



April 1, 2013

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

Re: Docket No. FDA-2012-N-1032-0001, Smokeless Tobacco Product Warning Statements

The undersigned organizations submit these comments in response to the request by the Food and Drug Administration (FDA) for comments on what changes to the current statutory warnings on smokeless tobacco products, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

In summary form, these comments support the following conclusions about the statutory smokeless tobacco warnings:

- (1) The current statutory smokeless tobacco warnings are accurate and continue to be essential to public health. The scientific evidence leaves no doubt that smokeless

- tobacco causes mouth cancer, gum disease and tooth loss, that it is highly addictive and that it is not a safe alternative to cigarettes.
- (2) Strong warnings on smokeless tobacco products are needed because smokeless tobacco use has increased among adolescents in response to increased advertising and promotion aimed at adolescents.
 - (3) Contrary to the allegations of R.J. Reynolds (Reynolds or RJR), it is not misleading to warn the public that smokeless tobacco is not a safe alternative to cigarettes; the warnings were accurate when Congress adopted them and nothing has changed since then that would alter that conclusion. The warnings simply state what the science has proven: these products cause serious disease.
 - (4) Contrary to tobacco industry claims, the current smokeless tobacco warnings raise no constitutional issues.
 - (5) FDA should reject any attempt by tobacco companies to transform smokeless tobacco warnings into claims of modified risk. To do so would undermine the rigorous requirements in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) for making such claims, which were enacted to avoid repetition of the industry's deadly history of using false claims of reduced risk to keep people smoking.
 - (6) Revising the statutory warnings to make a claim of modified risk for smokeless tobacco products would not benefit public health because there is substantial scientific evidence that smokers would not quit using cigarettes and switch to smokeless tobacco, that greater promotion of smokeless tobacco as a harm reduction strategy would lead to greater, and more dangerous, dual use of cigarettes and smokeless tobacco products, and that use of smokeless tobacco would become an even greater gateway to smoking. Moreover, the promotion of smokeless tobacco products by major cigarette companies is calculated to keep people smoking and maintain cigarette sales.
 - (7) Rather than misusing the warning label provisions of the Tobacco Control Act to sponsor modified risk claims for deadly smokeless tobacco products, FDA should maximize the effectiveness of smoking cessation products already proven to be safe and effective for that use.
 - (8) FDA sponsorship of modified risk claims through revision of the statutory smokeless tobacco warnings would be inconsistent with the intent of Congress in enacting the Tobacco Control Act.

(9) FDA should examine whether the existing warning labels on smokeless tobacco have worn out and whether the existing warnings are still effective in ensuring that the public understands the health risks of smokeless tobacco and consider whether changes are needed to enhance that understanding.

I. STATUTORY AND REGULATORY BACKGROUND

In recognition of the well-established danger to public health of smokeless tobacco products, the Tobacco Control Act makes smokeless tobacco products (along with cigarettes, cigarette tobacco, and roll-your-own tobacco) expressly subject to the authority of FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect public health. Sec. 204(a) of the Tobacco Control Act mandates that smokeless tobacco manufacturers include, on a rotating basis on their product packages (and on its advertising as well), four warnings about the health consequences of smokeless tobacco:

“WARNING: This product can cause mouth cancer.”

“WARNING: This product can cause gum disease and tooth loss.”

“WARNING: This product is not a safe alternative to cigarettes.”

“WARNING: Smokeless tobacco is addictive.”

Sec. 204 also mandates detailed specifications as to the size and placement of the required warnings, both on packages and on advertising.

Recognizing the need to ensure the effectiveness of the warnings over time, Sec. 205 of the TCA gives FDA the authority to revise the content and presentation of the warnings through a rulemaking proceeding:

AUTHORITY TO REVISE WARNING LABEL STATEMENTS. The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

By Federal Register Notice of January 29, 2013,¹ FDA has requested “comments, supported by scientific evidence, regarding what changes, if any, to the smokeless tobacco product warnings would promote greater public understanding of the risks associated with the use of smokeless tobacco products.” The Notice goes on to note that the term “public” should be understood to mean “both tobacco users and nonusers (i.e. never users and former users).”

II. THE CURRENT STATUTORY WARNINGS ARE ACCURATE AND ESSENTIAL TO PUBLIC HEALTH

A. Smokeless Tobacco Causes Disease, is Addictive and is Not a Safe Alternative to Cigarettes

It is unquestionably true that the use of smokeless tobacco can cause oral cancer, gum disease, and tooth loss; that smokeless tobacco is addictive; and that the use of smokeless tobacco is not a safe alternative to smoking cigarettes. Numerous reviews of the evidence by authoritative organizations support these conclusions. As early as 1986, the Surgeon General concluded that “the oral use of smokeless tobacco presents a significant health risk. It is not a safe substitute for smoking cigarettes. It can cause cancer and a number of non-cancerous oral conditions and can lead to nicotine addiction and dependence.”² Since then, other major health organizations evaluating the evidence, such as the National Cancer Institute, the National Toxicology Program, and the World Health Organization (WHO) Scientific Advisory Committee on Tobacco Product Regulation have all reached the same conclusions.³ Most recently, in 2012, after a comprehensive review of the literature on smokeless tobacco, the International Agency for Research on Cancer (IARC) concluded that “there is strong evidence in humans that smokeless tobacco causes cancer of the oral cavity.”⁴ Even the manufacturers of smokeless tobacco products concede the truth of these statements.⁵ Although some studies have shown that there is no association between oral cancer and the use of snus in Sweden, Swedish snus has virtually no market in the United States and users of the kinds of smokeless

¹ 78 Fed. Reg. 6056 (January 29, 2013).

