there are a number of leading medical and research institutions around the world and many researchers who already believe the data that is there to conclude that smokeless tobacco is significantly less harmful than cigarettes. The question is, should that information be communicated to adult smokers who do not quit and do not use medicinal nicotine products? After all, that market is 50 million adult smokers. The fact is that no person under the age of 18 need ever take up smokeless tobacco because the 50 million adult smokers is a huge opportunity to market to.

There are steps that we can take to make sure that these communications are not directed at nonconsumers, at persons under the age of 18, or at persons who have already quit. So we believe that while the process—and we believe this is a process. The process has started over a number of years. A step in the process was

the Institute of Medicine report. A step in this process, frankly, was our filing with the Federal Trade Commission, because that is the agency which is charged with regulating tobacco advertising, tobacco communications.

We went to the Federal Trade Commission because we thought it was the responsible thing to do in terms of starting to make these types of communications to adult smokers. We are all here because there is significant controversy about doing that. So, at the time, the Federal Trade Commission was the agency charged with doing so. We know that they are quite able to go to FDA and to any other arm of the government, as Chairman Muris testified in the other hearing this morning, or to go to outside experts to evaluate the science and the line of claims. We thought that would be a significant advance of the process, as are this hearing this afternoon and the hearing this morning also significant steps in this process.

Chairman TOM DAVIS. Thank you.

Let me just ask quickly, Dr. Burns, you've had extensive experience in this through the years. The Swedish experience is often sited as an example of reduced tobacco in action. Could you offer your thoughts? Is smokeless tobacco less harmful than cigarettes? And, if so, is it responsible to convey this information to current smokers?

Mr. BURNS. The answer to your question is both yes and no. There is no question that smokeless tobacco is less harmful than cigarette smoking for individuals who have used it exclusively for their lifetime. That information is only relevant to individuals who have never used either product, and the clear public health recommendation for those individuals is not to start using either.

We lack three critical pieces of information. The first is the harm to people who have switched after substantial use of cigarettes to smokeless tobacco. We don't have data on that. We also don't have data that individuals who would not otherwise quit can be persuaded to switch to smokeless tobacco as adults. And, third, we don't know the impact of a harm reduction message keyed to adults on the absolute rate of initiation of smokeless tobacco use among adolescents.

Those questions are very critical ones to allow—that would need information in order to allow us to assess whether or not that type of claim should be made and whether, if the claim is made, it will create a benefit or cost to society.

Chairman TOM DAVIS. Thank you very much. My time is up.

Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

If we are going to have risk reduction kinds of products, it seems to me that the place to evaluate it is among scientists; and the FDA has been entrusted with looking to see whether a product, if it is marketed for a medical or health result, is efficacious, it actually accomplishes that result.

Now it seems to me that your position is that the FDA should have that power. Is that right, Mr. Szymanczyck?

Mr. SZYMANCZYCK. That is correct.

Mr. WAXMAN. Now, Mr. Verheij, don't you think the FDA ought to have that power?

Mr. VERHEIJ. Well, I think—we've looked at the current FDA proposals, and the concern we have with any of the current FDA proposals is they would actually—the mechanisms would preclude the types of cross-category claims that we would like to make against the products that Mr. Szymanczyck's company makes. We have laid out in a——

Mr. WAXMAN. I don't understand why that is the case. If you want to make a claim that using smokeless tobacco is less harmful than cigarette smoking and that people ought to use smokeless tobacco instead of cigarettes, it seems to me that there is some scientific findings that have to be made before we reach the conclusion that is a good recommendation to the American people. The place to do that is among scientists, and FDA has always been the place where scientists have made those kinds of evaluations.

Mr. VERHEIJ. Well, I think I am talking more about structural impediments in many of the current FDA proposals, such as—and we met with your staff about 10 days ago, I think, including your bill, Congressman, which would preclude those types of claims which, from our standpoint, doesn't make sense.

Mr. WAXMAN. OK. Let me ask you this. I understand that you are hesitant to say FDA ought to do it. My view is, if you go to the Federal Trade Commission, they can only act after the fact. So in effect what we are doing is trusting U.S. Tobacco to regulate itself, and I want to ask whether that is a wise decision. It is my understanding that U.S. Tobacco has never accepted that smokeless tobacco causes mouth cancer or that smokeless tobacco is addictive. Is that still your position?

Mr. VERHEIJ. Well, first of all, as defined by the Surgeon General, smokeless tobacco is considered to be addictive.

Mr. WAXMAN. Did you accept that? Is that your position? Not just the Surgeon General's position.

Mr. VERHEIJ. Well, as defined by the Surgeon General, it is considered addictive. And I think there is really——

Mr. WAXMAN. Do you agree with the Surgeon General?

Mr. VERHEIJ. Well, as defined by the Surgeon General, exactly, it is considered addictive. No doubt.

Mr. WAXMAN. I see. And it does cause mouth cancer?

Mr. VERHEIJ. Well, based on the scientific data, scientific literature, taken as a whole, we have not taken a position that the product is safe.

Mr. WAXMAN. I haven't heard such a way of avoiding an answer since I had the CEOs in 1994 before me. They have all come around to admitting the connections between cigarette smoking and disease. It seems to me you are hedging on that issue.

Last month, I wrote to all Members to express my concern about UST's request to market smokeless tobacco with health claims, and UST sent me a response about 10 days ago. Since receiving that response, I have obtained copies of internal documents that flatly contradict U.S. Tobacco's statements.

I want to ask unanimous consent to include in the record a letter I have written to Chairman Davis that describes and attaches these documents.

Chairman TOM DAVIS. Without objection, it will be made part of the record.

[The information referred to follows:]

TOM DAVIS, VIRGINIA,
CHAIRMAN

DAN BURTON, INDIANA
CHRISTOPHER SHAYS, CONNECTICUT
ILEANA ROS-LEHTINEN, FLORIDA
JOHN M. McHUGH, NEW YORK
JOHN L. MICA, FLORIDA
MARK E. SOUDER, INDIANA
STEVEN C. LaTOURETTE, OHIO
DOUG OSE, CALIFORNIA
RON LEWIS, KENTUCKY
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BERNARD SANDERS, VERMONT,
INDEPENDENT

June 3, 2003

The Honorable Tom Davis
Chairman
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

You may have recently received a copy of a May 23, 2003, letter from U.S. Smokeless Tobacco Company (UST) in connection with today's hearings on "reduced risk" tobacco products. As you consider this letter, you should know that it is deceptive on important issues.

The UST letter was written in response to a "Dear Colleague" letter that I wrote on April 28, 2003. My Dear Colleague made two major points: (1) that public health authorities have concluded that "reduced risk" claims for tobacco products should be made only in the context of strict regulatory oversight and (2) that the need for regulatory oversight of such claims is underscored by UST's history of untrustworthy marketing. The Dear Colleague attached two fact sheets from the Campaign for Tobacco Free Kids. The fact sheets detailed UST's use of a "graduation strategy" to hook young users on low-nicotine products and then "graduate" them to higher-nicotine products. They also described the company's strategy of appealing to children through the use of cherry flavoring in its "starter" products.

In its May 23 response, UST dismisses the allegation that the company "has engaged in strategies to hook kids" as "inaccurate or misleading." UST claims that it does not and has never used a "graduation strategy," certainly not one related to marketing to youth. UST also rejects as "baseless" the suggestion that its cherry-flavored products were designed to appeal to children.

Since receiving UST's May 23 letter, I have obtained copies of internal company documents that validate the points made in my Dear Colleague and conflict with the assertions in UST's letter. These documents show that the company planned a "graduation strategy" starting with "young" consumers, that the company has long known that flavoring in smokeless tobacco products appeals to young smokeless tobacco users, and that UST deliberately adds flavoring to "starter products." The documents also indicate that UST marketed its products to children as

young as 13 or 14. Copies of these previously undisclosed documents are enclosed with this letter.

These documents and UST's response are relevant to the Committee's consideration of UST's request for permission to market smokeless tobacco as safer than cigarettes. While UST may say that it would never abuse authority to make "reduced risk" claims, the company's past practices — and its recent correspondence denying these practices — call the company's veracity seriously into question.

UST's Graduation Strategy

UST states that it never employed a "graduation strategy" in marketing its tobacco products and that any documents from officials at the company discussing the strategy merely reflected a "hypothesis," "did not relate to marketing to youth," and "did not drive the Company's marketing strategies."

This claim is difficult to believe in light of the documents that I have obtained. The documents show definitively that a graduation strategy aimed at youth was in fact the company's goal and that implementing this strategy was the objective of the highest-ranking officials in the company. In particular, a 1980 memo from the Senior Vice President for Marketing and Sales to the Chairman of the Board and President of UST sets forth two of the company's marketing "objectives" as follows:

- *Introduce an easy-to-use, "starter" product*
- *Provide new users with an easy graduation process.*[1]

That this graduation process is aimed at young customers is expressly stated later in the document. A chart labeled "Marketing Action/Staging," which includes specific dates for implementation of each action as early as two months from the date of the memo, reads as follows:

BRAND/SEGMENT	*OBJECTIVE*
Ball'n Chew	*Introduce easy to use, "starter" product*
Wintergreen	*to increase consumer base,*
Plastic Can	*especially among the young.*

[1] Memo from Barry J. Nova, Sr., Vice President Marketing and Sales, to Louis P. Bantle, Chairman of the Board and President, UST, Re: 'Moist' Development, 1 (Jan. 4, 1980).

* * * *

Skoal Straight Plastic Can	*Introduce line extension to support "natural vertical" graduation process.*[2]

This document also contains a chart, entitled "Product Development and Positioning," that depicts "young, newer" "light" users at the bottom of a continuum that ends in "older, confirmed" "heavy" users. Marching up this continuum are the company's smokeless products, with the lightest products at the bottom and the strongest products at the top.

Use of Flavored Products to Appeal to Youth

UST claims that cherry flavoring is common in adult products like Maalox and Tums and therefore that there is no basis to believe that the company used sweet flavors to appeal to children. But the company had clear understanding that flavors appeal to young users and not to adults. In the document quoted above, the Senior Vice President for Marketing and Sales states the following "assumptions":

ASSUMPTIONS:

- *Younger and lighter users prefer a flavor, not a natural*
- *Older and heavier users prefer real tobacco taste and strength*

* * * *

- *Happy Days [a lighter product] can be a better brand and better "graduator" with a change in flavor.*[3]

UST's Marketing to Children

Another document indicates that the UST's sales force marketed to children as young as 13 or 14. A memo from a regional sales manager to UST's National Sales Manager describes the effect of a competing product on sales of UST products. The memo states that retailers report that Hawken, a product from a UST competitor:

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[2] *Id.* at 6.

[3] *Id.* at 5.

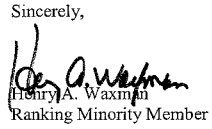
> *is being used by young kids and young adults. The age of the kids is from 9 years old and up. I believe this to be true because outlets located close to schools (all grades) are definitely the heavier Hawken outlets we visited. . . . Also, the people who knew about mouth tobaccos felt the sweet taste was a definite factor with the kids.*[4]

This memo goes on to say that Hawken "has reached kids four or five years earlier than we have contacted them in the past."[5] Because the memo is describing a product being used by 9-year-olds, the clear indication is that UST was marketing to kids of 13 or 14 years.

Conclusion

As we consider UST's desire to market its products as safer than cigarettes, we must keep in mind both the company's marketing history and its continuing deceptions. Essentially, UST is asking Congress to trust that the company will make responsible claims about its products. But it is hard to see how such trust is warranted given the company's track record. Certainly, the company should not be permitted to make "reduced risk" claims about its products without strict regulatory oversight.

Sincerely,



Henry A. Waxman
Ranking Minority Member

Enclosures (2)

cc: Members of the Committee on Government Reform

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[4] Memo from A.H. Cameron, Regional Sales Manager, UST, to R.R. Marconi, National Sales Manager, 2 (Jan. 21, 1980).

[5] *Id.*

cc: RLR, TBO, ML, AEM, RK, BS, PS, TS

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INTRA-COMPANY CORRESPONDENCE

FROM: Barry J. Nova, Sr. Vice President Marketing and Sales
TO: Louis F. Bantle, Chairman of the Board and President

January 4, 1980

Subject: "Moist" Development

U. S. Tobacco has "made" the market in moist smokeless tobacco; a segment that remains in the early stages of growth on a product life cycle graph. We must continue to "lead" the category in order to:

- Enlarge our consumer base
- Preempt probable competition
- Maintain corporate growth and profit

A recent document from Peter directed itself to "product leadership"; to the methods of ascertaining the right products in the right positions to meet potential user needs. While some of the choices and recommendations might be questioned, it is not the intent of the writer to mark down a good beginning. Rather, in conjunction with those carboned above it is the purpose of this memorandum to further define marketing action needed to meet the following objectives:

- Introduce an easy-to-use, "starter" product
- Provide new users with an easy graduation process
- Develop better packaging
- Maintain a simplicity in the product line

Easy Graduation Process

There are two "leaders" extant in today's marketplace: Skoal, with a wintergreen flavor; and Copenhagen, with a more natural tobacco taste. While Skoal is the biggest seller, reasonable percentage growth is still apparent in the Copenhagen brand; and both continue to outpace Happy Days (mint) - where about 20% of current poundage is samples - on a poundage growth basis.

