



American Heart Association
Learn and Live



AMERICAN LUNG ASSOCIATION



American Public Health Association

September 23, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0443

To Whom It May Concern:

The American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids & the American Public Health Association are pleased to provide comments to the Center for Tobacco Products (CTP) at the Food and Drug Administration (FDA) on the standards for regulations and guidance regarding modified risk products and claims in the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The standards for scientific evidence required for making claims for modified risk tobacco products and for post-market studies of the marketing, sale and use of such products is critical. It will be extremely important to FDA as it develops and implements standards to ensure that any products for which modified risk claims are allowed and any claims made about such products actually significantly improve public health and avoid the mistakes of the past that properly prompted Congress to set such rigorous standards.

INTRODUCTION

The CTP's Workshop on Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications generated a stimulating and useful discussion. It also brought to light several key points for the CTP to consider as it moves to establish these standards.

- First, the statutory requirement sets rigorous standards to protect public health that were designed to ensure that consumers are not misled again and that claims for modified risk products actually and significantly reduce the overall harm caused by tobacco products, taking into account the impact on the population as a whole. The goal of the Modified Risk Section (911) of the legislation is to protect the public, not to serve as a marketing tool for tobacco companies. These rigorous standards are necessary given the tobacco industry's history of claims that misled the public, deterred people from quitting and undermined evidence based prevention and cessation efforts. The intent of the statute is to ensure that any modified risk claims actually significantly improve public health for the population as a whole – taking into account not only the impact on the individual smoker but on promoting smoking initiation and discouraging smoking cessation. While some at the workshop made reference to an earlier Institute of Medicine (IOM) Report, Clearing the Smoke, the standards set out in the statute are more rigorous and more

comprehensive than those set out in the IOM Report.¹ Thus, it is the FSPTCA that must guide FDA's decision making, not the weaker criteria set out in Clearing the Smoke.

- The high standard for modified risk claims was incorporated into the statute for a reason. As detailed later in these comments, the industry has a decades-long history of misleading consumers about the health effects of their products. The tobacco companies have successfully used health claims to market deadly products to the American public. Those claims were false or misleading and/or prompted millions of consumers to switch rather than quit with tragic public health results. Congress drafted Section 911 after the National Cancer Institute published Monograph 13, which detailed how the marketing of light and low cigarettes was a public health disaster. The goal of Section 911 is to prevent any recurrence of this sad history.
- Section 911 does not prevent any product from being marketed. It is addressed solely to when health claims can be made about those products and is designed to ensure that any such claims will not mislead consumers into initiating or continuing tobacco use and will benefit the public health.
- History has shown that the tobacco companies act only to serve their bottom-line financial interests without regard to the impact of their actions on the health of Americans. They have demonstrated that they are willing to make false or misleading health claims about their products in order to serve those interests and/or make marketing claims to keep people smoking who otherwise would have quit. This is why the bottom line for the FDA must be to protect the public health, as outlined in the legislation. The statute is clear that the public health must be the FDA's top and sole priority and requires FDA to ensure that before permitting any claims, the FDA must determine that allowing the tobacco companies to make a claim benefits the public health.
- When modified risk claims are allowed, post-market surveillance will be critical to confirming what has been shown in pre-market research. However, post-market surveillance is not a substitute for meeting the standards set forth in the legislation for modified risk claims. FDA should not adopt a trial-and-error process in which the agency waits for post-market surveillance to indicate what works. Experience has demonstrated that such an approach can have disastrous public health consequences.
- Much of the discussion in the workshop concerned non-combustible tobacco products and a continuum of risk. However, it is critical to understand how these products and their marketing affect initiation of tobacco use and suppression of quitting. The smokeless tobacco companies also have a history of marketing their products in ways that lead to increased initiation, and recent marketing campaigns are clearly designed to decrease cessation.² When smokeless tobacco products are marketed in ways that increase youth initiation and undermine policies and programs that increase cessation, they run counter to the goal of the statute. As a result, the legislation requires the smokeless manufacturer to not only demonstrate the health impact of the use of the product, but also the impact of how the product will be marketed. The burden is