² U.S. Department of Health and Human Services (HHS), *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, NIH Publication No. 86-2874 (April 4, 1986).

³ National Institutes of Health (NIH), National Cancer Institute (NCI), *Smoking and Tobacco Control Monograph No. 2: Smokeless Tobacco or Health: An International Perspective*, September 1992; US Department of Health and Human Services (HHS), Public Health Service, National Toxicology Program, *Report on Carcinogens, Eleventh Edition* (January 31, 2005); World Health Organization, Scientific Advisory Committee on Tobacco Product Regulation, *Recommendation on Smokeless Tobacco Products* (2003).

⁴ IARC Monograph 100E, *A Review of Human Carcinogens: Personal Habits and Indoor Combustions* (2012) at 295. This conclusion confirmed a nearly identical conclusion reached in the 2007 IARC Monograph (*infra* at note 9), which had surveyed the literature as of 2004.

⁵ R.J. Reynolds Citizen Petition (July 28, 2011) (“RJR Citizen Petition”), discussed further *infra* at Part II.C.

tobacco commonly sold in the United States are far more likely to develop oral cancer than never users.⁶

The epidemiological evidence is supported by analysis of the chemistry of smokeless tobacco products. In 2012, FDA published a list of 93 harmful and potentially harmful constituents found in cigarettes or smokeless tobacco products.⁷ Of these, at least 36 are carcinogens that are found in smokeless tobacco products.⁸

In addition, smokeless tobacco use is associated with elevated levels of biomarkers of oral cancer. According to IARC:

multiple features of the carcinogenic process have been observed to occur *in vitro* and *in situ* in the oral cavity of smokeless tobacco chewers and in experimental animals treated with smokeless tobacco. Collectively, the available data on biomarkers provide convincing evidence that carcinogen uptake, activation and binding to cellular macromolecules are higher in smokeless tobacco users than in non-users. Smokeless tobacco is genotoxic in humans and in experimental animals.⁹

The epidemiological evidence demonstrates that use of smokeless tobacco products can cause other types of cancer as well. A recent study by IARC concluded that smokeless tobacco users have an 80 percent higher risk of developing oral cancer and a 60 percent higher risk of developing pancreatic and esophageal cancer than non-users.¹⁰ The most recent review of the scientific literature published by IARC concludes that “Smokeless tobacco causes cancers of the oral cavity, oesophagus and pancreas.”¹¹ The existing warning, which is limited to a statement

⁶ Boffetta, P, et al., “Smokeless Tobacco and Cancer,” *The Lancet Oncology* 9: 667-75 (2008).

⁷ U.S. Food and Drug Administration (FDA), *Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry* (March 2012), <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297752.htm>.

⁸ Carcinogens found in smokeless tobacco products include acetaldehyde, aflatoxin B-1, anabasine, arsenic, benz[*a*]anthracene, benzo[*b*]fluoroanthene, benzo[*k*]fluoroanthene, benzo[*a*]pyrene, beryllium, cadmium, chromium, chrysene, cotonaldehyde, dibenz[*a,h*]anthracene, ethyl carbamate (urethane), formaldehyde, indeno[1,2,3-*cd*]pyrene, lead, mercury, NNK, naphthalene, nickel, nitrate, nitrite, *N'*-nitrosoanabasine, *N*-nitrosodiethanolamine, *N*-nitrosodimethylamine, *N*-nitrosomorpholine, *N'*-nitrosornicotine, *N*-nitrosopiperidine, *N*-nitrosopyrrolidine, *N*-nitrososarcosine, nornicotine, polonium-210, uranium-235, and uranium-238. Hecht, S, “Recommendations from the Tobacco Product Constituents Subcommittee,” Presentation at the August 30 Meeting of the Tobacco Products Scientific Advisory Committee (August 30, 2010), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM224807.pdf>.

⁹ IARC Monograph 89, *Smokeless Tobacco and Some Tobacco-specific N-Nitrosamines* (2007a) at 362.

¹⁰ Boffeta, *supra* note 6, at 668, 669.

¹¹ IARC, *supra* note 4, at 309.

concerning oral cancer, understates the risk of cancer posed by smokeless tobacco products by omitting the mention of other forms of cancer that are associated with smokeless tobacco use.