In addition, two other "natural"-brands continue to show strength with very limited promotional support - W B Cut and Key.

Simply, then, we should concentrate on the two proven areas of acceptability - Wintergreen and Natural; and build vertically in these two flavors, permitting the consumer to "move-up" or strengthen his pleasure in a taste that he is used to and comfortable with. Even our new looms leaf chew would fit comfortably in the pattern.

And while we do feel that mint/spearmint is an acceptable American flavoring in food and gums, it has not yet been completely proven as a tobacco additive; and a triple flavor track rather than a vertical duality would be too complex now.

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Simplified Product Line

We cannot, and should not, attempt to be "all things to all people" now. After all, it must be remembered that we are just beginning to tap the market's potential, and that the brands we sell, in most cases, seem to meet a need or a want. To proliferate many new products/line extensions might very well cause:

- Confusion among potential new users as to where to begin and with what.

- Confusion among current users regarding what to move to; possibly creating no new business, just a transfer of business intra-line.

- Problems in media promotion: difficulty in creating strong, separate positioning statements; lack of frequency to explain all various elements.

- Trade dismay and lack of support. Moist has been "welcomed" by the trade, but for the next four to five years we will not be at the point where we can demand two to three times the warehouse or retail shelf space that we now enjoy. To try to put out a myriad of products is to run the severe risk of alienating a carefully built trade rapport based on good sales from consumer demand, as well as inviting an ever-increasing damaged goods problem.

"Easy-To-Use"/Starter Product Development and Intro

This must be our priority niche at present, for the obvious reasons:

- Expansion demands a continually enlarging new user base.

- "Floating" and saliva build-up are still negatives to the "beginner".

- Most readily available entry segment for competition on both a product development basis and ratio of pay-back to investment. (And who is to say that a so-called "starter" product cannot carve-out, in part, its own on-going user base.)

Happy Days, because of some difficulty in use and apparent ill-defined flavor, may not be the best effort we can make for "starters". It can be improved, and then perhaps, could be positioned as part of the "regular" line.

Good Luck, a technological advance in packaging rather than a break through in taste, is selling reasonably well in most test areas; but requires better flavor and a final, true evaluation before capital is expended on additional machinery.

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Our new, shag cut, "balling" smokeless brand (whether it is truly "balled" or just flattened between the fingers) is the one that "gut" feelings tell us can be the most successful entry. It is easy to use. Saliva build-up is minimal. It takes flavoring well. Raw materials are available. Production methods have been proven. A machine to pack both it and W B Cut could be ready by the fourth quarter of '80. However, only thorough testing of the concept will prove its validity.

Better Packaging

The general view is that the plastic can would be a positive packaging step:

- Lower manufacturing costs
- Decreases freight costs
- Easier to open
- Stands-up better in the wearing
- Adaptable to holding lesser amounts of tobacco
- May keep product fresher, longer

A small amount of research done in our overseas market, coupled with some results from Hawken testing in Jonesboro indicate good consumer acceptance for the plastic container. And it is understood that both Happy Days and Skoal can be packed this way now, without any loss in product quality.

However, we can visualize the possibility of some problems that might occur:

- Consumer perception that change in package means a change in formula and flavor. Panel testing can prove or disprove this.

- Keeping the product fresher, longer could negate the "built-in obsolescence" in the present container, thereby lessening poundage. Still, good users might just use more because it is fresher. The answer might be gotten through focus groups.

Finally, one important facet of plastic packaging - its adaptability - needs further commentary regarding how important it could become in creating new users and meeting competitive pressure:

Supposition	Strategy
New users "pinch" less often and will use less tobacco per "dip".	Build up bottom of plastic can - without changing height and circumference - in order to pack a "full" lower weight in a "starter" product; i.e. .6 ounces.
Pricing can be a determinant to trial; and may well be used as a competitive advantage.	Lower price on "starter" brands to increase trial, lower sampling costs, and preempt competitive, "low ball" pricing. For example:

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	UST	Jobber	Retail
present can price	42c	52c	65c

(Packing half as much tobacco may save 20% or more while maintaining margins)

"reduced" can price	33c	41c	50c

Possible result: More new users, happy with a "fair" entry price, unconcerned with lesser amounts of product, who can be graduated to one of our "regular" products at a "regular" price (and may want to "move" there faster since 1.2 ounces at 65c is a better "deal") .... and competitors who probably will have to cut their own margins to find a price point entry meaningfully below ours.

The foregoing discussions point the way to the recomendations included on the Product Development and Positioning Chart that follows; after which a Marketing Action Staging form indicates the R & D, research and market testing required to prove their viability.

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PRODUCT DEVELOPMENT AND POSITIONING

VERTICAL DUALITY

ASSUMPITONS:

- Younger and lighter users prefer a flavor, not a "natural"
- Older and heavier users prefer real tobacco taste and strength
- Skoal is our largest selling and fastest growing product (and best known); all "starter" products should acquaint people with its taste.
- Copenhagen is our second largest selling product and its growth could improve with a lead-in from a "natural" line extension, whose name and blend have proven themselves.
- Happy Days can be a better brand and a better "graduator" with a change in flavor.
- The "top of the line" - W B - may yet be our fastest growing product and deserves a place in both "verticals".

user	usage	WINTERGREEN FLAVOR	NATURAL FLAVOR
older confirmed	heavy	W B Cut (2) (P)	W B Cut (1) (P)
			Copenhagen (1) (CT)
		Skoal (1) (CT)	Skoal Straight (3) (PC)
		Happy Days (2) (PC) wintermint	
		Ball'n Chew (4) (PC)	
young never	light	Good Luck (2) (PC) wintermint	
		Stetson (4) (P) (loose leaf)	Stetson (4) (P) (loose leaf)

(1) Manufactured at present; requires no change
(2) Manufactured at present; requires indicated flavor additive
(3) Manufactured at present; requires new labeling
(4) Manufacturing to finalize development
Packaging: (P)-Pouch; (PC)-Plastic Can; (CT)-Cardboard and Tin

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MARKETING ACTION

STAGING

BRAND/SEGMENT	OBJECTIVE	MANUFACTURE/DEVELOP PERIOD	RESEARCH/PERIOD	TEST MARKET/PERIOD	ROLL-OUT/PERIOD
Ball'n Chew Wintergreen/ Plastic Can	Introduce easy-to-use, "starter" product, to increase consumer base especially among the young.	Blend and flavor-2/80 Hand pack for research -3/80 Hand pack for test markets - 8-12/80 Develop machine packing by 1/81 Name and label development-3/80	Taste test with new Happy Days user panel, vs. Good Luck and Hawken. In addition, test in potential user focus groups vs. Good Luck, Hawken and Happy Days 4/80 thru 8/80	4 Markets: 2 control w/media 2 reduced price and weight w/media 9/80 thru 12/80	By region, with promotional support, during 1981.
Good Luck Winterminf/ Plastic Can	Change to a new taste. Evaluate "bag" concept in terms of future sales potential and machine needs.	Blend and flavor-3/80 Full production-6/80 Prototype machinery -9/80	Taste test with user panel -new vs. present product also gather user profile and concept acceptance data -3/80-6/80. Audit selected outlets in current areas to determine future national volume.	Current areas utilizing present production capacity fully.	By region as machinery becomes available.
Skoal Straight Plastic Can	Introduce line extension to support "natural vertical" graduation process	Utilize existing Key blend, and change label-3/80	Audit in test markets at retail and wholesale to ascertain new sales growth vs. "pull down" from existing brands. 4/80 thru 9/80	4 Markets: 2 Copenhagen areas, one with local adv. 2 Skoal Areas one with local adv. 4/80 thru 9/80	National, supported by "...Skoal, and new Skoal Straight." network TV spot.
Happy Days Winterminf/ Plastic CAn	Change to a new taste and evaluate with current users.	Blend and flavor-3/80 Full production-7/80	Taste test-existing vs. new-with large Happy Days user panel. 5/80-7/80	None	National distribution - 8/80
W B Cut Wintergreen/ Pouch	Introduce line extension to create a "top-of-the line" duality	Blend and flavor-5/80 Packing machinery developed and full production by 1/81.	Taste test in panel of W B Cut users. 6/80-10/80	None	Region by region distribution only after further acceptance of natural brand is accomplished. 1/81 thru 12/81

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MARKETING ACTION

STAGING

BRAND/SEGMENT	OBJECTIVE	MANUFACTURE/DEVELOP PERIOD	RESEARCH/PERIOD	TEST MARKET/PERIOD	ROLL-OUT/PERIOD
Plastic Packaging	Evaluate consumer acceptance of plastic can concept	Label development-4/80 Possible new can colorations-4/80	Full, large panel test for Happy Days with Happy Days users-5/80-9/80. Full, large panel test for Skoal with Skoal users-5/80-9/80. Results should be at least 95% positive.	None	National distribution beginning -1/81
Stetson Natural/ Wintergreen -Pouch	Introduce a loose leaf chewing entry point toward capture of 10% of market in three years	Per T. Cornell: Blend and flavor-2/80 Samples production-3/80- Production for test markets-7/80-1/81 Full production 2/81	Full, loose leaf user panel tests-Stetson vs. Levi Garrett, Red Man, Beechnut 4/80-7/80. Name and package design perception testing in 2 focus groups, 4/80-7/80 Audit at wholesale and retail to determine movement and and growth vs. competition.	8 test markets conducted in strong loose leaf areas: 2 Stetson natural lower media 2 Stetson natural -higher media 2Stetson wintergreen -lower media 2 Stetson wintergreen -higher media 8/20-2/81	National distribution 3/81-6/81; supported by national media effort

A more complete and fine-lined consumer research and workset test program will be prepared as approvals are given for "staging".

*NOTE: Panel taste test will measure various intensities of flavor

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RJN LJG AEM DJG FFL RJZ HJ PJS

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INTRA-COMPANY CORRESPONDENCE

FROM: A. H. Cameron, Regional Sales Manager
TO: Mr. R. R. Marconi, National Sales Manager

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January 21, 1980

RE: HAWKEN REVIEW

Tuesday and Wednesday was spent in the tri-city area (Bristol, Tennessee; Bristol, Virginia; and Johnson City, Tennessee) in an attempt to further evaluate Conwood's new item "Hawken". I spent this time working with Mr. C. E. Jordan, division manager. Factual information was hard to come by in some of the areas; however, I will attempt to cover what we found from consumers, retailers, and distributors.

Consumers

We were only able to actually discuss Hawken with two consumers who have used the brand for any length of time. One of these was a convenience store manager (male about 55 years old). This man was supplied with samples on a regular basis for at least four to five weeks. By this time he had developed a taste for Hawken and now believes the flavor and taste last longer than SKOAL, the brand he used before Hawken. The second consumer was a 12 year old male and his mother. He stated, and it was confirmed by his mother, that all other brands of mouth tobacco he had tried to use would make him sick. This included SKOAL, HAPPY DAYS MINT, and several brands of scrap. He felt the cause with SKOAL and HAPPY DAYS MINT was the brands were too hard to use, he could never keep them together. Scrap produced too much juice and he swallowed too much. He also felt Hawken's flavor lasted longer. A very interesting observation - his mother was delighted he had finally found a mouth tobacco he could use. During my questioning of this lady, it was clearly evident that she believes mouth tobacco is the least harmful of many habits her son could develop; therefore, she openly encourages him to chew. The price made no difference to these two consumers.

Retailers

While contacting most of the retailers we have had on the "Tracking Program", we could only find two who definitely believe Hawken is still increasing in sales. All others state the brand has peaked and most report a decline in sales. Every retailer stated that SKOAL definitely was hurt the worst; however, they all state that SKOAL is coming back and is either at, or close to its previous sales level. They all report consumers of all ages are buying

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Hawken. Also, all type of consumers are using Hawken. These retailers all agree that the majority of Hawken is being used by young kids and young adults. The age of the kids is from 9 years old and up. I believe this to be true because outlets located close to schools (all grades) are definitely the heavier Hawken outlets we visited. Several retailers indicated that price was a factor with the young kids. Also, the people who knew about mouth tobaccos felt the sweet taste was a definite factor with the kids. No retailer expressed any problem with the lower price of Hawken. They all state their mark-up is the same percentage as on SKOAL and other tobaccos.

Distributors

Distributors all state that they did no more on Hawken than any other new item. They all report that the brand has peaked and they are seeing declines. No distributor indicated any promotional activity was planned for Hawken.

As you can see, all levels are pointing the same way on Hawken. I believe the brand has hurt SKOAL and HAPPY DAYS MINT as much as it is going to. Figures prove Hawken killed our increase on SKOAL (30 percent); and at this point, we are showing about 9 percent decrease in sales where Hawken is available. At one point, our loss was well over 20 percent. This has turned around and I believe SKOAL will be back to a break-even point within the next few weeks. I feel by the end of the next three-month tracking period, our increase will be back to normal. I am not at all sure our increase won't be greater than ever. It definitely is a fact that Hawken has brought a lot of new consumers into the mouth tobacco market. I think this brand has reached kids four or five years earlier than we have contacted them in the past. Indications are that some of these new users are moving up to a stronger brand. Also, indications are that some older consumers are moving from Hawken back to the brands they were using before, and some consumers have begun mixing Hawken with SKOAL and Levi Scrap. If these trends continue, Hawken may prove to be a very good starter product for SKOAL.