properly placed on the manufacturer. While much reference was made during the CTP workshop to the Snus experience in Sweden, there are critical differences in the product itself, the culture and history of use, and most of all, the marketing that makes the Swedish experience an inappropriate predictor of results in the United States market. The prevalence of snus in Sweden is not the result of modified risk claims. Not only are modified risk claims not allowed in Sweden, there is no advertising for the product.³ Nor is the product marketed as snus in the United States comparable to the product marketed as snus in Sweden. Understanding the product, the use trajectories, and the impact of marketing will be critical for any application under Section 911. In addition, while the smokeless industry narrowly talks about its snus products, the rise in smokeless tobacco use that has accompanied the increased marketing of snus has largely occurred in other smokeless tobacco products that have far higher levels of nitrosamines, and other substances than Swedish snus.⁴

REQUIREMENTS OF SECTION 911

Section 911(l)(1) requires the FDA to issue regulations or guidance by December 22, 2011 on the scientific evidence required to make an assessment and ongoing review of modified risk tobacco products. The subject matter of such regulations and guidance is set forth in subparagraphs (A) through (F) of that paragraph. Section 911 (l)(2) provides that such regulations and guidelines shall be developed in consultation with the Institute of Medicine and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

In order to understand the scope of the scientific evidence required to address all these issues, the FDA must take account all the numerous factors that the statute requires it to consider and the findings it is required to make before it may grant an application for a modified risk claim to be made.

The overarching standard that FDA must apply in evaluating such applications is whether the applicant has demonstrated that such product, *as it is actually marketed and used by consumers*, will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Sec. 911 (g)(1)

It is thus important to understand the scope of these questions and the kind of standard that the statute has created. Part (B) of the fundamental standard—a determination of whether granting the application will “benefit the health of population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products” is a population-based public health standard that recurs in numerous sections of the Tobacco Control Act. It applies, with small variations, to the establishment of tobacco product standards under Section 907 and to the establishment of standards for new tobacco products under Section 910.

In determining whether granting a modified risk application will “benefit the health of the population as a whole,” the FDA will have to determine whether the commercial marketing of the product and its actual use by consumers, as well as the claims made about such product, will increase or decrease the likelihood that existing users of tobacco products will stop using such products, whether it will increase or decrease the likelihood that those who do not use tobacco products will start using such

products, and how the risks and benefits of the product compare to the use of smoking cessation products approved under chapter V to treat nicotine dependence. Sec. 911 (g)(4). Put another way, the FDA will have to consider not only the effects of the product on those who use it, but also the effects of the marketing of the product on initiation, use, cessation, and relapse among the population as a whole.

Such a determination will require FDA to consider scientific evidence concerning consumer responses to the availability of the product, the claims that are made for it, and the marketing of the product. If a product is actually less hazardous than other tobacco products and will benefit a smoker who can't otherwise quit, but its availability and marketing would result in greater initiation of tobacco use or diminished cessation, the agency is required to weigh the benefits against the risks in making its determination. The question of whether commercial availability and marketing would result in greater initiation or diminished cessation is one that is to be answered by scientific evidence. The kind of scientific evidence needed to answer the question is evidence about consumers' likely response to the availability of the product and to the appeal of the marketing. Answering such a question requires scientific evidence different from scientific evidence about the physical effect of using the product. FDA must therefore identify the kinds of evidence it will need to make the decisions it is required to make under Section 911(g), i.e., what kinds of scientific evidence are required to evaluate the effect of the commercial availability and marketing of the product in question on initiation and cessation.

The scientific evidence called for must relate to products as they are "actually used by consumers." Sec. 911(g)(1). Thus, the scientific evidence cannot be limited to evidence from machine smoking. In addition, as noted above, the requirements of the statute require the agency to consider consumer behavior in response to the commercial availability and marketing of the product. Thus, the scope of the relevant scientific evidence is considerably broader than a focus on the effect of the product on an individual user.

The statute places the burden on the applicant to provide the scientific evidence that demonstrates the legal standard has been met. The burden, quite appropriately, is a difficult one to satisfy. One of FDA's central tasks is to identify the scientific evidence necessary for an applicant to satisfy each of the elements it is required to show and the kinds of tests and studies an applicant should be required to perform in support of its application. The statute requires the Institute of Medicine to advise FDA in identifying the necessary evidence.

Moreover, in developing its standard, the FDA should do so with the recognition that unjustified claims of reduced risk have seriously damaged the public health for many years and that strict standards should be applied to prevent a recurrence of these events.