The second warning, “this product can cause gum disease and tooth loss,” is also true beyond dispute. Smokeless tobacco use is a cause of gingivitis.¹² A study by the National Institutes of Health and the Centers for Disease Control and Prevention found that users of smokeless tobacco in the United States were four times more likely than non-users to have decayed dental root surfaces.¹³

It is also beyond dispute that smokeless tobacco is addictive. Smokeless tobacco contains nicotine, the principal addictive substance in cigarettes. Saliva cotinine levels among regular smokeless tobacco users are similar to those seen in regular cigarette smokers.¹⁴ The 1986 Surgeon General report, *The Health Consequences of Using Smokeless Tobacco*, concluded that the use of smokeless tobacco products can lead to nicotine dependence.¹⁵ This conclusion has been reaffirmed on numerous occasions.¹⁶ Based upon an overwhelming body of evidence, IARC has also concluded that smokeless tobacco is an addictive and dependence-producing substance.¹⁷

Moreover, manufacturers have engineered smokeless tobacco products to make them even more addictive. The addictiveness of a tobacco product is largely determined by the amount of unprotonated (“free”) nicotine delivered to the brain. This level is, in turn, responsive to the pH level in the product: the more alkaline the product (i.e., the higher the pH), the more free nicotine is available. Between 2000 and 2006, the second largest domestic smokeless tobacco manufacturer, Conwood Smokeless Tobacco Company (now American Snuff Company, a subsidiary of Reynolds American, Inc., also America’s second-largest cigarette manufacturer) increased the free nicotine level in its products by 31.1 percent.¹⁸

¹² The Smokeless Tobacco Outreach and Prevention Guide, Applied Behavioral Science Press (1997).

¹³ Tomar, SL, “Chewing Tobacco Use and Dental Caries Among U.S. Men,” *Journal of the American Dental Association* 130: 160 (1999).

¹⁴ Hatsukami, D, Gust, SW & Keenan, RM, “Physiologic and subjective changes from smokeless tobacco withdrawal,” *Clinical Pharmacology and Therapeutics* 41(1): 103-7 (1987); Hatsukami, D, Keenan, RM, Anton, DJ, “Topographical features of smokeless tobacco use,” *Psychopharmacology* 96(3): 428-9 (1988).

¹⁵ HHS, *supra* note 2, at vii.

¹⁶ See HHS, *The Health Consequences of Smoking: Nicotine Addiction: A report of the Surgeon General* (1988) at 214; Henningfield, JE, Fant, RV, Tomar, SL, “Smokeless tobacco: an addicting drug,” *Advances in Dental Research* 11(3): 330-5 (1997); Henningfield, JE & Fant, RV, “Tobacco use as drug addiction: the scientific foundation,” *Nicotine and Tobacco Research* 1 Suppl 2: S31-5 (1999).

¹⁷ IARC, *supra* note 9, at 281.

¹⁸ Alpert, HR, et al., “Free nicotine content and strategic marketing of moist snuff tobacco products in the United States, 2000-2006,” *Tobacco Control* 17: 332-38 (2008).

The final warning, “This product is not a safe alternative to cigarettes,” follows necessarily from the other three warnings. No product that may cause mouth cancer, gum disease and tooth loss, and is addictive is safe.

B. The Statutory Warnings Are Needed Now More than Ever Because Smokeless Tobacco Use Has Increased Among Adolescents in Response to Increased Advertising and Promotion Aimed at Adolescents.

In recent years, use of smokeless tobacco by adolescents has increased substantially. This increase has been documented in all the leading national surveys. The 2012 Monitoring the Future Survey found that current use of smokeless tobacco among twelfth graders had increased by 18 percent between 2004 and 2012 and smokeless tobacco use among tenth graders had increased by 31 percent during the same period.¹⁹ The Center for Disease Control and Prevention’s Youth Risk Behavior Survey found that in 2011, 12.8 percent of high school boys were current smokeless tobacco users. In at least nine states, use of smokeless tobacco by high school boys exceeded 20 percent.²⁰ Moreover, disturbingly, the survey data suggest a high rate of dual use among adolescents. From 2002 to 2007, nearly 53 percent of youth aged 12 through 17 who used smokeless tobacco also reported cigarette smoking during the past month.²¹ Another survey found that high school boys who use smokeless tobacco were five times more likely to smoke at least half a pack of cigarettes per day than high school boys who did not use smokeless tobacco.²²

The increased use of smokeless tobacco by young people is the result of a concerted strategy pursued for many years by manufacturers of smokeless tobacco products. Internal tobacco company documents demonstrate that the leading U.S. manufacturer of smokeless tobacco products, U.S. Smokeless Tobacco Company (UST, now a subsidiary of Altria, the largest cigarette maker in the U.S.), developed and implemented a strategy to addict adolescents in the 1980s. A document from 1984 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

¹⁹ Johnson, LD, et al., *Monitoring the Future Survey* (2012), http://www.monitoringthefuture.org/data/12data/pr12cig_4.pdf.