I am convinced we must continue our tracking of Hawken for at least another three months before our questions can be answered. However, all figures indicate Hawken, when introduced in a new market, will kill our increase on SKOAL and, in fact, cause a 10 to 20 percent loss for the first three months.

Our field personnel will continue to supply all information possible on Hawken.

Sincerely,

A. H. Cameron

AHC:dc

Mr. P. J. GHILONI
Rec'd
Date Ans'd
SEE ATTACHED

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Mr. WAXMAN. In UST's response to me 2 weeks ago, the company claimed it never employed a graduation strategy to hook young people on starter products and then move them to more addictive products. Is this still your position?

Mr. VERHEIJ. Well, I think we were asked that same question 10 years ago and we had thought we had adequately responded to that in terms of the graduation process or the discussion by some people. The company never drove the marketing strategies of our company, because——

Mr. WAXMAN. One document I have, and I have introduced today, was a memo from the senior vice president of marketing to the president of the company; and it shows the company's objective is, "provide new users with an easy graduation process." Now, UST also wrote me that it was baseless to suggest that cherry flavoring was added to smokeless tobacco in order to attract young people. Is that still your position?

Mr. VERHEIJ. Absolutely. I think if you go into the local pharmaceutical today, there are a lot of cherry-flavored products like Maalox, all intended for adults. In fact, they have a proviso on the back of the label that says, keep out of the hands of children. Cherry is a very appealing flavor amongst adults, and it has been a flavor that has been used in conjunction with tobacco products for over 150 years.

Mr. WAXMAN. Well, the document that is now in the record demonstrates that there was a clear understanding by the senior vice president of marketing and president, they understood that, "younger and lighter users prefer a flavor, not unnatural," while older and heavier users prefer real tobacco taste. Do you still think it is baseless to think that cherry flavors were added to appeal to young consumers?

Mr. VERHEIJ. As I said, there are a number of products clearly intended for adults on drugstore shelves today.

Mr. WAXMAN. What about your product? What about your product? Was that intended to attract kids to use your product?

Mr. VERHEIJ. Not at all. We found that cherry flavor was a flavor that appealed to adult tobacco consumers.

Mr. WAXMAN. Well, my point, Mr. Chairman—I know the time is up. But my point I think is made: U.S. Tobacco simply can't be trusted to regulate itself. I think the result could easily be a public health disaster. And I know they are trying to play games with the Federal Trade Commission to get them to back away from striking down these irresponsible claims the U.S. Tobacco wants be making. I think it is irresponsible, and I have other questions in the second round as to whether this is really a risk reduction or harm reduction strategy or another public health disaster in the making.

Chairman TOM DAVIS. The gentleman's time has expired.

Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. I will defer to my other colleagues but before the first round is over I will have some questions.

Chairman TOM DAVIS. Mr. Schrock.

Any questions over here? Any other questions?

The gentlelady from California.

Ms. WATSON. Thank you so much, Mr. Chairman.

It is too late to deny that tobacco is an addictive drug that has destroyed the health and caused the early deaths of millions of people. There is too much at this time damning scientific evidence about the dangers of nicotine for anyone to claim that nicotine can somehow be made healthier or less harmful. Now, I have said—and I want to commend all of the panelists, the first panel and now the second panelists. But I just heard a discourse that I would call ridiculous. The gentleman on the end as he was questioned avoided answering questions.

To me, cigarette smoking is like rat poison. Any amount of rat poison is still rat poison. And nicotine, I don't care who studies, who researches or who uses it or what flavors you put in, it is still rat poison; and I think any scientific-minded and thinking person would agree to that.

But I want to ask—is it Mr. Verheij?

Mr. VERHEIJ. Yes.

Ms. WATSON. OK. I want to be sure I pronounce your name correctly.

I am sitting here with cancer facts: Snuff or smokeless tobacco is a finely ground or shredded tobacco. And chewing tobacco—and I am going to ask you if this is true and would you agree with it. Chewing tobacco and snuff contain 28 cancer-causing agents. Would you agree?

Mr. VERHEIJ. Well, looking at the—as I——

Ms. WATSON. Wait a minute. Give me a yes or a no.

Mr. VERHEIJ. Well, these are——

Ms. WATSON. My time is short. Give me a yes or no.

Mr. VERHEIJ. I think, if I recall the list correctly——

Ms. WATSON. Excuse me. Can you answer yes or no? You might say, no, you can't answer.

Mr. VERHEIJ. I would need to give a complete answer to respond to your question.

Ms. WATSON. Thank you.

Smokeless tobacco users have an increased risk developing cancer of the oral cavity. Is that a true statement, yes or no?

Mr. VERHEIJ. Based on the studies that were available in 1986, that is what the Surgeon General concluded.

Ms. WATSON. OK. Is there any redeemable features of using snuff or spit tobacco?

Mr. VERHEIJ. Well, as I think I indicated in the opening remarks, the——

Ms. WATSON. Can you answer me directly when I raise a question with you? Because my time is short. Do not force me to run out of time.

Mr. VERHEIJ. In the context of tobacco harm-reduction strategy, many people believe that smokeless tobacco is an option that should be taken seriously, yes.

Ms. WATSON. You believe smoking tobacco can be taken seriously—smokeless tobacco can be taken seriously?

Mr. VERHEIJ. I think we heard a number of people on this panel indicate that it should be taken seriously, yes.

Ms. WATSON. When chewing tobacco and snuff contain 28 carcinogens, you think that it should be taken seriously?

Mr. VERHEIJ. I think a number of leading research and medical institutions agree with that statement, it should be taken seriously as an option.

Ms. WATSON. What do you agree with?

Mr. VERHEIJ. I think they make a very compelling case; and, indeed, a number of people on this panel have made a very compelling case for smokeless tobacco as an option for those adult smokers who do not quit.

Ms. WATSON. Mr. Chairman, I have heard these bizarre arguments and that reduced exposure or reduced-risk tobacco products are better for your health than regular tobacco products. If I understand the reasoning correctly, this is kind of like saying a smaller or lethal dose is better for those who are trying to stop using tobacco products. I was hoping that in this hearing we would hear the kind of information necessary to support the creation of a regulatory framework which would save our children from the dangers of nicotine. I have heard at least two of the presenters talk about market share. I have heard them talk about the marketplace. I am saddened that the people who are representing the tobacco industry are looking at market share and marketplace more than look at saving our children from the dangers of nicotine in any size, form, dosage, or whatever.

So, Mr. Chairman, I want to thank you for providing us this hearing so I could hear for myself.

I want to commend the ranking member, because I watched continuously the hearings that you held many years ago when you had the representatives of the tobacco industry raise their hands and you asked them the question: Is nicotine addictive? And they said no. So I hope we can gain more information. And thank you for indulging me.

Chairman TOM DAVIS. Thank you. Let me just note, I think we have heard today that we didn't hear those comments today. I think at least in the part of when testifying today that the industry takes a more responsive view today.

Any questions over here? Mr. Shays.

Mr. SHAYS. Thank you.

Basically, I come to this hearing with some heartfelt feelings. One is that you had to be an idiot not to know that smoking was harmful to your health. For as long as I have lived, practically, but certainly by the time I was in elementary school but clearly by the time I was in high school, and I graduated high school in 1964, I knew that smoking was very harmful to your health. So I have wrestled with some of the court cases that have taken place in which people take no ownership for what they do.

It is very clear that Philip Morris has said that it is harmful. When they said it wasn't harmful, I frankly thought, well, that is a foolish statement, because it was harmful many, many years ago.

I am here because I know people are going to continue to smoke in spite of the fact they know it is harmful. And I am intrigued by the process of saying is it a wise public policy for us to see if we can have less harmful products? Should we incentivize Philip Morris to come in with a product that is less harmful?

And I agree with you, Mr. Szymanczyck, there is no way that someone is going to believe the tobacco company. We need to have someone from the outside basically pass judgment.

I intuitively believe that if you chew tobacco it is less harmful. My answer to the question that was asked to you would have been that, there is no question, Mr. Verheij. I would have said, you know, it does cause cancer and we know it. But I guess we are not there yet in saying it. But in terms of—because both are harmful. And I think you know that, and I think you have basically said it without saying it.

So I would like to ask the health care folks. I would say intuitively that smokeless tobacco is less harmful, but it is still harmful. I would like to just go down the line with you, Dr. Hatsukami and Dr. Kozlowski, and I guess, Mr. Sweanor, you are the only one who is not a health care expert, is that correct, on this issue? Am I right or wrong?

Mr. SWEANOR. I would probably still hold myself out as an expert.

Mr. SHAYS. Well, then let's go from our two bookends and answer the question: Is smokeless tobacco less harmful?

Dr. HATSUKAMI. I think that on the surface it appears to be less harmful when you take a look at the effects of smokeless tobacco products on health compared to cigarettes. But you have to look a little bit deeper than that. There are a lot more concerns associated with it. You have to take a look at the effects on the individual as well as the population level.

On the individual level, people do not do what you want them to do or what you expect them to do. And my concern about the claim that smokeless tobacco is less harmful, is that people will use both cigarettes and smokeless tobacco products.

Mr. SHAYS. So let me put it in my words, and if I can go on—and disagree with me if I am wrong. What I sense you saying is, if we are successful and we do see a number of smokers and tobacco users, either if it is smoking or chewing tobaccos, that is the best way to improve the health situation. If in fact we come up with better products but don't increase the number of people who use tobacco, then we will have made a positive forward movement. But if in the process of coming in with better products we create a lot more tobacco users, then it is a negative.

Dr. HATSUKAMI. That is right. If we create more tobacco users, it is a negative. And if we have dual use of tobacco products, that may be potentially a negative.

Mr. SHAYS. OK. Then let's just keep on now. Thank you. That's helpful.

Yes, sir.

Dr. HENNINGFIELD. Smokeless tobacco is deadly for the young people who never would have taken up tobacco but for the advertising. It is deadly for the adults who keep smoking because now they don't have to quit. It is theoretically possible that it could offer reduced risk for some individuals, but we don't know the conditions under which that would occur. So it depends. How it is used is as important as how it is made.

Mr. SHAYS. Fair enough.

Doctor.

Dr. KOZLOWSKI. I think smokeless tobacco is less dangerous for the individual user. I think if someone came to an informed toxicologist, epidemiologist and said, I am going to use smokeless tobacco, I am going to use cigarettes, is one of them more dangerous than the other? I can't imagine an informed person saying that they are equally dangerous. They would say that the smokeless tobacco is less dangerous to the individual user.

Mr. SHAYS. Thank you.

Mr. SWEANOR. Yes. On a one-for-one basis, smokeless tobacco is certainly much less hazardous than smoking cigarettes, though still more hazardous than something like medicinal nicotine or using nothing at all.

Mr. SHAYS. Fair enough. Thank you. And I am sorry I made some false assumptions here.

Go ahead.

Dr. BURNS. My opinion is that smokeless tobacco is clearly less hazardous for individuals who have only used smokeless in comparison to individuals who have only used tobacco cigarettes. That is, however, not the choice that is being offered in a harm reduction strategy to adult confirmed smokers, and we simply do not have the evidence on that. It is a promise, but it is a promise for which we lack the evidence.

Mr. SHAYS. So we need information.

Chairman TOM DAVIS. Thank you all.

Any other questions? Mr. Sullivan.

Mr. SULLIVAN. Thank you, Mr. Chairman. These are some questions you already asked, but I came in late, and I would like to ask them again.

And, first, it's Mr. Verheij. What is your understanding of the prevailing view in the public health community regarding the comparative health risk of traditional smokeless tobacco products such as Skoal and Copenhagen compared to cigarette smoking? Has the U.S. Smokeless Tobacco Co. communicated this comparative risk information to adult cigarette smokers?

Mr. VERHEIJ. We have not. Our initial step in the process was to go to the Federal Trade Commission to get some guidance on to how we might communicate this information. You know, I think part of the debate and part of the process here is to resolve whether—with what—in conjunction with what types of products can these types of communications be made and who should make these types of communications.

I think, to respond to Congressman Waxman's concerns about the company making a communication, frankly, you could take the company out of the equation; and then the question is, what obligation does the Federal Government and the public health community have to communicate to adult smokers who are not quitting that—fairly much a consensus here—under a certain set of circumstances that smokeless tobacco is significantly less harmful? So it is not only limited to a communication from the company through some broad advertising campaign. We are talking about information going to adult smokers through some mechanism.

Mr. SULLIVAN. Also, what is your understanding of the perception of adult cigarette smokers regarding the comparative health risks of smokeless tobacco compared to cigarette smoking?