Any assessment of standards for reduced risk products should take account of three facts.

(1) The tobacco industry has long promoted the possibility that some products might potentially reduce a smoker's risk of disease to discourage people from quitting and create an image among young people that not all tobacco products are equally hazardous. And they did so for products that did not actually reduce the risk of disease and with marketing clearly intended to keep people smoking.⁵

(2) We know that there is no such thing as a safe cigarette. As the recently released Surgeon General's Report on How Tobacco Smoke Causes Disease concluded, "The evidence on the mechanisms by which smoking causes disease indicates that there is no risk-free level of exposure to tobacco smoke."⁶ Thus, the only way to eliminate further risk is to quit – or of course, to never start. This is why it is critical that any promotion of reduced risk products not have the effect of decreasing quit attempts by smokers.

(3) There is a history of the marketing of smokeless tobacco products that led to increased use among youth;⁷ that some smokeless tobacco marketing appears targeted to those who would have otherwise quit; and that there must be safeguards to ensure that the advertising of low nitrosamine smokeless products does not result in the increase of the use of other smokeless tobacco products.

The FSPTCA addresses each of these issues. It provides a set of criteria for determining which products will genuinely reduce harm to the population as a whole, and it provides a path to market for such products, but only if the product, as it will actually be marketed, will genuinely reduce harm to public health. In doing so, the statute strikes a balance between ensuring that such products and their marketing will in fact reduce harm for the population as a whole, including users and non-users, and encouraging innovation to reduce harm to individuals who already use tobacco and are unable to quit. With the passage of the FSPTCA, for the first time ever, the tobacco companies' claims that certain tobacco products reduce the risk of disease or the exposure to harmful substances will be regulated by the FDA. Decisions about the claims that can be made about these products will now be made for the benefit of public health rather than solely and exclusively for the economic benefit of the tobacco companies.

The scientific standard agreed upon by Congress for making modified risk claims is a high one – and it should be. The history of so-called reduced harm products like light and low tar cigarettes demonstrates the consequence of permitting reduced risk claims to be made without an adequate scientific basis or an adequate appreciation of the effects of such claims on consumer perception. For decades, tobacco manufacturers marketed "light" and "low tar" products with claims that these cigarettes were less risky, leading millions of consumers to switch to these products thinking they were actually reducing their risk of disease or that they were taking a first step towards quitting.⁸ The National Cancer Institute, the U.S. Surgeon General and other credible scientific bodies have subsequently concluded that "light and "low tar" products did not reduce the risk of disease and deterred millions of smokers from quitting.⁹ The tobacco companies knew this and even referred in their own documents to the difference between "health image" products and actual "health-oriented" products. We will be paying the public health price for this deception for years yet to come.

In order to fulfill the statutory mandate, the FDA, with the assistance of the IOM, is called upon to address the scientific standards that will apply in evaluating both product design and—importantly—the effect of the proposed marketing of such products—on the way consumers will perceive such products and the way the availability of products so marketed will affect initiation, cessation and relapse among the population as a whole. Indeed, the statute defines a modified risk product as one for which the "label, labeling, or advertising" make reduced risk or reduced exposure claims. The statute further defines as a modified risk product any one for which the manufacturer has "taken any action through the media or

otherwise” that would lead consumers to believe it presents a lower risk or reduced exposure. Thus, the agency will have to identify the level of scientific evidence and the types of studies necessary for the following:

Significant Reduction in Individual Harm. As the bill states, scientific studies must show a “substantial reduction in morbidity or mortality among individual tobacco users.” Sec. 911 (l) The bill requires a high burden of scientific proof and certainty and further requires that this analysis should be based on how the product is actually used by individual smokers, not by a machine, and not under abnormal conditions of use. These requirements guide the type of evidence required to demonstrate that the product, as used by smokers, will result in harm reduction. It cannot just reduce one type of harm or reduce just one harmful constituent without regard to potential increases in other constituents or harms; those should obviously be taken into account as well. A statistically significant reduction is not necessarily sufficient, as very small changes can be statistically significant given large enough sample sizes yet result in no real health benefit.