²⁰ U.S. Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance—United States 2011,” *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* (SS-4) (June 8, 2012).

²¹ Substance Abuse and Mental Health Services Administration (SAMHSA), *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*, Rockville, MD: Office of Applied Studies (March 5, 2009).

²² Tomar, SL, Albert, HR, & Connolly, GN, “Patterns of dual use of cigarettes and smokeless tobacco among US males: findings from national surveys,” *Tobacco Control* 19: 104-109 (2010).

natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated “tobacco taste” than the entry brand.²³

Following this strategy, UST and other manufacturers have introduced a wide array of flavored brands designed to appeal to the youth market. Brands with flavors such as strawberry, chocolate, and cherry, have, as their sponsors intended, attracted a youth market.²⁴ The second key element of the strategy is to introduce new users to brands with relatively low nicotine yields (i.e., brands that are not “fully flavored”) and gradually increasing the nicotine yield (i.e., tobacco flavor). Between 1983 and 1984, UST introduced Skoal Bandits and Skoal Long Cut, designed to graduate new users from beginner strength to stronger, more potent products. An internal UST newsletter states, “Skoal Bandits is the introductory product, and then we look towards establishing a normal graduation process.”²⁵ 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.²⁶

In recent years, smokeless tobacco manufacturers have greatly expanded their advertising programs that reach youth populations. From 1998 to 2010 (the most recent year for which data are available), the total advertising and marketing expenditures of the top-five smokeless tobacco companies in the U.S. (Altria Group, Inc.; North Atlantic Trading Company, Inc.; Reynolds American, Inc.; Swedish Match North America, Inc.; and Swisher International Group, Inc.) increased by 205.4 percent. In 2010, these smokeless tobacco companies spent \$444.2 million to advertise and market their products—an increase of more than 77 percent from 2005 expenditures (\$250.8 million).²⁷ Some of these funds pay for smokeless tobacco ads in magazines with high youth readership, such as *Sports Illustrated* and *Rolling Stone*.²⁸ In fact, despite the restrictions placed on youth advertising by the 1998 Smokeless Tobacco Master Settlement Agreement (STMSA), UST continued to advertise in youth-oriented magazines.

²³ “The Graduation Theory,” Draft Memo from David Weiss Associates for UST (November 16, 1984).

²⁴ A UST sales representative characterized Cherry Skoal as being “for somebody who likes the taste of candy, if you know what I’m saying.” Freedman, AM, “How a Tobacco Giant Doctors Snuff Brands to Boost Their Kick,” *The Wall Street Journal* (October 26, 1994).

²⁵ Connolly, GN, “The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer,” *Tobacco Control* 4(1): 73-79 (1995).

²⁶ Alpert, HR, et al., “Free nicotine content and strategic marketing of moist snuff tobacco products in the United States, 2000-2006” *Tobacco Control* 17: 332-338 (2008).

²⁷ Federal Trade Commission (FTC), *Smokeless Tobacco Report for 2009 and 2010* (2012), <http://www.ftc.gov/os/2012/09/120921tobaccoreport.pdf>

²⁸ Morrison, MA, et al., “Under the Radar: Smokeless Tobacco Advertising in Magazines With Substantial Youth Readership,” *American Journal of Public Health* 98: 543-548 (2008). See also, *Sports Illustrated* (July 30, 2001) and *Rolling Stone* (July 5, 2001).

From 1997 to 2001, UST's expenditures in youth magazines increased 161 percent, from \$3.6 million to \$9.4 million.²⁹

Not only have smokeless tobacco product manufacturers expanded their advertising programs, but they have also focused those programs on markets that reach youth. Smokeless tobacco products have been marketed to youth through a number of channels, including sporting events like auto racing and rodeos that are widely attended by kids. Although the STMSA and the Tobacco Control Act³⁰ have limited UST's brand-name sponsorships of events and teams, UST continues to be a promotional sponsor of both professional motorsports and rodeo and bull riding where it can.³¹ As the general manager of the College Finals said, "U.S. Tobacco is the oldest and best friend college rodeo ever had."³² In addition, smokeless tobacco companies set up tents and trailers at popular music festivals such as Austin's South by Southwest and Chicago's North Coast Music Fest that draw crowds of young people. Given the prevalence of these promotional strategies, it is hardly surprising that usage of smokeless tobacco products by young people is on the rise.

A study published in 2008 examined the levels of nicotine in moist snuff tobacco products in the United States, which accounted for 71 percent of the smokeless tobacco product market (Alpert, HR, Koh, H, and Connolly, GN, "Free nicotine content and strategic marketing of moist snuff products in the United States: 2000-2006," *Tobacco Control* 17:332-38 (July 2008)). The study, which examined trends in the market during the period 2000-2006, yielded several important results. The authors found that the levels of free nicotine in most snuff products (i.e., nicotine most easily absorbed) had increased over time for several major manufacturers, that marketing through price and advertising had increased, and that youth use had increased. *Id.* Moreover, the authors found that "manufacturers have also created a variety of brands and sub-brands which incorporate strategies such as sweet candy-like flavors" that make nicotine dosing more attractive. The study notes the relationship between the marketing of flavored smokeless products and the increase in youth usage.