Mr. VERHEIJ. Well, I think it is documented by some in the public health community that more than 80 percent of adult smokers believe that smokeless tobacco is as dangerous as cigarette smoking; and that is consistent with what we are finding in focus groups as we—you know, as we move forward and try and address some of these concerns about unintended consequences and misinterpretations of the message, we would sit with these focus groups; and to a person they all believe that at this time, based on the information they have been given to date, smokeless tobacco is as dangerous as cigarette smoking, which obviously you heard is not the view of some of the people on the panel.

Mr. SULLIVAN. Thank you.

I have another question for Dr. Henningfield. Two questions. What obligation does a tobacco product manufacturer have today if it has a product that it believes would provide a reduced risk to smoking cigarettes?

Dr. HENNINGFIELD. I think that today there is no reason that a tobacco manufacturer cannot and should not be making all of their products with as low of levels of poisons as possible. We know that tobacco products are made with higher levels of poisons than is necessary. I don't see any reason that they can't be reducing those poison levels immediately. The question is, what claims should be made? Because claims could undermine the theoretical benefit.

Mr. SULLIVAN. Also, does the manufacturer have an obligation to inform adult smokers that there is a less harmful way for that smoker to satisfy his or her need for nicotine than smoking regular cigarettes?

Dr. HENNINGFIELD. I think the obligation is to make the products with as few poisons as possible and to market them in ways that recruit as few new people as possible. But the statement to somebody that might—a statement such as you mentioned may recruit new smokers, may recruit new tobacco users, may keep people who are using tobacco using. And so those kinds of statements have potential to do great harm, and that is why I believe they should be regulated.

Mr. SULLIVAN. Thank you.

Chairman TOM DAVIS. Thank you very much.

I have got a couple questions. Dr. Kozlowski, in your testimony—well, much has been said about the research challenges that—attending harm reduction products. From reading your paper, which agrees on tobacco industry funding of university research, it seems that the entrenched positions of some involved parties might be one of the hardest challenges to overcome. Do you agree?

Dr. KOZLOWSKI. Yes. I think there are strongly held entrenched positions here.

Chairman TOM DAVIS. Do you think the scientific community is willing to objectively examine the science behind reduced risk claims?

Dr. KOZLOWSKI. I think they are. But I think it would be very helpful to have strong FDA-type oversight. I mean, I think you need a regulatory context.

Chairman TOM DAVIS. Kind of an umpire to help?

Dr. KOZLOWSKI. Right.

Chairman TOM DAVIS. OK. Mr. Szymanczyck, let me ask, on page 221 of the IOM study, the question's asked whether tobacco manufacturers would be willing to demonstrate their good faith by agreeing to voluntarily submit claims to reduced exposure or reduced harm to FDA, FTC, CDC, or some other appropriate agency for their review and comments and to conform to agency suggestions. What are your thoughts on that?

Mr. SZYMANCZYCK. Well, I don't think it should be a voluntary process. I think it should be mandatory.

Chairman TOM DAVIS. OK. I think you have been pretty clear on that at this point.

Mr. SZYMANCZYCK. And I think it should be FDA.

Chairman TOM DAVIS. Also, Dr. Kozlowski, in your testimony you cite a government Web site that claims smoking and smokeless use are equally dangerous; and you I think assert that is untrue. Have you informed the government entity responsible for the maintenance of this site of this?

Dr. KOZLOWSKI. Not directly. The CDC made a similar mistake. I did inform them, and that Web site was changed. And I published a paper in Public Health Reports this month on that.

Chairman TOM DAVIS. We would be happy to have that, if you want to submit it.

Dr. KOZLOWSKI. I have submitted it.

Chairman TOM DAVIS. Thank you.

Mr. Sweanor, let me ask you. If we look at Sweden as a model—and we've talked about the Swedish model here today—are there perhaps demographic issues peculiar to that country that would not apply here in the United States?

Mr. SWEANOR. I am sure there are. I'm not sure what that would do in terms of the applicability of the model. I mean, clearly they're different countries, different populations, different cultures.

Chairman TOM DAVIS. OK. Canada employs many of the tobacco control methods the United States currently does not. These include large picture-based warnings, inserts, giving health information, comprehensive disclosure of additives. Some say we should concentrate our efforts on these measures rather than the idea of tobacco harm reduction. Have you got any comments on that, any experience whether that is working?

Mr. SWEANOR. Sure. I think it is certainly working, the combination of what we are doing, particularly having had very significant price increases. We have seen per capita consumption fall by just over 12 percent in the last 12 months, which is unprecedented. These are made in the United States. These are just Canadian cigarettes that are sold in Canada with the warnings, the package inserts. We have in some of our provinces made medicinal nicotine products available free of charge for people who want to quit smoking. We have an advertising ban, sponsorship bans, the whole range of public health measures.

Chairman TOM DAVIS. I will let you finish, but, also, what does this do to the underground market? Because we see in the United States sometimes, when the rates go up, you get an underground market that has more problems.

Mr. SWEANOR. Sure. We had a significant problem in the early 1990's. Because of U.S. taxes being as low as they were, the Cana-

dian manufacturers started shipping very large quantities, billions of Canadian-style cigarettes, in upstate New York, which not very surprisingly came right back into the country illegally. That forced our taxes down, brought our prices down, and delayed a whole lot of the measures that we were doing. So our declines per capita consumption ended, leveled off; and it is only now that they are starting to go down again.

I think the question is, what is the combination of measures that the totality of which gives the greatest gains in terms of public health. And that is why I say we do need to do things that reduce the onset of smoking, that encourage and facilitate cessation, and that reduce toxicity. The fact is we may have reduced per capita consumption by about 20 percent in the last 2½ years. That means 80 percent of them are still there. What are we going to do for them?

Chairman TOM DAVIS. And I think it's a question of how far down can you go. And what—there will always be the usage, at least in the present. And then how we handle that is one of the purposes of the hearing.

Mr. SWEANOR. I think we have to look at how do we individualize. As successful as we have been in the 20 years that I have been very involved in this, I don't think we have been very successful in certain subgroups of the population. I don't think we have reduced smoking among schizophrenics, for instance. I think we do have to look at what sort of interventions can we make to get the greatest overall benefit to public health, and there is no single measure that replaces everything else. It's a combination.

Chairman TOM DAVIS. Thank you very much.

Mr. Waxman.

Mr. WAXMAN. That was an interesting point that you made. I gather Canada has many aggressive policies to discourage people from smoking and to get them to give up smoking or not to even start than the United States has. Is that right?

Mr. SWEANOR. Yes. I might point out, it isn't hard to do more than the United States has on some of these things. Other countries around the world also have much larger warnings. Ours are picture-based. I would be pleased to pass them around with the package inserts.

The idea—I mean, it ties back to Congressman Shays's question. Well, everybody knows this is bad for them. They have known that for a long time. We try to push the whole idea of informed consent. It means more than knowing something is bad for you. I mean, I know that flying back to Ottawa tonight could be harmful to my health. I need to know, is that because someone is going to gun me down on my way to Dulles, or is it because it is just a normal risk of taking an airplane? For smokers, they need to know what are the things that can happen to them.

Mr. WAXMAN. So they need to be more informed, and there needs to be more of an aggressive policy to try to get that information to them and to try to raise the prices and do other things that would discourage people from smoking. Let me just ask you that, yes or no, because——

Mr. SWEANOR. Yes. But you want to combine the motivation and facilitation. It is one thing to have a whole lot of people who are

now very interested in quitting and trying to; it is another thing to make available for them the products and services that make it more likely they will be successful in doing that.

Mr. WAXMAN. That is a very good point.

And, Dr. Hatsukami, following up on that point, do you think we have reached the point in this country where we could say we are at a plateau and we should just figure those who smoke are going to continue to smoke and let's see if we can reduce the harm to them with something else? Or can we do more to reduce the number of smokers in this country?

Dr. HATSUKAMI. I think that we can do more to reduce the number of smokers in this country.

There was a wonderful document that was presented to the Interagency Committee on Health and Smoking that Dr. Fiore was chairing that laid out a comprehensive approach to trying to get people to quit smoking, including developing new treatments, making treatments available to individuals; and I think that if we follow that proposal we can in fact reduce the amount of smoking in this country among those who remain smokers.

Mr. WAXMAN. Then the key point is, if some people are going to continue to smoke, are there products that might do them less harm? And that I think is the essential issue of this hearing.

Mr. Szymanczyck, Philip Morris is sending a message it supports FDA regulation of tobacco products, and you will work to accomplish this goal this year. As a long-time supporter of FDA regulation, I am pleased to hear that message. However, I point out that all FDA regulation is not created equal. Strong regulation could prevent millions of children from smoking, help millions more smokers quit, and reduce the risks of those who remain. Weak regulation could provide government approval for poorly justified claims and wind up repeating the light and low tar experience which was a public health disaster.

So what I want to explore with you is, in this bill, H.R. 140, which you support, there are some provisions there that I wonder if it leads to more harm than good in the goal of FDA handling this matter. For example, you give FDA authority, but then they can't ban any class of cigarettes or tobacco products. What is a class? Would a cherry-flavored product that is made to appeal to kids be a class that FDA should not be able to regulate?

Mr. SZYMANCZYCK. Well, Congressman, I believe that refers to a class being like cigarettes or class being like smokeless. I don't believe it refers to a particular flavor or an ingredient. The FDA would have an authority under H.R. 140 to make those kinds of decisions.

Mr. WAXMAN. Do you think they should?

Mr. SZYMANCZYCK. Absolutely. I think that H.R. 140 does give them the authority to make determinations regarding ingredients.

Mr. WAXMAN. Another part of the bill says FDA can't regulate to make products unacceptable to consumers. Now, some people raise the issue, well, that can be an issue, that can be a phrase that can be litigated every time an industry doesn't like what FDA is doing. Dr. Henningfield, do you have any thoughts on this bill and how some of these provisions in the way the bill is written

might keep FDA from doing the things that I think maybe everybody here should say they should do?

Dr. HENNINGFIELD. Yes. Very briefly, there are things in cigarettes that are designed to make them more attractive, like adding chocolate, menthol, and other things. I think these kinds of substances need to be evaluated. If FDA, for example, determined that chocolate, which turns carcinogenic when burned, should be banned, that should be an FDA decision even if that banning made the cigarette taste a little less good.

Mr. WAXMAN. What do you think about that, Mr. Szymanczyck?

Mr. SZYMANCZYCK. Congressman, I think that, once again, the bill is designed, as I understand it, to give the FDA the authority to make the decision about ingredients. The consumer acceptability part of it is simply designed to make sure that there aren't unintended consequences. So in terms of what Dr. Henningfield has said, I think I would agree with them. I think the protocols have to be put in place to make sure that any of those decisions made don't result in unintended consequences.

I really don't see that as any different relative to reduced risk or reduced exposure products. There could be unintended consequences there, too, like people not quitting who might have quit, like kids starting to smoke. I think the message here relative to these particular items that have been put into H.R. 140 like the one you are mentioning are all designed to have the FDA understand as a part of its authority it needs to focus on unintended consequences as well as the public health goal that it has.

Mr. WAXMAN. I think you make a very good point. One of the unintended consequences of the drafting of a bill is that, if we don't draft it clearly, it could mean that the kinds of things that you and I both believe FDA should have the power to do could be litigated when they do it because someone could make an argument that, in effect, these restrictions on FDA's authority would be violated.

So my point to you in the limited time I have is, if we agree—which is pretty historic for Philip Morris and I to agree—that FDA ought to have jurisdiction, if we do agree on that, I think we have to be very careful and clear in drafting the legislation to make sure that FDA has the full authority to do what is important for the public health. Not to make products unacceptable to the consumers in a broad sense but to make sure that the products that are going to be marketed that consumers still may want to use—and they have a right to use them—be as safe as possible. So I raise that issue, and I want to put it out there.

Mr. Chairman. I see my time is up.

Chairman TOM DAVIS. I will grant you more time, if I can just interject one comment.

Mr. WAXMAN. Sure.

Chairman TOM DAVIS. I mean, one of the purposes of the section you referred to in the legislation is so the FDA couldn't come out and just basically abolish it. We think that should be—being cigarettes—that ought to be a legislative action, that should not be a regulatory action, and that is basically the safeguard that was put in there. However inartfully it may be worded, I believe that Representative McIntyre who authored the bill, but I co-sponsored it, putting down our marker that there ought to be FDA regulation,

it ought to be strong, it ought to be forceful. The consumers ought to be able to rely on it.

But there would have to be some limits on it in terms of abolishing a product with as many users that it has in accomplishing through regulation what they couldn't do through judicial fiat and couldn't do legislatively. So there is a lot of—I want to assure my friend that there is a lot of room to work on this, and I appreciate him clarifying his concerns.

Mr. WAXMAN. I don't believe in prohibition. As much as I wish people wouldn't smoke, I don't believe in refusing the rights of adults to smoke. I would, however, limit the marketing and especially to kids the attempts to get them to smoke. And when it comes to these products that may be safer alternatives for those who are going to smoke no matter what, I want a clear, scientific evaluation of whether we are getting something worthwhile and making a public health improvement or whether we are buying into something that can turn out to be a serious mistake. I must say that I want to make that very, very clear.