Benefitting the Health of the Population as a Whole. The standard for making a modified risk claim must also address the impact of the product and its marketing on tobacco use initiation and cessation, and relapse. In order not to offset any gains to the individual user, it is necessary to eliminate or at least minimize the possibility that there will be new users and or existing users who would otherwise have quit as a result of the introduction of the new modified risk product and its marketing. Thus, the science should also include consumer research addressing the reactions of non-users and users of tobacco products to the modified risk product and its marketing. The statute provides that it is the manufacturer wishing to make the modified risk claim who bears the burden of proving that the product, as marketed, will not increase use in ways that will offset any reductions in harm to the individual user. For example, in determining if smokeless products could be marketed with a modified risk claim, it would be necessary to look not only at whether the smokeless product is less harmful than the comparison product (e.g. conventional cigarette), but also at the impact of the marketing of the modified risk product on discouraging smokeless users from quitting, encouraging initiation of smokeless, discouraging smokers from quitting, and or encouraging initiation of tobacco use and eventual smoking by non-users. Indeed, many of today’s smokeless products are being marketed to smokers for use in places where they can no longer smoke and may well have the effect of discouraging quit attempts that would otherwise be prompted by smoke-free laws. It would also require evidence that smokers actually quit using smokeless tobacco.

Special Rule for Reduced Exposure Claims. The FSPTCA establishes special rules applicable to certain “reduced exposure” claims. “Reduced exposure” claims are claims that are limited to “an explicit or implicit representation that [the] tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents reduced exposure to a substance in tobacco smoke.” The special rule applies only to such products for which the scientific evidence to make a reduced exposure claim is not available and cannot be made available using the best available science without long-term epidemiological studies necessary for the application. However, the standard for making claims of reduced exposure are different and go farther than the IOM’s Clearing the Smoke report. Thus, the FDA must identify the scientific evidence necessary to establish that:

- The order allowing the claim would be appropriate to promote the public health, taking into account both users of tobacco products as well as non-users, and their reactions to the product and its marketing.
- The statute places the burden on the manufacturer to produce adequate evidence as established by FDA that a measurable and substantial reduction in morbidity or mortality among individual users is reasonably likely in subsequent studies. If the manufacturer cannot demonstrate that the reduction in exposure provided by a product is reasonably likely to reduce risk, it cannot make a reduced exposure claim.
- The magnitude of reductions in exposure are substantial, the substances reduced are harmful, and the reductions claimed occur as the product is actually used.
- The reduced exposure to these substances does not result in increased exposure to other harmful substances that may offset gains from reduced exposure to substances about which the claim is made.

Given the evidence that consumers today often believe that a claim that a product that reduces their exposure to a harmful substance also reduces their risk of disease, the statute requires the manufacturer to do prior testing to demonstrate that consumers will not be misled into believing that the product has been demonstrated to be less harmful or has been demonstrated to present less risk of disease than other products.¹⁰ Proof in advance that consumers will not be misled is a pre-condition to being permitted to making a claim; it is insufficient for a manufacturer to make such a claim without such proof.

It is important to note that the special rule for reduced exposure claims applies only in those instances when the evidence for making a modified risk claim cannot be made available. When that is no longer the case, the special rule no longer applies. In addition, reduced exposure claims allowed under this section are time-limited to five years unless renewed by the Secretary.

Consumer Comprehension. Manufacturers making modified risk or reduced exposure claims will also have to demonstrate that the public actually can comprehend any advertising or labeling concerning modified risk products and understand what it means in the context of the health-related issues caused by tobacco use.

The evidence required to meet these standards will go well beyond measures of tobacco harm and disease risk but should include measures of consumer perception and behavior to fully understand the impact of the introduction of these products and their marketing.

Post-Market Surveillance. The FSPTCA also requires post-market surveillance to ensure that any reduced harm (or reduced exposure) product about which claims are made meet the public health standard after introduction to the actual market. This will require studies of possible uptake of the product among users and non-users of tobacco, including impacts on quitting behavior, and the impact of this change in the market on public health. These ongoing studies of consumer perceptions, behavior and health will allow the FDA to review the accuracy of its previous determination allowing the introduction of the modified risk product. Post-market surveillance, however, is not a substitute for meeting the standards for making the claim in the first place. Rather, post-market surveillance is a check to make absolutely sure

that the evidence presented in the application process holds up when the product is sold and reduced harm claims are made. The FSPTCA is designed to prevent the kind of public health disasters like that brought about by light and low tar cigarettes – not to discover them after they happen.