²⁹ Massachusetts Department of Public Health, *Smokeless Tobacco Advertising Expenditures Before and After the Smokeless Tobacco Master Settlement Agreement: A Report of the Massachusetts Department of Public Health* (May 2002), <http://archives.lib.state.ma.us/bitstream/handle/2452/49479/ocm50878863.pdf>.

³⁰ The Family Smoking Prevention and Tobacco Control Act mandated that no tobacco company can sponsor an event using its product brand name and smokeless tobacco companies can only distribute their products at events under strict guidelines that specify the type of enclosed and secure structures. See: "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents," 75 Federal Register 53 (March 19, 2010), pp. 13225-13232.

³¹ UST website, accessed May 7, 2008.

³² *Rocky Mountain News* (June 22, 1996).

C. Contrary to the Allegations by R.J. Reynolds, It is Not Misleading to Warn the Public that Smokeless Tobacco is Not a Safe Alternative to Cigarettes

The current warning, literally mandated by statute, states, “This product is not a safe alternative to cigarettes.” In a Citizen Petition filed in July of 2011, R.J. Reynolds Tobacco Company (Reynolds or RJR) and its smokeless tobacco subsidiary, American Snuff Company, requested the initiation of a rulemaking proceeding to alter the text of this warning to read: “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”³³ Reynolds concedes that the current warning is true but contends that it is misleading because it implies that smokeless tobacco products are as dangerous as cigarettes when in fact they are not.³⁴ Contrary to Reynolds’ contentions, the warning is not only true, but it is also not misleading. Nothing in the warning states or implies that smokeless tobacco products are as dangerous as cigarettes and Reynolds cites no study relating the language of the warning to any such public understanding.

Reynolds argues that the language of the warning is “radically incomplete” because it does not inform consumers that smokeless tobacco products are not as harmful as cigarettes.³⁵ However, it is not the function of a warning label to provide a comprehensive catalog of information: rather the function of a warning label is to inform consumers of dangers that may occur if they use a product. It is entirely appropriate to frame a warning so that any potential consumer understands clearly that the product poses a health risk. There is no requirement for such a warning to compare the magnitude of that risk to that posed by other products. Such a warning is even more important for a product that has introduced so many young people to tobacco use. Reynolds concedes that the warning informs consumers of dangers actually associated with use of the product. No further proof is needed to support the legality of the warning label.

Reynolds argues that studies show that many consumers mistakenly believe that smokeless tobacco products are as dangerous as cigarettes.³⁶ Even if this were the case, however, Reynolds presents no evidence that links such supposedly mistaken beliefs to the warning labels. Since the warning label neither says nor implies that smokeless tobacco products are as dangerous as cigarettes, Reynolds fails to demonstrate any link between the warning labels and any such mistaken belief. Rather, Reynolds seems to be arguing that because some may believe that smokeless tobacco products are as dangerous as cigarettes, there is an obligation for the government to use the warning label to correct such a belief. Reynolds’ argument fundamentally misconceives the nature and function of warning labels and

³³ RJR Citizen Petition, *supra* note 5, at 1.

³⁴ *Id.* at 3-4.

³⁵ *Id.* at 27.

³⁶ *Id.* at 23.

ignores the provisions of the Tobacco Control Act that enable tobacco product manufacturers to provide such information. Furthermore, adoption of such an amendment could increase the risk that consumers—smokers and non-smokers alike—would erroneously conclude that use of smokeless products is in fact safe or that it is a safe alternative to smoking.

As noted above, although the accuracy of the warning and the harmfulness of smokeless tobacco products is undisputed, the harmfulness of smokeless tobacco products relative to other products containing nicotine is a far more complex issue that depends on (1) the nature of the particular smokeless product; (2) whether the smokeless tobacco product is being used to initiate tobacco use; (3) whether, if it is being used to initiate tobacco use, the user would have initiated tobacco use with another product instead; (4) whether initiation of tobacco use with the smokeless tobacco product makes it more or less likely that the user will eventually become a cigarette smoker; (5) whether current smokers are likely to use the smokeless tobacco product as a means of obtaining nicotine when smoking is not an option (e.g., when they are at work) and thus to prolong their usage of cigarettes; (6) whether current smokers are likely to use the smokeless tobacco product exclusively instead of quitting; (7) whether current smokers are likely to use the smokeless tobacco product instead of using nicotine replacement therapy products that the FDA has found to be safe and effective to promote smoking cessation. These factors are illustrative and not exhaustive of the potentially relevant information. Such issues, however important, cannot all be addressed in a set of warning labels.³⁷