That is why I come back to where you are, Mr. Szymanczyck, that FDA is the agency that should have that authority, because it is basically science that ought to dictate this, not the marketing ambitions of the smokeless tobacco people or regular cigarette companies or anyone else that stands to make some extra money out of it. It ought to be based on good science in the public interest.

So, with that, Mr. Chairman, I have other questions, but I think what we have done at this hearing has been worthwhile, and so I am going to yield back the balance of my time.

Chairman TOM DAVIS. All right. Anyone else want to add anything? The gentleman from Connecticut, Mr. Shays.

Mr. SHAYS. You know, the only thing I would add is to thank you for taking on a heavy-hitting issue and that we could have a conversation about it in a fairly instructive way which I think is a sign of maturity on the part of the industry as well as the committee. I thank you for that and yield back, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Let me thank this panel, all of you; and let me particularly thank the tobacco executives that are here coming up. This is a historic first. It is the first step in a long journey, but it is a step forward, as opposed to where I think we have been going before. Obviously, a lot of diversity of opinion here as there is on the panel. But as we try to get to this and look at legislation this I think will go down as a historic hearing.

We appreciate everyone's indulgence and preparation in answer to questions. If anyone wants to submit something that maybe they weren't asked or want to put it in the record, you have 5 days, and we will be happy to make that part of the record as well.

Thank you all very much. These proceedings are adjourned.

[NOTE.—Additional statements and information may be found in committee files.]

[Whereupon, at 4:44 p.m., the committee was adjourned.]

[The prepared statements of Hon. Edolphus Towns and Hon. Chris Bell and additional information submitted for the hearing record follows:]

EDOLPHUS "ED" TOWNS
MEMBER OF CONGRESS
10TH DISTRICT, NEW YORK

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STATEMENT OF CONGRESSMAN ED TOWNS
Committee on Government Reform
Oversight Hearing

"Potential Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Possible Public Health Impact and Regulatory Challenges"

Tuesday, June 3, 2003

Mr. Chairman, and fellow Members, today's hearing raises an important issue--do "harm reduction" products have a role in addressing the health issues associated with smoking.

This issue of public health policy is of great importance. More than 50 million adult Americans smoke. The question we seek to address in this hearing is how may we, as policymakers, improve the health of those 50 million individuals. It should go without saying that public health policy of this nature cannot be made in a vacuum; we must take into account the ability, and indeed the rights, of

individuals to make their own choices regarding their health.

The Constitution recognizes that individuals should be allowed to hear and evaluate product information for themselves. In no other area of life is this right more important than in the area of personal behavior and health. These choices may affect not only the health and well being of the individual, but also the health and well being of family members. As such, those decisions should be well informed, based on accurate, uncensored, truthful and nonmisleading information.

That is what is at the heart of this hearing today—the right of individuals to know the facts about products that impact their behavior and health. Today's witnesses have suggested in their written testimony that the facts are in dispute about the ability of tobacco "harm reduction" products to improve the health of those smokers who have not been able to quit smoking. Even if the research is unsettled on this issue, it does not mean that discussions should not begin on this matter. Mr. Chairman, I am hopeful that today's hearing will be the beginning of a dialogue on the question of "harm reduction" products and their relationship to health improvements for smokers.

Congressman Chris Bell
Statement on the Government Reform hearing on, "Potential Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Possible Public Health Impact and Regulatory Challenges."
June 3, 2003

Mr. Chairman I would like to thank you for calling this hearing on such an important issue facing the health of this nation.

We are all aware of the harmful effects of long-term tobacco use. With more than 400,000 Americans dying of smoking-related illnesses every year, reducing morbidity and mortality, understandably, has become a primary objective of the public health community in the United States.

According to the Institute of Medicine, tobacco smoke is the single largest environmental cause of death and disease in the United States and is the cause of the most deadly epidemic of modern times – yet roughly 48 million adults continue to smoke cigarettes.

The horrific personal and public toll of smoking on our society has prompted the public health community to search for means to reduce the harm of tobacco; resulting in the emergence of products referred to as Potential Reduced Risk Products (PREPs). These include medicinal nicotine (MN) products, such as the nicotine patch and gum, cigarette-style products that attempt to provide the consumer with a less-lethal supply of nicotine, and smokeless tobacco options.

Today's hearing is meant to address the absence of federal regulation of these so-called "reduced risk" tobacco products. Many in the public health community have expressed concerns that consumers may be misled by these products claim to lower health risk. As a result, the U.S. Food and Drug Administration enlisted the help of the Institute of Medicine (IOM), which convened a committee of experts to lay out the scientific methods and standard by which these products and their effect on public health could be assessed.

In sum, the committee determined it both feasible and desirable to implement a comprehensive, scientifically based program that promotes and assesses the use of PREPs. It is important to note, that although more scientific evidence is needed, current research shows that harm reduction products have the potential to lower the risk of developing tobacco related diseases such as cardiovascular disease and lung cancer compared to conventional tobacco products.

Although there are a number of factors that contribute to a reduction in the use cigarette products, many refer to the success experienced by Sweden, who achieved a smoking rate of 17% - the only country to meet the goal of 20% set out by the World Health Organization. Some even argue the "Swedish Experience" is an example of reduced risk products in action.

Mr. Chairman, while we may not agree on ~~much~~ everything, there is one thing we all support and that's regulation providing for adequate research to ensure the public receives critical information on the risks and benefits of these products to make informed decisions.

I look forward to the testimony of our witnesses and future discussions on the role of regulation in reducing smoking-related health risk.

EDOLPHUS "ED" TOWNS
MEMBER OF CONGRESS
10TH DISTRICT, NEW YORK

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June 10, 2003

The Honorable Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I am requesting that the following questions be forwarded to the panel members from the hearing on June 3, 2003 (Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction). I am also requesting that these questions be responded to in writing.

Thank you for your assistance in this matter.

Sincerely,

Edolphus Towns
Member of Congress

PANEL ONE

Directed at HHS Representative

1. Has the Department of Health and Human Services reviewed public health information available on government websites to determine whether or not this "tobacco harm reduction" message is being communicated?

Other Panelists on Panel One

2. Wouldn't someone who continues to smoke cigarettes and has not been successful trying medicinal nicotine products be better off switching to smokeless tobacco?

3 Would you agree that the public – particularly those adults who continue to smoke – should have access to " harm reduction" information so they can make informed decisions about tobacco products they will use?

Directed at HHS Representative

1. Has the Department of Health and Human Services reviewed public health information available on government websites to determine whether or not this "tobacco harm reduction" message is being communicated?

2. The Royal College of Physicians in London has concluded that "the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product." Are you aware of any studies performed by or under grant by HHS that would refute this conclusion?

3. Would you agree that the public – particularly those adults who continue to smoke – should have access to this information so they can make informed decisions about tobacco products they will use?

Questions for Government Reform Hearing, June 3rd 2pm

PANEL TWO

Richard Verheij
Executive Vice President – External Affairs
U.S. Smokeless Tobacco Company

I understand the company is willing to consider FDA regulation of tobacco products. What form of regulation would your Company consider accepting? Why?

Other Panelists

1) In your view, should harm reduction products be promoted as a legitimate means of halting smoking along with cessation programs?

2) Is it possible to advocate for the use of "harm reduction" products without also confusing some populations, like our youth, that these products are really not harmful?

3) Under current law, what agency should be responsible for permitting companies to advertise their product as a "harm reduction" product?

Response to Congressman Edolphus Towns
Prepared by DCCPS 7/1/03
Contact Stacey Vandor x46786

Question 1: **Has the Department of Health and Human Services (DHHS) reviewed public health information available on government Web sites to determine whether or not this "tobacco harm reduction" message is being communicated?**

We have reviewed DHHS websites relevant to the topic of tobacco harm reduction, including Web sites of the National Cancer Institute (NCI), the Centers for Disease Control and Prevention (CDC), and the National Institute for Dental and Craniofacial Research (NIDCR). These Web sites contain information about smokeless tobacco, oral cancer, and harm reduction issues, among other topics. The information is presented in several forms, including reports of the Surgeons General, fact sheets, guides, and manuals. Both NCI and NIDCR note that smokeless tobacco (also called spit tobacco) is not a safe alternative to cigarettes and is a cause of cancer and oral diseases. With regard to harm reduction, the main messages communicated to the public are that all tobacco use causes cancer and other diseases and that more research is needed to determine whether any tobacco products reduce harm to the individual user and to the population as a whole.

In November 2001, NCI published a monograph entitled *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine,* which is available on the NCI Web site. The monograph concludes "that epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years." The monograph's findings have important implications for future harm reduction research.

NCI intends to place on its Web site the testimony of Dr. Scott Leischow, Chief of the Tobacco Control Research Branch, before the Committee on Government Reform's June 3, 2003 hearing on harm reduction issues. As stated in this testimony, NCI believes that all new tobacco products must undergo rigorous, objective scientific scrutiny to determine their impact or potential impact on both individual and population health. Providing the public with additional information on harm reduction will require a greater evidence base than is presently available.

Question 2: **The Royal College of Physicians in London has concluded that, "the consumption of non-combustible tobacco is of the order of 10 – 1,000 times less hazardous than smoking, depending on the product." Are you aware of any studies performed by or under grant by HHS that would refute this conclusion?**

In its 2002 report entitled, "Protecting smokers, saving lives: The case for a tobacco and nicotine regulatory authority," the Royal College of Physicians in London stated that, "As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10-1000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community." This report is a follow-up to an earlier Royal College Report, "Nicotine addiction in Britain," which highlighted the importance of regulating tobacco products. The latter report is aimed at taking the earlier report's recommendations forward, "to encourage the [British]

government to address the strategic issue of how it should regulate the tobacco industry and tobacco and other nicotine products."

In NCI's view, a product would be "harm reducing" if it reduced disease and death for both individuals and the population as a whole. A tobacco product that claims reduced harm may be shown to reduce disease risk on an individual basis, yet its widespread availability on the commercial market may have harmful consequences for the population. For example, smokers may see reduced harm products as a viable alternative to quitting or smokers who have quit may return to using tobacco because they think that these products make it safe to do so. In this way, a product promoted to reduce harm could actually have no effect, or actually increase harm to the population as a whole.

The Royal College Report appears to express an opinion on the hazard of individual risks only. We do not have data to refute a risk reduction on an individual basis. However, NCI cannot support the promotion of any product, including non-combustible tobacco products, that cause cancer, nor can we support the promotion of products that have the clear potential to result in increased harm to the population as a whole. At this time, more research is needed to properly assess the risks of non-combustible products, both to the individual and the potential risks that would be incurred if use of these products for harm reduction were to be promoted.

Question 3: **Would you agree that the public – particularly those adults who continue to smoke – should have access to tobacco harm reduction information so they can make informed decisions about tobacco products they will use.**

The public, especially adults and children who are addicted to tobacco, has a critical need for evidence-based health information about the importance of not initiating tobacco use, the devastating health effects of tobacco use, the enormous health benefits of quitting, and information to facilitate quitting. This view reflects the fact that, at present, the only proven way to reduce the health risks of tobacco use is to prevent people from becoming addicted to tobacco and to assist those who are addicted to quit. The potential impact of harm reduction – positive or negative – is as yet unknown.

As Dr. Scott Leischow stated in testimony to the U.S. House Committee on Government Reform, the use of nicotine replacement medication is the safest form of nicotine delivery to date - safer than all tobacco products, smoked or smokeless. Nicotine replacement medications undergo extensive testing for safety and effectiveness, and are subject to objective scientific review, prior to their release to the public. Approximately 25% of people who use these medications as directed are able to quit smoking. There is no clinical evidence that long-term use of nicotine replacement medications causes harm. Unlike nicotine replacement medications, tobacco products do not undergo rigorous objective scrutiny either for their product constituents or health-related claims.

There is much to be learned about potential reduced harm tobacco products. NCI's sustained investment in tobacco research is an important component of collaborative efforts by government and the private sector to reduce the impact of cancer on society. Expanded tobacco use prevention and cessation research, as well as research on potential reduced-harm tobacco products will help us continue our steady decrease in the prevalence of all forms of tobacco use, and consequently, tobacco-related cancers.

Health Information National Trends Survey (HINTS)

SAMPLE QUESTIONS ABOUT

TOBACCO PRODUCTS AND USE BEHAVIOR

National Institutes of Health (NIH)

HINTS

HEALTH INFORMATION NATIONAL TRENDS SURVEY

MAIN STUDY INTERVIEW INSTRUMENT

April 2003

Annotated Version

NATIONAL CANCER INSTITUTE (NCI)

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TOBACCO USE (TU)

TOBACCO SCREENER

Now, I'd like to ask you about your use of tobacco.

TU-1. Have you smoked at least 100 cigarettes in your entire life?
[IF NEEDED: 5 Packs = 100 Cigarettes.]

YES 1
NO 2
..... (BOX TU-4)

TU-2. Do you now smoke cigarettes . . .

every day, ... 1
some days, or 2
..... (TU-4)
not at all? 3
..... (BOX TU-1)
DK 9
..... (BOX TU-4)
RF 8
..... (BOX TU-4)

TU-3. On the average, how many cigarettes do you now smoke a day?

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

|___|___|
NUMBER OF CIGARETTES

GO TO TU-5.