As noted above, the FSPTCA does provide a path for modified risk products to be marketed as such when the evidence is convincing that they will improve public health as defined in the law. However, it is important to note that Section 911 of the FSPTCA is not the only way that reduced harm products can reach the market. Tobacco products that reduce harm can be introduced to the market without a modified risk claim if they meet the standards of Section 910 for new products, allowing the industry and FDA to study the impact of these products on consumers before the evidence is adequate to determine whether they qualify under Section 911.

THE HISTORY OF MODIFIED RISK CLAIMS

The need for stringent standards applicable to modified risk claims can be appreciated only with an understanding that explicit and implicit health claims by tobacco product manufacturers over the course of many decades have been responsible for addicting and killing many millions of Americans and persuading millions of smokers to continue using tobacco rather than quitting.¹¹ The nature of such claims evolved over many years to respond to changing consumer concerns regarding the health risks of tobacco use. Such claims were spectacularly successful in persuading American smokers to use new tobacco products in the belief that such products presented a lower risk of tobacco-related disease than the products they had been using.¹² In enacting Section 911, the Congress was understandably concerned that the tobacco industry would once again seek to protect its market by attempting to persuade consumers that changes in tobacco products had somehow decreased the health risks they posed.

Beginning in the 1950s, when evidence of the dangers posed by cigarette smoking came to light, the industry's response was to mount advertising campaigns alleging that adding filters to cigarettes made cigarettes less dangerous to health even though there was no evidence that this was the case. Despite growing evidence that cigarettes caused fatal disease, the incidence of smoking continued to rise, and the large majority of smokers turned to filtered cigarettes in response to the industry's successful effort to portray them as less harmful.¹³

In the 1970s, the industry began to promote cigarettes labeled as "light" or "low-tar" as a less harmful alternative. In fact, as the industry was well aware, such cigarettes, as actually used by smokers, were no less dangerous. In spite of the fact that such cigarettes presented no lower risk of harm, smokers concerned about their health switched to these brands in huge numbers.¹⁴ As of 1998, 82 percent of cigarettes sold in the United States were "light" or "ultra light."¹⁵ Once again the tobacco industry succeeded in maintaining its market through false claims that its products were less risky than they actually were. The tobacco industry's conduct in deceptively promoting light cigarettes as less harmful over the course of many decades, while it knew that such claims were false, coupled with the enormous success of its marketing efforts, demonstrates the need for effective regulation of potential industry claims that any tobacco products present a reduced risk of harm or exposure.

An enormous amount of evidence concerning the industry's promotion of light and ultra-light cigarettes was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris*.¹⁶ The court made extensive findings of fact, including the following:

2023. For several decades, Defendants have marketed and promoted their low tar brands as being less harmful than conventional cigarettes. This claim is false, as these Findings of Fact demonstrate. By making these false claims, Defendants have given smokers an acceptable alternative to quitting smoking, as well as an excuse for not quitting.
2024. []Defendants marketing has emphasized claims of low tar and nicotine delivery accompanied by statements that smoking these brands would reduce exposure to the "controversial" elements of cigarette smoke (i.e., tar). Since the 1970s, Defendants also have used so-called brand descriptors such as "light" and "ultra light" to communicate reassuring messages that these are healthier cigarettes and to suggest that smoking low tar cigarettes is an acceptable alternative to quitting. In addition to appealing advertising and easily-remembered brand descriptors, Defendants have used sophisticated marketing imagery such as lighter color cigarette packaging and white tipping paper to reinforce the same message that these brands were low in tar and therefore less harmful.
2025. Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal industry documents reveal Defendants' awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.
2026. []Defendants' internal documents demonstrate their understanding that, in order to obtain an amount of nicotine sufficient to satisfy their addiction, smokers of low tar cigarettes modify their smoking behavior, or "compensate," for the reduced nicotine yields by taking more frequent puffs, inhaling smoke more deeply, holding smoke in their lungs longer, covering cigarette ventilation holes with fingers or lips, and/or smoking more cigarettes....
2027. Defendants did not disclose the full extent and depth of their knowledge and understanding of smoker compensation to the public health community or to government regulators.
2028. Defendants' conduct relating to low tar cigarettes was intended to further their overarching economic goal: to keep smokers smoking; to stop smokers from quitting; to encourage people, especially young people, to start smoking; and to maintain or increase corporate profits.