Reynolds' argument also ignores the fact that the Congress itself mandated this specific warning and did so after considering a large amount of evidence presented in extensive hearings.³⁸ Unlike the graphic warning labels for cigarettes that were considered in *R.J. Reynolds v. FDA*, FDA had no role whatsoever in formulating the warnings for smokeless tobacco products. Moreover, Congress mandated these particular warnings only after it had held extensive hearings on and thoroughly considered the arguments that Reynolds raised in its Citizen Petition.³⁹ Congress considered and rejected legislative amendments and alternatives that would have introduced language similar to that which Reynolds is now seeking for the warning labels for smokeless tobacco products.⁴⁰

Reynolds argues that Congress cannot mandate a warning that does not inform consumers that the use of smokeless tobacco products is less harmful than using cigarettes. It claims that the failure to make this disclosure is both misleading and incomplete. However, as

³⁷ Indeed, as the discussion *infra* at Parts III.E.1-4 shows, the scientific evidence on these issues strongly indicates that adoption of RJR's proposed warning would not be beneficial to public health.

³⁸ The history of Congressional consideration of the dangers of ST products vs. cigarettes, and the accuracy of the ST warnings, is presented in detail, *infra* at Part III.F.2.

³⁹ See *infra* at Part III.F.2.

⁴⁰ See *infra* at Part III.F.2.

noted above, there are many issues that the warning does not address. The warning does not say that there are nicotine replacement products that FDA has found to be safe and effective. The warning does not say that some smokeless tobacco products contain far higher levels of carcinogens than other smokeless tobacco products and hence are, potentially, more dangerous. The warning does not say that some smokeless tobacco products contain far higher levels of nicotine or deliver far greater doses of unprotonated nicotine—and hence are far more likely to cause addiction—than other smokeless tobacco products. In short, there is a virtually unlimited catalog of statements that would be necessary to provide consumers with comprehensive information about the dangers of one product in comparison with those of another. A warning label is not invalid simply because it does not provide such comprehensive information.

Congress gave FDA authority to alter the smokeless tobacco warnings if it finds that “such a change would promote greater public understanding of the risks associated with the risks of smokeless tobacco products.”⁴¹ The warnings established by statute are presumptively valid unless and until FDA makes such a finding. A party seeking to persuade FDA that an alteration in the warnings must bear the burden of demonstrating that the change that is sought would promote greater public understanding of the risks associated with smokeless tobacco products. In this case, Reynolds cannot carry this burden. The language it seeks to require FDA to adopt would itself be highly incomplete and misleading and could severely harm the public health objectives of the Tobacco Control Act.

D. Retention of the Warning, “This Product is Not a Safe Alternative to Cigarettes,” Raises No Constitutional Issues.

Reynolds contends that the warning, “This product is not a safe alternative to cigarettes” is an unconstitutional regulation of commercial speech because it is misleading.⁴² However, as discussed at length *infra* at Parts III.E.1-4, the warning is true and not misleading. As such, its retention raises no constitutional issue.

III. FDA SHOULD REJECT ANY ATTEMPT BY TOBACCO COMPANIES TO TRANSFORM SMOKELESS TOBACCO WARNINGS INTO CLAIMS OF MODIFIED RISK

As previously noted, RJR has filed a Citizen Petition requesting the initiation of a rulemaking proceeding to alter the text of one of the statutorily-required smokeless tobacco warnings. The RJR Petition is supported by Philip Morris USA, Inc. (“Philip Morris”), the other major cigarette company that now has a smokeless tobacco subsidiary.

⁴¹ Pub. L. 111-31, section 205; 15 USC 4402(d).

⁴² RJR Citizen Petition, *supra* note 5, at 34-41.

Although presented as a request under Sec. 205 of the TCA to revise the warning labels, in reality the RJR Petition is a transparent attempt to secure FDA's support for the industry's effort to market smokeless tobacco as a safer product than cigarettes without making the demanding evidentiary showing required by Section 911 of the Food, Drug and Cosmetic Act ("FDCA") before a tobacco company may make such a "modified risk" claim. FDA should reject this attempt to evade Section 911 because it would subvert the statutory scheme and have serious adverse consequences for public health.

A. RJR's Suggested Revision of the Smokeless Tobacco Warnings Would Transform Them into Modified Risk Claims in Derogation of the Statutory Framework for Assessing Such Claims

The RJR Citizen Petition charges that the third statutory smokeless tobacco warning – "This product is not a safe alternative to cigarettes" – is misleading because, in RJR's words, "it implies that ST [smokeless tobacco] products and cigarettes present equal risks, whereas the truth is that the scientific consensus is that ST products are substantially less risky or 'safer' than cigarettes."⁴³ RJR asks FDA to substitute this alternative warning: "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes."⁴⁴

As discussed above, there is no basis for RJR's contention that the statutory warning is misleading. Moreover, it is critical to recognize that RJR is expressly and unambiguously asking FDA to allow, *indeed to require*, that a claim of modified risk be made with respect to smokeless tobacco products, in defiance of the statutory scheme carefully constructed in Sec. 911 of the FDCA to regulate such modified risk claims.