TU-4. On the average, when you smoked during the past 30 days, about how many cigarettes did you smoke a
day?

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

|___|___|
NUMBER OF CIGARETTES

CURRENT SMOKERS

TU-5. Would you say that . . .

you plan to quit smoking,	1
you don't plan to quit, or	2
you're undecided?	3

BOX TU-1
IF SMOKE EVERY DAY OR SOME DAYS, GO TO TU-9. OTHERWISE, CONTINUE.

FORMER SMOKERS

TU-6. About how long has it been since you last smoked cigarettes?

LESS THAN 1 MONTH AGO	1
1 MONTH TO LESS THAN 3 MONTHS AGO	2
3 MONTHS TO LESS THAN 6 MONTHS AGO	3
6 MONTHS TO LESS THAN 1 YEAR AGO	4
1 YEAR TO LESS THAN 5 YEARS AGO	5
5 YEARS TO LESS THAN 15 YEARS AGO	6
15 OR MORE YEARS AGO	7

TU-7. On the average, when you smoked, about how many cigarettes did you smoke a day?

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

|__|__|
NUMBER OF CIGARETTES

ALL SMOKERS

TU-8 DELETED

TU-9. I am going to read you some statements people might make about smoking. For each, tell me how much you agree or disagree, or if you have no opinion?

	STRONGLY AGREE	SOMEWHAT AGREE	SOMEWHAT DISAGREE	STRONGLY DISAGREE	NO OPINION
a. Exercise can undo most of the effects of smoking. Would you say you strongly agree, somewhat agree, somewhat disagree, strongly disagree, or you have no opinion?	1	2	3	4	5
b. Vitamins can undo most of the effects of smoking. (Would you say you...)	1	2	3	4	5
c. There's no risk of getting cancer if someone only smokes a few years. (Would you say you...)	1	2	3	4	5
d. Whether a person gets lung cancer depends more on genes than anything else. (Would you say you...)	1	2	3	4	5

BOX TU-2

IF NO LONGER SMOKE, GO TO TU-12.
OTHERWISE IF SMOKE EVERY DAY OR SOME DAYS, CONTINUE.

TU-10. What type of cigarette do you now smoke most often—a regular, light, ultra light, or some other type?

REGULAR/FULL-FLAVOR ..... (TU-12)	1
LIGHT/MILD	2
ULTRA-LIGHT	3
NO USUAL TYPE ..... (TU-12)	4
SOME OTHER TYPE (E.G., OMNI, ECLIPSE, ETC.) _____	91

TU-11. What is the main reason why you now smoke {lights/ultra-lights/this type of cigarette}?..Is it . . .

a way to reduce the health risks of smoking, ...	1
to try to quit smoking, ...	2
because of the taste, or	3
for some other reason? (SPECIFY)_____	91

TU-12. If a new cigarette were advertised as less harmful than current cigarettes, how interested would you
be in trying it? Would you say . . .

very interested, ...	1
somewhat interested, or	2
not interested?	3

BOX TU-3

IF RESPONDENT STOPPED SMOKING 5 OR MORE YEARS AGO, GO TO BOX TU-4.
OTHERWISE, CONTINUE.

TU-13. Tobacco companies have recently introduced new types of cigarettes that are claimed to have fewer
harmful chemicals or carcinogens. These have names like Eclipse, Accord, Advance, and Omni. Have you ever tried one of these products?

YES	1
NO	2

TU-14. Tobacco companies have also recently introduced new types of smokeless tobacco products. These have names like Arriva, Exalt, and Revel. Have you ever tried one of these products?

YES	1
NO	2

BOX TU-4

IF RESPONDENT HAS HAD LUNG CANCER,
GO TO NEXT SECTION.
OTHERWISE IF CURRENT OR FORMER SMOKER, RANDOMLY ASSIGN HALF TO GET TU-15 AND HALF TO GET TU-16.
OTHERWISE, GO TO TU-17.

PERSONAL RISK

TU-15. How likely do you think it is that the average {male/female} cigarette smoker will develop lung cancer in the future? Would you say that {his/her} chance is . . .

very low,	1
somewhat low,	2
moderate,	3
somewhat high, or	4
very high?	5

GO TO TU-17.

TU-16. How likely do you think it is that you will develop lung cancer in the future? Would you say your
chance of getting lung cancer is . . .

very low,	1
somewhat low,	2
moderate,	3
somewhat high, or	4
very high?	5

DETECTION/CURABILITY

TU-17. Overall, how many people who develop lung cancer do you think are cured? Your best guess is fine.
Would you say . . .

less than a quarter,	1
about a quarter,	2
about half,	3
about three-quarters, or	4
nearly all?	5

BOX TU-5

IF DO NOT SMOKE, CONTINUE.
IF CURRENT SMOKER, RANDOMLY SELECT HALF TO ANSWER TU-18 AND HALF TO ANSWER TU-19.

TU-18. Would you say the average smoker has about the same lung cancer risk as a non-smoker, a little higher lung cancer risk than a non-smoker, twice the non-smoker's risk, 5 times the non-smoker's risk or 10 or more times the non-smoker's risk?

ABOUT THE SAME AS A NON-SMOKER,	1
A LITTLE HIGHER THAN A NON-SMOKER,	2
TWICE AS HIGH AS A NON-SMOKER,	3
5 TIMES HIGHER THAN A NON-SMOKER,	4
1O OR MORE TIMES HIGHER THAN A NON-SMOKER	5

GO TO NEXT SECTION.

TU-19. Would you say you have about the same lung cancer risk as a non-smoker, a little higher lung cancer risk than a non-smoker, twice the non-smoker's risk, 5 times the non-smoker's risk, or 10 or more times the non-smoker's risk?

ABOUT THE SAME AS A NON-SMOKER,	1
A LITTLE HIGHER THAN A NON-SMOKER,	2
TWICE AS HIGH AS A NON-SMOKER,	3
5 TIMES HIGHER THAN A NON-SMOKER,	4
1O OR MORE TIMES HIGHER THAN A NON-SMOKER	5

CANCER FACTS

National Cancer Institute • National Institutes of Health
Department of Health and Human Services

Smokeless Tobacco and Cancer: Questions and Answers

Key Points

- Snuff is a finely ground or shredded tobacco that is either sniffed through the nose or placed between the cheek and gum. Chewing tobacco is used by putting a wad of tobacco inside the cheek (see Question 1).
- Chewing tobacco and snuff contain 28 cancer-causing agents (see Question 2).
- Smokeless tobacco users have an increased risk of developing cancer of the oral cavity (see Question 3).
- Several national organizations offer information about the health risks of smokeless tobacco and how to quit (see Question 8).

1. What is smokeless tobacco?

There are two types of smokeless tobacco—snuff and chewing tobacco. **Snuff**, a finely ground or shredded tobacco, is packaged as dry, moist, or in sachets (tea bag-like pouches). Typically, the user places a pinch or dip between the cheek and gum. **Chewing tobacco** is available in loose leaf, plug (plug-firm and plug-moist), or twist forms, with the user putting a wad of tobacco inside the cheek. Smokeless tobacco is sometimes called "spit" or "spitting" tobacco because people spit out the tobacco juices and saliva that build up in the mouth.

2. What harmful chemicals are found in smokeless tobacco?

- Chewing tobacco and snuff contain 28 carcinogens (cancer-causing agents). The most harmful carcinogens in smokeless tobacco are the tobacco-specific nitrosamines (TSNAs). They are formed during the growing, curing, fermenting, and aging of

tobacco. TSNAs have been detected in some smokeless tobacco products at levels many times higher than levels of other types of nitrosamines that are allowed in foods, such as bacon and beer.

- Other cancer-causing substances in smokeless tobacco include *N*-nitrosamino acids, volatile *N*-nitrosamines, benzo(a)pyrene, volatile aldehydes, formaldehyde, acetaldehyde, crotonaldehyde, hydrazine, arsenic, nickel, cadmium, benzopyrene, and polonium–210.

- All tobacco, including smokeless tobacco, contains nicotine, which is addictive. The amount of nicotine absorbed from smokeless tobacco is 3 to 4 times the amount delivered by a cigarette. Nicotine is absorbed more slowly from smokeless tobacco than from cigarettes, but more nicotine per dose is absorbed from smokeless tobacco than from cigarettes. Also, the nicotine stays in the bloodstream for a longer time.

3. What cancers are caused by or associated with smokeless tobacco use?

- Smokeless tobacco users increase their risk for cancer of the oral cavity. Oral cancer can include cancer of the lip, tongue, cheeks, gums, and the floor and roof of the mouth.

- People who use oral snuff for a long time have a much greater risk for cancer of the cheek and gum than people who do not use smokeless tobacco.

- The possible increased risk for other types of cancer from smokeless tobacco is being studied.

4. What are some of the other ways smokeless tobacco can harm users' health?

Some of the other effects of smokeless tobacco use include addiction to nicotine, oral leukoplakia (white mouth lesions that can become cancerous), gum disease, and gum recession (when the gum pulls away from the teeth). Possible increased risks for heart disease, diabetes, and reproductive problems are being studied.

5. Is smokeless tobacco a good substitute for cigarettes?

In 1986, the Surgeon General concluded that the use of smokeless tobacco "is not a safe substitute for smoking cigarettes. It can cause cancer and a number of noncancerous conditions and can lead to nicotine addiction and dependence." Since 1991 NCI has officially recommended that the public avoid and discontinue the use of all tobacco products, including smokeless tobacco. NCI also recognizes that nitrosamines, found in tobacco products, are not safe at any level. The accumulated scientific evidence does not support changing this position.

6. What about using smokeless tobacco to quit cigarettes?

Because all tobacco use causes disease and addiction, NCI recommends that tobacco use be avoided and discontinued. Several non-tobacco methods have been shown to be effective for quitting cigarettes. These methods include pharmacotherapies such as nicotine replacement therapy and bupropion SR, individual and group counseling, and telephone quitlines.

7. Who uses smokeless tobacco?

In the United States, the 2000 National Household Survey on Drug Abuse, which was conducted by the Substance Abuse and Mental Health Services Administration, reported the following statistics:

- An estimated 7.6 million Americans age 12 and older (3.4 percent) had used smokeless tobacco in the past month.
- Smokeless tobacco use was most common among young adults ages 18 to 25.
- Men were 10 times more likely than women to report using smokeless tobacco (6.5 percent of men age 12 and older compared with 0.5 percent of women).

People in many other countries and regions, including India, parts of Africa, and some Central Asian countries, have a long history of using smokeless tobacco products.

8. Where can people find help to quit using smokeless tobacco?

Several national organizations provide information about the health risks of smokeless tobacco and how to quit:

The **National Institute of Dental and Craniofacial Research's National Oral Health Information Clearinghouse** offers educational booklets that discuss spit tobacco use in a colorful and graphic format. These booklets are designed specifically for young men who have decided to quit or are thinking about it.

Organization:	National Oral Health Information Clearinghouse National Institute of Dental and Craniofacial Research
Address:	One NOHIC Way Bethesda, MD 20892–3500
Telephone:	301–402–7364
E-mail:	nohic@nidcr.nih.gov
Internet:	http://www.nohic.nidcr.nih.gov/

The **Centers for Disease Control and Prevention's Office on Smoking and Health** distributes a brochure for teens who are trying to quit cigarettes or smokeless tobacco. The Office also maintains a database of smoking and health-related materials.

Organization:	The Office on Smoking and Health Centers for Disease Control and Prevention
Address:	Mail Stop K–50 4770 Buford Highway, NE. Atlanta, GA 30341–3724
Telephone:	1–800–232–1311 (1–800–CDC–1311)
E-mail:	tobaccoinfo@cdc.gov
Web site:	http://www.cdc.gov/tobacco/how2quit.htm

The mission of the **National Spit Tobacco Education Program** (NSTEP) is to prevent people, especially young people, from starting to use tobacco, and to help users to quit. NSTEP offers information and materials on spit tobacco use, prevention, and cessation.

Organization:	National Spit Tobacco Education Program Oral Health America
Address:	Suite 352 410 North Michigan Avenue Chicago, IL 60611
Telephone:	312–836–9900
Web site:	http://www.nstep.org

The **American Cancer Society** publishes a series of pamphlets with helpful tips and techniques for smokeless tobacco users who want to quit.

Organization:	American Cancer Society
Address:	1599 Clifton Road, NE. Atlanta, GA 30329
Telephone:	1–800–227–2345 (1–800–ACS–2345)
Web site:	http://www.cancer.org

The **American Academy of Family Physicians** has a fact sheet with information on how to quit using smokeless tobacco. The fact sheet is available at http://familydoctor.org/handouts/177.html on the Internet.

Organization:	American Academy of Family Physicians
Address:	11400 Tomahawk Creek Parkway Leawood, KS 66211–2672
E-mail:	email@familydoctor.org
Web site:	http://familydoctor.org

A number of other organizations provide information about where to find help to stop using smokeless tobacco. State and local health agencies often have information about community tobacco cessation programs. The local or county government section in the phone book (blue pages) has phone numbers for health agencies. Information to help smokers who want to quit is also available through community hospitals, the yellow pages (under "drug abuse and addiction"), public libraries, health maintenance organizations, health fairs, and community helplines.