The court's opinion contains a wealth of detail to support these conclusions, including evidence of express misrepresentations by tobacco companies that their cigarettes were safe or that they positively promoted health. The FTC successfully prosecuted the major tobacco companies for such misrepresentations, but these prosecutions did not deter the industry from continuing its deceptive course of conduct.¹⁷

The Court also concluded that, continuing through the time of trial, the tobacco companies were still making false and misleading statements designed to communicate that low-tar cigarettes were less harmful than full flavor cigarettes to reassure smokers and dissuade them from quitting.¹⁸

NCI Monograph 13 also provides extensive documentation of the mistaken policies that permitted the tobacco industry to persuade consumers that low-tar cigarettes were less harmful to their health.¹⁹ The Monograph concludes that low-tar cigarettes were deliberately designed by the tobacco industry to produce very low yields of tar when tested using the FTC protocol but to yield a much higher dose of nicotine when the cigarettes were smoked by actual smokers with the puffing profiles the companies knew they would use (p. 4). The report documented that cigarettes were deliberately engineered to facilitate a wide range of compensatory smoking behaviors that permit smokers to take in the amount of nicotine necessary to sustain their addiction.

The Monograph also addressed consumer perceptions of low-tar cigarettes and the public health consequences that have resulted from these perceptions. The Monograph concluded that smokers choose light or ultra-light brands because they are misled into believing that they are not as harmful and cause fewer health problems than full flavor cigarettes; that switching to such brands reduces the motivation to stop smoking; and that the availability of such cigarettes has kept many smokers interested in protecting their health from quitting (p. 197).

The light and low debacle was not the only or even most recent effort by the tobacco companies to keep smokers smoking by claiming reduced harm. Indeed, major tobacco companies have continued to make unwarranted health claims. Under the Master Settlement Agreement, the major tobacco companies agreed not to make any material misrepresentation with regard to the health consequences of using any tobacco products. Master Settlement Agreement Sec. II(r). In spite of this commitment, R.J. Reynolds Tobacco Company made claims concerning Eclipse, a product being test marketed, "that compared to other cigarettes, Eclipse may present less risk of cancer, chronic bronchitis, and possibly emphysema." *Vermont v. R.J. Reynolds Tobacco Company*, ___A3d___ (Vt. Sup. Ct.) (2010). The State of Vermont brought an action alleging that the marketing campaign for Eclipse constituted material misrepresentations regarding its health consequences and the court, after a lengthy hearing, found that Reynolds' claims constituted material misrepresentations under the MSA and violated the Vermont Consumer Fraud Act.²⁰

Development of an appropriate regime for the regulation of modified risk products must take the history of low-tar cigarettes as a cautionary tale. Despite the FSPTCA's ban on the use of the deceptive terms "light," "mild" and "low-tar", tobacco companies are using color-coding schemes to circumvent the ban and perpetuate the deception. Lighter-colored packaging is now used for light brands, and terms such as "gold" and "silver" have replaced "light" and "ultra-light". Given the behavior of the tobacco industry over the course of many decades and its successful effort to mislead consumers into believing that low-tar

cigarettes were an acceptable alternative to quitting, there is every reason for current policymakers to be extremely cautious in permitting manufacturers to make claims that their products present reduced risk or reduced exposure to harmful substances.

HISTORY OF SMOKELESS TOBACCO ENCOURAGING INITIATION AND DISCOURAGING CESSATION

As noted above, there was extensive discussion at the workshop regarding the potential for modified risk claims for smokeless or other non-combustible tobacco products. The industry history of using these products to promote initiation of tobacco use and discourage cessation demands that the same public health standard for the population as a whole be applied to applications for modified risk claims for these products.