If RJR's requested "adjustment" to the statutory warning were to be adopted by FDA, it would have the effect of granting all smokeless tobacco products the status of modified risk tobacco products under Sec. 911. That section defines "modified risk tobacco product" to mean "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." A tobacco product "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" is defined as a tobacco product meeting at least one of several specified conditions. One of those conditions is that "the label, labeling, or advertising of which represents explicitly or implicitly that the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products."

⁴³ RJR Citizen Petition, *supra* note 5, at 4.

⁴⁴ *Id.* at 1.

RJR's proposed "adjusted text" would make an express claim that smokeless tobacco products are "lower risk" than cigarettes – undeniably making smokeless tobacco products "modified risk tobacco products" as that term is defined in Sec. 911, with no necessity for smokeless tobacco manufacturers like RJR and Philip Morris to comply with the Sec. 911 requirements enacted to govern such products.

B. The Rigorous Standards for Modified Risk Claims under Sec. 911 Are Central to the TCA Statutory Scheme and Evasion of Those Standards Should Not Be Permitted

Under Sec. 911(g)(1), the burden is on the applicant seeking to market a modified risk product to demonstrate that the product, "as it is actually used by consumers will (A) significantly reduce harm and risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."

Section 911(g)(4) further delineates the empirical factors the FDA must take into account in determining whether these standards have been met:

(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted "modified risk" product on those who use it, but also its effects on tobacco use initiation, cessation, and relapse in the population as a whole; FDA must also assess the likelihood that smokers would actually switch to the modified risk product. Even if a product were shown to be less hazardous to users than other tobacco products, if its availability and marketing would lead to greater initiation of tobacco use or diminished cessation of tobacco use, the applicant is required by the statute to demonstrate that the benefits of risk reduction to the individual outweigh the impact of the

availability and marketing of the product on initiation and cessation, as supported by scientific evidence. To make the required showing, the applicant would need to offer scientific evidence about consumers' likely response to the availability of the product if marketed as a "modified risk" product. This is evidence of a fundamentally different nature than evidence about the physical effect of using the product.

FDA's Draft Guidance for Industry on Modified Risk Product Applications underscores the rigor of the scientific assessment necessary to approve products with modified risk claims.⁴⁵ Section VI.A., setting out the "Key Areas of Investigation Regarding the Effect" of a Modified Risk Tobacco Product, advises applicants to address not only the "health risks of the tobacco product," but also "the effect the tobacco product and its marketing may have on tobacco use behavior among current tobacco users, the effect the tobacco product and its marketing may have on tobacco use initiation among non-users (both never users and former users), the effect of the tobacco product's marketing on consumer understanding and perceptions, and the effect the tobacco product and its marketing may have on the population as a whole."⁴⁶ The Draft Guidance then provides twelve pages of detailed discussion of the scientific evidence needed to inform each of these considerations.⁴⁷

The RJR Petition does not even purport to address the full range of statutory showings needed to support a claim of modified risk under Sec. 911. To the extent that evidence is presented in the Petition, it purports to concern only the relative physical effects of smokeless tobacco products and cigarettes on the user and the public perception of their relative risks, and omits any evidence bearing on such crucial issues as whether smokeless tobacco products, marketed as lower risk than cigarettes, would cause non-users or lapsed users to begin tobacco use; whether smokeless tobacco products function as a "gateway" to smoking, particularly for young people; whether current smokers would switch to smokeless tobacco products; whether smokers would simply use smokeless tobacco as a "bridge product" in places that do not allow smoking rather than quitting; and other questions essential to evaluating the health impact of smokeless tobacco as a modified risk product on the "population as a whole." These issues are either ignored in the Petition, or are the subject of the kind of unsupported speculation that would never suffice under Sec. 911 (e.g. ". . . [M]any smokers of cigarettes are unwilling to stop consuming tobacco, and are unwilling to use (or have been unsuccessful in using) a medicinal nicotine product to stop, *but might be willing to switch to a less risky type of tobacco product if adequately informed of the relative risks of cigarettes and ST products.*").⁴⁸

⁴⁵ Guidance for Industry, Modified Risk Tobacco Product Applications, *Draft Guidance*, Food and Drug Administration, Center for Tobacco Products (March 2012) ("Guidance for Industry").

⁴⁶ *Id.* at 16-17.

⁴⁷ *Id.* at 17-29.

⁴⁸ RJR Citizen Petition, *supra* note 5, at 4 (emphasis added).

If RJR believes that marketing all smokeless tobacco products (RJR does not distinguish between various types of smokeless tobacco products) as lower risk promotes the public health, it should file a Sec. 911 application as contemplated by the statute. It has not submitted any such application.