9. What other resources are available?

A person's dentist or doctor can be a good source of information about the health risks of smokeless tobacco and about quitting. Friends, family members, teachers, and coaches can help a person quit smokeless tobacco use by giving them support and encouragement.

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1–800–4–CANCER (1–800–422–6237)
TTY (for deaf and hard of hearing callers): 1–800–332–8615

NCI Online

Internet

Use http://cancer.gov to reach the NCI's Web site.

LiveHelp

Cancer Information Specialists offer online assistance through the *LiveHelp* link on the NCI's Web site.

This fact sheet was reviewed on 5/12/03

New Tobacco Products with Implied Health Claims

- **In 2000, 46 million people in the U.S. (23.3% of the adult population 18 years of age or older) were smokers and 44.3 million adults (22.2%) were former smokers.** (CDC MMWR, July 2002) The National Cancer Institute (NCI) concluded, "Lung cancer, the leading cause of cancer death, would be a rare disease in the absence of smoking. Smoking is the leading cause of cancer of the lung, mouth, larynx, esophagus, and bladder, and plays a role in cancers of the pancreas, cervix and kidney. The devastating impact of tobacco use and tobacco smoke exposure on the incidence of cancer, heart disease, and stroke is both compelling and conclusive. Tobacco use causes more premature deaths (approximately 430,000 per year in the United States) than do all drugs of abuse combined. In 2002, about 170,000 people will die of cancer because of their use of tobacco products." (NIH, 2002)

- **The tobacco industry began altering its products in the 1950s once research established a causal relationship between cigarette smoking and lung cancer.** (Wynder and Graham, 1950; Doll and Hill, 1950) In response to pressing health concerns, tobacco companies initially added filters to cigarettes, which reduced emissions of mainstream smoke constituents - as measured using standard machine-smoking methods. The product modification continued rapidly thereafter, utilizing a variety of cigarette design tools including filtration, filter ventilation, modified cigarette paper, and modified forms of tobacco and tobacco blends. (Norman, 1999) Currently, there are more than 1000 brands of cigarettes in the U.S. market; these products deliver a wide range of nicotine, tar, carbon monoxide, and other smoke constituents. (U.S. FTC, 2000)

- **A recent review of the risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine, as published in the NCI's Smoking and Tobacco Control Monograph 13, revealed that smokers who switched from regular to light cigarettes experienced very little or no reduction in cancer risk** (Burns and Benowitz, 2001). A minor decrease in risk occurred only among the exclusive users of low-yield cigarettes, brands that deliver 9 mg tar in the mainstream smoke. (IARC, 1986) These brands accounted for 25.3% of the U.S. market in 1999. (FTC, 2002) A possible explanation for the NCI's findings was that smokers responded to increasing health concerns, on one hand, and aggressive promotion and marketing of modified cigarettes by the tobacco industry, on the other hand, by switching to lower-yield products and spontaneously changing their smoking behaviors to obtain the desired dose of nicotine (e.g., smoking greater number of cigarettes per day, drawing larger puffs more frequently, and blocking the ventilation holes on the filter tips). More intense smoking patterns resulted not only in increasing smokers' exposure to addictive nicotine but to cancer-causing agents as well. (Djordjevic et al., 2000) In addition to failing to reduce cancer risk, low-yield cigarettes may have played a significant role in promoting initiation and impeding cessation, the most important determinants of smoking-related diseases. (Burns and Benowitz, 2001)

- **The best means to reduce the disease caused by tobacco use is to prevent the initiation of use and to help users to achieve complete and lasting abstinence.** That is and must remain the highest priority. According to the International Agency for Research on Cancer (IARC), "Quitting by adult smokers offers the only realistic way in which widespread changes in smoking status can prevent large numbers of tobacco deaths over the next half-century. Widely practicable ways of helping large numbers of young people not to become smokers could avoid hundreds of millions of tobacco deaths worldwide in the middle and second half of the century." (IARC, 2002)

- **Continued tobacco use and high relapse rates led to an increased interest in products and strategies that are suggested to have the potential to reduce the harm incurred by tobacco use**. Harm reduction products, as defined in the report of the Institute of Medicine (IOM), are "products that lower total tobacco-caused morbidity and mortality, even though they might involve continued exposure to one or more tobacco-related toxins." (Stratton, 2001) In recent years, there has been a proliferation of new potentially reduced-exposure tobacco products that are marketed and advertised with claims that imply safety. These products have been specifically targeted by the tobacco industry at: (a) smokers who are unable to quit or are unwilling to quit smoking; (b) health-conscious individuals who perceive switching to a "safer" product as beneficial and more appealing than trying to quit; and (c) smokers who want an alternative to cigarettes when they are in smoke-free environments (workplace, home, during travel, and other environments).
(http://directory.google.com/Top/Recreation/Tobacco/Manufacturers/Cigarettes)

- **Currently, a number of new products are being introduced in the United States and in markets worldwide for which reduced exposure, reduced toxicity, and reduced health risk claims are being made**. These products include:
    - Cigarettes made with either modified tobacco or filter, or both, that deliver lower yields of toxins and carcinogens in smoke as compared to conventional products (e.g., Advance, Omni, Quest, SCOR);
    - Cigarette-like delivery products that employ unconventional technologies that purportedly reduce their toxicity (e.g., Eclipse, Accord);
    - Oral tobacco products, especially moist snuff, made with tobacco-containing reduced amounts of nicotine-derived carcinogens such as NNN and NNK (e.g., Ariva, Stonewall, Revel, Exalt).

- **In the past, tobacco companies have marketed products that claimed lower emissions.** (Pollay and Dewhirst, 2002) The marketing of new reduced-exposure products primarily utilizes the claims of reduced cancer-causing chemicals/toxins and reduced risk of cancer and lung diseases, (Slade et al., 2002; Henningfield, 2002) and future claims are likely to be made without regulatory oversight. Some products (e.g., Quest) are marketed as a cessation aid, without FDA approval. Reduced-exposure products are relatively new and most of the information on their alleged harm-reducing properties comes from the tobacco industry.
(http://directory.google.com/Top/Recreation/Tobacco/Manufacturers/Cigarettes)

- **According to the WHO, lower levels of selected toxicants in tobacco products or tobacco smoke may not lead to reduced harm in the population.** (SACTob, 2002) Many of these products have not yet been widely used in larger populations and their toxicology is generally unknown, as is their potential impact on both individual and public health. The outcome of a small, short-term, clinical study (10 male and 10 female smokers) suggested that neither Accord nor Eclipse is likely to be an effective reduced-exposure product for smokers. (Breland et al., 2002) In another study, 12 smokers who switched to a reduced-nitrosamine cigarette, Advance, received lower exposure to the lung carcinogen NNK than when using regular cigarettes, but more NNK exposure than when not smoking. (Breland et al., 2002) These two studies represent the limited state of the nontobacco industry-funded published literature in that they are far too small to develop conclusions regarding the products tested.

- **However, even if new reduced-exposure products are shown to be less toxic to the individual, unintended consequences need to be investigated, such as a possible reduction in quitting rates, an increase in initiation of tobacco use by youth and young adults, and a secondary initiation by ex-smokers.** For example, a recent study found that youth who began using smokeless tobacco were more likely to become cigarette smokers. (Tomar, 2002) Moreover, it is possible that smokers of conventional cigarettes will not completely switch to new products but will continue using multiple products to obtain desired level of nicotine. (Tomar, 2002a) There are also the issues regarding the harm to non-users/bystanders. Some new products claim reductions in environmental tobacco smoke generation and there is a clear reduction when shifting from burned tobacco products to products that heat-rather-than-burn tobacco, or smokeless tobacco. However, there may be an increase in second hand smoke exposure if smoking duration or prevalence increases. (SACTob, 2002)

- **In 2001, at the request of the U.S. Food and Drug Administration (FDA), the Institute of Medicine reviewed the science available to determine differences in harm that might result from use of newer tobacco products and the scientific methods that might be used to examine harm reduction claims.** (Stratton, 2001) The Institute of Medicine (IOM) report concluded: (a) existing scientific evidence is not sufficient to allow definition of differences in human uptake of toxicants, toxicity, or harm between newly engineered tobacco products and currently existing products; (b) a scientific methodology to establish toxicity and harm differences for these products does not currently exist; and (c) a structure for regulatory oversight would be essential to any scientific assessment of claims for reduced harm. In May 2001, the National Cancer Institute (NCI), National Institute on Drug Abuse (NIDA), Centers for Disease Control and Prevention (CDC), Robert Wood Johnson Foundation (RWJF), and American Legacy Foundation (ALF) convened the "Reducing Tobacco Harm Conference" to develop research recommendations aimed at addressing knowledge gaps. These were recently published by Hatsukami, et al. in 2002. The major research recommendations were in the areas of products and methods for reduced tobacco toxin exposure and harm reduction, exposure and toxicity assessment for reducing tobacco harm, and public health impact (e.g., communication, surveillance, and regulation).

- **These new tobacco products have been engineered, manufactured, marketed, and promoted by the tobacco industry as less harmful because they allegedly deliver lower amounts of toxic and/or carcinogenic agents to the user compared with standard brands.** However, to date, there is little scientific data generated by independent research to back these claims. It is possible that the reduction or elimination of specific toxins and carcinogens from tobacco or tobacco smoke, or the reduction of smoke yields in general, may result in reduction of exposure, and eventually the risk of developing tobacco-related diseases, among people who discontinue or reduce use of conventional tobacco products, and continue the exclusive use of products purported to reduce harm. It is also possible that the existence of actual or perceived lower-risk products will promote smoking initiation among never and former smokers, as well as deter quitting. These consequences will, in turn, harm the public health. It is essential to find better ways to study the effects of these new products, than was done in the past.

- **Multidisciplinary research is needed to build a science base that can be used to inform personal, scientific, and public health decisions regarding the use and health risks of new reduced-exposure products.** In addition, it is crucial to provide additional stimulus to the research community to undertake studies aimed at better understanding the public health consequences of the use of new tobacco products.

The key research questions that the tobacco control community should aim to answer are:

- Are new reduced-exposure tobacco products, which are marketed as a safer alternative to conventional cigarettes, truly harm-reducing?
- Do design, chemical, and toxicological characteristics of new tobacco products correlate with reduced exposure to cancer-causing agents when controlling for behavior?
- How do biomarkers of exposure and dose correlate with early disease markers and actual disease endpoints?
- Are currently used biomarkers of exposure (e.g., external exposure, internal dose, biologically effective dose, early biological, and genetic effects) adequate and powerful enough to reflect differences in health effects of new potentially reduced-exposure products? Do new biomarkers need to be developed to serve as intermediate indicators of disease and disease risk?
- What is the impact of these products on the onset, continuation, and cessation of tobacco use among current and non-smokers and relapse among former smokers?
- What are the ingredients in new tobacco products and what are their chemical and physical characteristics?
- What is the level of toxins/carcinogens delivered under conditions reflecting actual use?
- What are appropriate animal models and *in vitro* assays of the pathogenesis of tobacco-attributable diseases?
- What is the smoke uptake by actual users of the product?
- What is the addictive potential of the product?
- How much cellular injury occurs from use of the product?
- What happens when multiple products are used simultaneously?
- What is the product's impact on secondhand smoke exposure (e.g., if smoking duration and prevalence increases)?

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NEW TOBACCO PRODUCTS WITH IMPLIED HEALTH CLAIMS

BACKGROUND

- The tobacco industry began altering its products in the 1950's by adding filters among other technologies to reduce tar and nicotine smoke yields as measured by standard machine-smoking methods.
- The tobacco industry continues to release modified and novel tobacco products onto the U.S. market that claim to reduce harm to their users or offer a safer alternative to traditional cigarettes.
- With these products the tobacco industry has targeted smokers who are unable to quit or are unwilling to quit smoking and health-conscious individuals who perceive switching to a "safer" product as beneficial and more appealing than quitting.
- The scientific evidence base for the characteristics of these new tobacco products, patterns of use, and impact on initiation, cessation, and relapse, has not yet been established.

PROGRESS

- Multiple grants at NIH have been awarded that assess the health impact of tobacco products.
- A CDC laboratory is dedicated to the analysis of the chemical composition of tobacco products and determining human uptake by measuring the levels of biomarkers of exposure to specific tobacco and smoke constituents (e.g., nicotine, lung carcinogens).
- The Health Information National Trends Survey (HINTS) is currently being used in the field, which includes questions about use of new tobacco products and perceptions of health risks associated with their use.
- Smoking and Tobacco Control Series: Monograph 13, about light and low-tar cigarettes (November 2001) reported that epidemiological and other scientific evidence does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years

NEXT STEPS

- Transdisciplinary research is needed to build a science base that can be used to inform personal, scientific, and public health decisions, as well as policies and regulation, regarding the use and health risks of new reduced-exposure products.
- Continue to initiate and develop a tobacco products network/consortium of government and non-government organizations to identify priority research goals and issues.
- NCI has identified research on new tobacco products as a priority by including it in the 2004 NCI Bypass Budget.
- Planning is underway to expand surveillance instruments (i.e., the Tobacco Use Supplement to the Current Population Survey) to ask about the use of new tobacco products in an effort to understand the impact of their implied health or harm-reducing claims on initiation or cessation of all tobacco products.