U.S. smokeless tobacco companies have a long history of creating new products that appeal to kids and marketing them aggressively to children.²¹ Tobacco documents show that U.S. Smokeless Tobacco Company (UST, a subsidiary of Altria, the parent company of Philip Morris USA) had a specific strategy to “graduate” new, young smokeless tobacco users from candy- or fruit-flavored starter products in pouches to more potent varieties. According to internal company documents, UST developed a strategy for hooking new spit-tobacco users, meaning kids, some time ago. As one document states:

New users of smokeless tobacco -- attracted to the product for a variety of reasons -- are most likely to begin with products that are milder tasting, more flavored, and/or easier to control in the mouth. After a period of time, there is a natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated 'tobacco taste' than the entry brand.²²

Following this strategy, between 1983 to 1984, UST introduced Skoal Bandits and Skoal Long Cut, designed to “graduate” new users from beginner strength to stronger, more potent products. A 1985 internal UST newsletter indicates the company’s desire to appeal to youth: “Skoal Bandits is the introductory product, and then we look towards establishing a normal graduation process.”²³ In 1993, cherry flavoring was added to UST’s Skoal Long Cut, another starter product. A former UST sales representative revealed that “Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”²⁴ According to UST’s 2005 Annual Report, flavored products (that now include flavors such as apple, peach, vanilla, berry blend, and citrus blend) account for more than 11 percent of all moist snuff sales.²⁵ UST launched “new and improved” Skoal Bandits in August 2006.²⁶ Between 2000 and 2006, UST increased the number of its sub-brands by 140 percent, creating a larger variety of products with which to “cast a wide net” and appeal to as many potential users as possible.²⁷ It is no wonder that smokeless tobacco use among boys increased by 36% between 2003 and 2009.²⁸

Initiation with smokeless tobacco can also lead to smoking. Youth prevalence data show that cigarette smoking and smokeless tobacco use declined between 1997 and 2003, but as the youth smoking decline has stalled since then, youth smokeless use has actually increased.²⁹ This suggests smokeless is not substituting for smoking but is adding to the number of tobacco users. From 2002 to 2007, more than half (52.8%) of youth aged 12 to 17 who used smokeless tobacco in the past month also reported past month cigarette smoking.³⁰

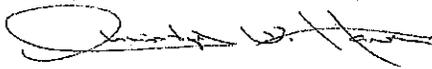
Smokeless tobacco has also been marketed in ways to discourage smokers from quitting in the face of new smoke-free laws that often encourage smokers to quit. Recent years have seen an increase in smokeless tobacco products using phrases in their marketing such as, "when smoking isn't an option" and "tobacco pleasure to enjoy virtually anytime, anywhere," tell smokers that they can use their products when smoking is not allowed instead of quitting. These products are only the beginning of a series of new products being unveiled by the tobacco companies – in most cases now a major cigarette company that owns a smokeless tobacco company – in an effort to provide an alternative product to individuals seriously considering quitting tobacco use altogether. In some instances, the smokeless products are even marketed with cigarettes, clearly sending the message that the smokeless product is a bridge to use between cigarettes in places where smoking is no longer allowed.

These impacts of modified risk products on tobacco use initiation and cessation must be taken into account when evaluating modified risk applications against the public health standard in the FSPTCA.

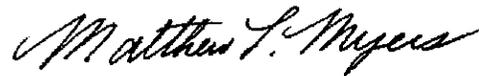
CONCLUSION

It is clear from the long history of tobacco company efforts to mislead consumers into initiating and sustaining tobacco use, from the toll that these successful efforts have taken on public health, and even from the discussion at the workshop, that the public health standard in the FSPTCA must be administered stringently in reviewing applications for modified risk claims. The bottom line for the FDA must be the protection of public health as outlined in the statute. This makes it critical that FDA issue strict guidelines for the type of evidence required to show the impact of modified risk products and claims not only on the individual user but on the population as a whole.

Sincerely,



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- ¹ Institute of Medicine, *Clearing the Smoke: The Science Base for Tobacco Harm Reduction*, February, 2001.
- ² See, e.g., Campaign for Tobacco-Free Kids factsheet, *Smokeless Tobacco and Kids*, <http://www.tobaccofreekids.org/research/factsheets/pdf/0003.pdf>, and *Smokeless Tobacco in the United States*, <http://www.tobaccofreekids.org/research/factsheets/pdf/0231.pdf>.
- ³ Sweden National Tobacco Act (1993:581), Section 14, <http://www.sweden.gov.se/content/1/c6/08/62/43/ea7210ac.pdf>.
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