- We need to assist the Federal Trade Commission (FTC) in revising their method for assessing tobacco product ingredients and emissions (in the case of smokeless tobacco products, emissions refer to substances released during the process of oral use (e.g., "chewing", "dipping").
- Data need to be generated to inform the FTC of the relative impact on public health of smokeless versus smoked tobacco use.

Questions and Answers for Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine

Posted Date:
Tuesday, November 27, 2001

1. What is Monograph 13?

Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine is the 13th volume in the Smoking and Tobacco Control Monograph Series of the National Cancer Institute (NCI). The monograph series was established in 1991 as a way to communicate important information to the public about health issues regarding smoking and tobacco use.

Former Secretary of Health and Human Services (HHS) Donna E. Shalala asked the NCI and other Department of HHS agencies in 1999 to review evidence of the relationship between machine-measured cigarette smoke and disease risk. In keeping with the secretary's request, the purpose of preparing Monograph 13 was to determine whether the scientific evidence, overall, shows that the changes in cigarette design over the last 50 years have reduced disease risks in smokers.

2. What is new about the monograph?

This monograph thoroughly reviews epidemiologic and other scientific evidence from the past 50 years on the public health effects of low-tar cigarettes. New analyses of data sets from the American Cancer Society and the California Tobacco Survey were conducted to explore and clarify the differences between epidemiologic evaluations and the national trends in lung cancer death rates.

The report also cites internal tobacco industry documents - made available to the public in 1998 by the state of Minnesota's settlement with the tobacco industry and by the Master Settlement Agreement - demonstrating tobacco companies' efforts to market "low-tar" cigarettes as a safer alternative to regular cigarettes.

Additionally, the monograph extends and confirms earlier findings that the current Federal Trade Commission (FTC) method of testing the amount of tar and nicotine that smokers inhale does not provide meaningful information to consumers.

3. What were the conclusions of the monograph?

The monograph concludes:

> Scientific evidence does not show that changes in cigarette design and manufacturing over

the last 50 years have benefited public health.

- When smokers switch to cigarettes that are called "low-tar", "light", "ultra-light" or "filtered", they change the way they smoke to compensate for the lower yield.
- The adoption of lower yield cigarettes in the United States has not prevented the continued increase in lung cancer among older smokers.
- Many smokers switch to lower-yield cigarettes out of concern for their health, believing that those cigarettes are less risky or are a step toward quitting.
- Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different cigarette brands.

4. Are low tar cigarettes safer than "regular" cigarettes? What do the conclusions in the monograph mean for the public?

There is no conclusive evidence of reduced risk from "low-tar" cigarettes. According to the monograph, cigarettes labeled "low-tar" do not typically deliver lower tar to smokers, and people who smoke low-tar cigarettes cannot expect to have fewer smoking-related health problems.

There is no such thing as a safe cigarette. The only proven way to reduce the disease risks associated with smoking is to quit.

5. Should doctors recommend that their patients switch to lower-yield brands?

No. Data on disease risk do not support making a recommendation that smokers switch cigarette brands. Such a recommendation can cause harm if it misleads smokers to delay or prevent efforts to quit smoking. Evidence also suggests that switching to light or ultra-light cigarettes may reduce the likelihood of quitting.

6. How is it determined what cigarettes are "light"?

Currently, the only information available to smokers on the levels of tar, nicotine, and carbon monoxide in cigarette smoke is obtained in the laboratory using the Federal Trade Commission (FTC) testing method. In this method, machines are programmed using specific settings to generate smoke for analysis of smoke components. According to current guidelines, cigarettes labeled "light" have up to 10 milligrams of tar and 0.8 milligrams of nicotine when measured by the FTC smoking machines.

Studies have shown, however, that the current FTC method does not mimic real-life smoking behaviors because smokers compensate for the lower yields of nicotine by changing the way that they smoke, and therefore the testing does not provide meaningful information to consumers. The current FTC method - based on the general observations of smokers in the 1930s when there were no filtered cigarettes - has been in place, largely unchanged, since 1966.

7. What are the FTC and NCI doing to take steps towards a better testing method?

The FTC has asked the Department of Health and Human Services (DHHS) for guidance to improve its testing method for tar and nicotine. NCI and other DHHS agencies will convene a working group by the summer of 2002 to review and synthesize the science on this issue and to determine how the testing method can be improved to better reflect real-life exposures.

8. How have cigarettes changed over the years?

Major changes in the makeup of cigarettes were introduced between 1950 and 1975, leading to reductions in machine-measured tar and nicotine levels. According to the monograph, however, there have been few substantive changes since that time to further reduce the toxic and cancer-causing potential of cigarette smoke.

Using the FTC method of measurement, the average yields of U.S. cigarettes decreased from about 37 milligrams of tar and 2.7 milligrams of nicotine in 1954 to 12 milligrams of tar and 0.88 milligrams of nicotine in 1998. During this time, changes in the agricultural, curing, and manufacturing processes of cigarettes have actually resulted in an increase in the amounts of some carcinogens (e.g., tobacco-specific nitrosamines) in cigarette smoke. These changes may have contributed to the increase in adenocarcinoma of the lung observed over the past several decades.

9. How have changes in cigarette design affected the amounts of nicotine and tar that are measured in cigarette smoke?

There are three main features of cigarettes that influence the levels of nicotine and tar measured by the FTC machines: length of tobacco column, nicotine content of tobacco, and filter ventilation.

Length of Tobacco Column or Rod

There is evidence that some cigarette companies have increased the length of the "overwrap" on their cigarettes (the paper wrap covering the outside of the filter) in order to decrease the number of puffs taken per cigarette in the machine testing. A longer "filter plus overwrap" leads to a longer cigarette butt remaining in the FTC smoking machine and, thus, fewer puffs per cigarette. However, tobacco exists under the overwrap that is still available to the human smoker. This additional tobacco would not be burned in the FTC test, resulting in a lower machine-measured yield, but a possibly higher yield for the smoker.

Nicotine Content of Tobacco

Different types of tobacco can contain different amounts of nicotine. Even different parts of the same tobacco plant can contain different nicotine levels depending on the nitrogen in the soil, the position of the stalk, and the curing process used. Tobacco blends, combined with the use of

fillers, additives, and specially formulated sheets of tobacco in the tobacco column of the cigarettes, can lead to variations in nicotine contents among brands. Tobacco companies manipulate these formulations to achieve specific deliveries of select smoke components.

Filter Ventilation

Perhaps the most dramatic change in cigarette design since the 1950s has been the addition of a filter on the tobacco rod of some cigarette brands. In fact, 97 percent of cigarettes sold in the United States today are filtered. Filter vents, which usually are one or more rings of small holes or perforations, dilute the smoke with air, thus reducing measured levels of tar, nicotine, and carbon monoxide. The location of vents usually ranges from 11 millimeters to 15 millimeters from the mouth end of the filter. According to the monograph, a recent study found that the filter ventilation levels of 32 U.S. cigarette brands ranged from zero to 83 percent. A cigarette with zero percent filter ventilation would produce a puff of smoke undiluted by air from filters. A cigarette with 83 percent ventilation would produce a puff that is 83 percent air from vents and 17 percent smoke undiluted by air from vents.

10. Do these changes in cigarette design decrease the amount of tar and nicotine that smokers actually inhale?

These changes in cigarette design do not reliably decrease the amount of tar and nicotine that smokers inhale. The monograph finds that smokers compensate for lower yields of tar and nicotine in a number of easy and effective ways, leading the current testing method to not give meaningful information to smokers on either the amounts of tar and nicotine they will receive from a cigarette, nor the relative amounts of tar and nicotine that they would receive from smoking different brands of cigarettes. In addition to simply increasing the number of cigarettes that they smoke per day, smokers compensate for lower yields of tar and nicotine by:

Increasing Puff Number

Smokers can take more puffs per cigarette. A recent laboratory study found that smokers of low-yield cigarettes (cigarettes with less than or equal to 0.8 milligrams of nicotine by FTC measurement) waited a significantly shorter period of time between puffs than did smokers of high-yield brands (cigarettes with between 0.9 milligrams and 1.2 milligrams of nicotine by FTC measurement).

Increasing Puff Volume

Smokers can also increase the amount of smoke they inhale per puff. A 1988 Surgeon General report confirmed that puff volumes are often different from the FTC standard. The monograph cites numerous studies finding that smokers change their puff sizes in response to the type of cigarette they smoke, leading the FTC test to underestimate the volume of smoke taken from low-tar cigarettes. Tobacco industry studies also show that smokers take far more in total volume of smoke than is predicted by the FTC test, with puff volumes increasing as standard yields decrease.

Blocking Filter Vents

Another technique smokers can use to increase the amount of smoke they inhale is to block the

filter vents on the cigarette. Filter vents are often not noticed by smokers and are placed just millimeters from lips and fingers. Studies have found that smokers can and do block the vents with either their lips or fingers, thereby decreasing or canceling out the air-dilution effect. According to the monograph, the cigarette industry has known for decades that smokers can easily and unknowingly compensate for low standard yields by interfering with the vents. Research has shown that a large portion of people who smoke filtered cigarettes - in one study as much as 58 percent - block the vents.

11. Who smokes "light" cigarettes?

Surveys have indicated that among the estimated 47 million adults who smoke in the United States, it is people who are most concerned about smoking risks, and who are most interested in quitting, who use brands labeled "light" or "ultra-light."

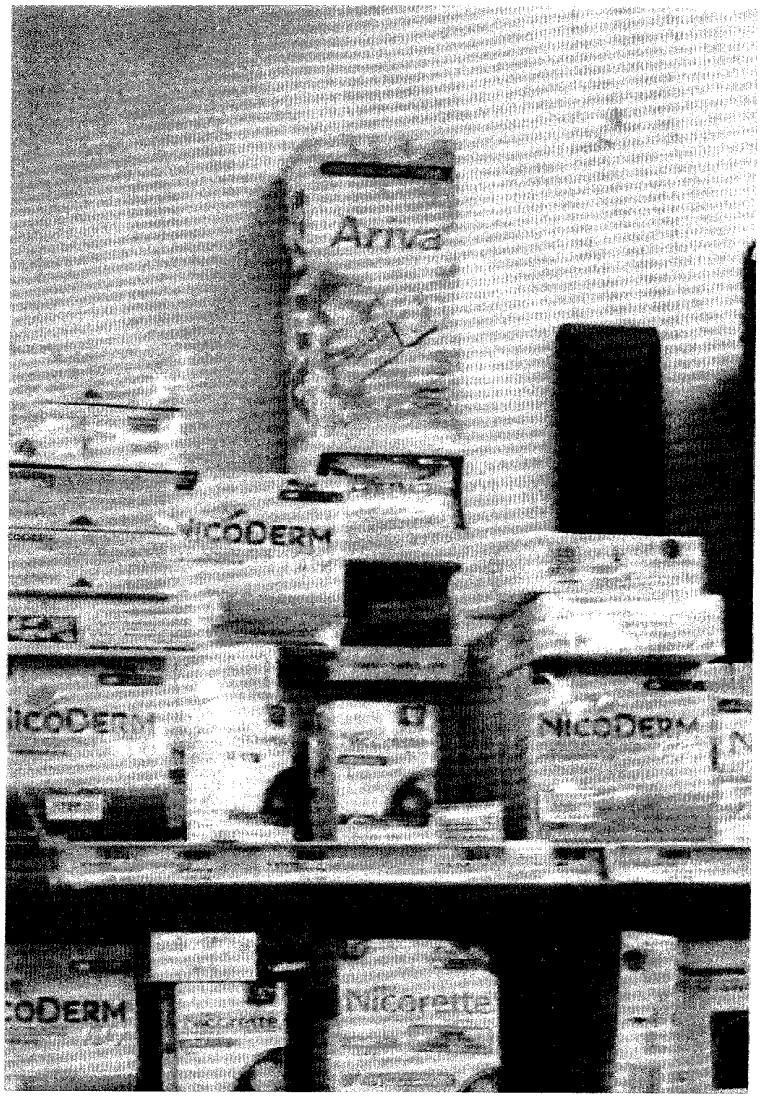
12. Has advertising for low-yield cigarettes been misleading?

Yes. Internal tobacco company documents in the monograph demonstrate that cigarette manufacturers recognized the inherent deception of advertising that offered cigarettes as "Light" or "Ultra-Light," or as having the lowest tar and nicotine yields.

13. Who wrote Monograph 13?

More than 10 public health experts from universities and organizations throughout the country contributed chapters to this monograph. Over 20 scientists, researchers, and others in universities, government, and the private sector provided comments and reviews.

David Burns, M.D., of the University of California, San Diego School of Medicine is the senior scientific editor and Neal L. Benowitz, M.D., of the University of California, San Francisco, is the co-scientific editor. Donald R. Shopland, former coordinator of the NCI Smoking and Tobacco Control Program, was the general editor of the monograph. Stephen Marcus, Ph.D., assumed responsibility for the monograph series when Shopland retired from NCI in January 2001.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