C. The Rigorous Statutory Requirements for Modified Risk Products Reflect the Congressional Response to the Tobacco Industry's History of False Claims of Reduced Risk

The demanding standards under Sec. 911 reflect Congress's efforts to halt the perpetuation of the tobacco industry's long and deadly history of making "reduced risk" and other health claims about its products, despite the industry's own knowledge that the claims were false, and despite the industry's recognition that the claims were likely to increase youth initiation of smoking and to discourage some smokers from quitting. For more than fifty years, cigarette manufacturers made health claims that caused millions of Americans to initiate cigarette smoking, who otherwise would not have done so, and caused millions of American smokers to continue smoking, who otherwise would have quit.⁴⁹ The United States District Court for the District of Columbia concluded, after an exhaustive evidentiary presentation, that "Defendants falsely marketed and promoted low tar/light cigarettes as less harmful than full-flavor cigarettes in order to keep people smoking and sustain corporate revenues."⁵⁰ Indeed, the RJR Petition should be viewed as the latest chapter in that tragic story, as RJR, supported by Philip Morris, seeks to enlist the FDA's support in evading the provisions of the TCA specifically enacted to prevent the industry from making unwarranted reduced risk claims.

In enacting the Tobacco Control Act, Congress made specific findings establishing the compelling need to protect the public from the harmful consequences of unsupported claims of reduced harm or marketing designed to discourage quitting or encourage new tobacco users. The Congressional findings made specific reference to the claims made about "light" and "low-tar" cigarettes, noting the National Cancer Institute's finding that "mistaken beliefs about the health consequences of smoking 'low tar' and 'light' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death." Congress further found that "[t]hose who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death." Congress thus found it "essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the

⁴⁹ National Cancer Institute ("NCI"), *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13 (November 2001).

⁵⁰ *U.S. v. Philip Morris, USA, Inc.*, 449 F. Supp. 2d 1, at 430; (D.D.C 2006), *aff'd in relevant part*, 566 F. 3d 1095, at 1121 (2009), *cert. denied*, 130 S.Ct. 3501 (2010).

population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.”

Section 911 was enacted in response to these findings. Congress placed rigorous requirements in the statute for a compelling reason: to prevent the repetition of deadly debacles like the marketing of filtered and low-tar cigarettes. FDA must ensure that tobacco product manufacturers do not evade the Sec. 911 standards.

Congress acted to remedy a long history of industry misconduct involving misleading claims by tobacco product manufacturers about the health consequences of their products. In the 1950s, after evidence of the dangers of cigarette smoking first came to the public’s attention, the industry responded by launching advertising campaigns alleging that adding filters to cigarettes made them less dangerous to health, even though no evidence supported that view. Despite growing evidence that cigarettes cause fatal disease, the incidence of smoking continued to increase, as a large majority of smokers turned to filtered cigarettes in response to the industry’s marketing of them as less harmful than unfiltered cigarettes.⁵¹

In the 1970s, the industry began to promote cigarettes labeled as “light” or “low-tar” as a less harmful alternative, even though the industry was well aware that such cigarettes, as actually used by smokers, were no less dangerous. The industry’s knowingly deceptive marketing was successful, as smokers concerned about their health switched to these brands in huge numbers instead of quitting.

In 2001, the National Cancer Institute issued its extensive monograph on the risks associated with so-called “light cigarettes,”⁵² citing voluminous internal tobacco company documents showing that the companies themselves recognized the inherent deception of advertising that offered cigarettes as “Light” or “Ultra Light,” or as having the lowest tar and nicotine yields.⁵³ Monograph 13 also found that advertisements of filtered and low-tar cigarettes were intended to reassure smokers who were worried about the health risks of smoking, were intended to prevent smokers from quitting based on those concerns, and were successful in getting smokers to use filtered and low-yield brands, even though, as used, they were just as hazardous as conventional cigarettes.⁵⁴ Advertisements for light cigarettes explicitly marketed them as alternatives to quitting. For example, one Lorillard advertising campaign featured an attractive model stating, “Considering all I’d heard, I decided to either

⁵¹ Today approximately 99.5% of the U.S. cigarette market is made up of filtered cigarettes. FTC, *Cigarette Report for 2009 and 2010* (2012), <http://ftc.gov/os/2012/09/120921cigarettereport.pdf>. Data for top five manufacturers only. NCI, *supra* note 49, at 200.

⁵² NCI, *supra* note 49, at 207.

⁵³ *Id.* at 69.

⁵⁴ *Id.* at 222.

quit or smoke True. I smoke True.”⁵⁵ A 2006 study in the *American Journal of Public Health* found that smokers who switched to light cigarettes to reduce health risks were about 50 percent less likely to quit smoking than those who smoked non-light cigarettes.⁵⁶

The voluminous evidence of the industry’s use of these false health-related claims was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris, U.S.A., Inc.*⁵⁷ and furnished critical support for the Court’s conclusion that the defendant tobacco companies had engaged in an illegal conspiracy to defraud the American public. The Court found:

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.⁵⁸

The Court further found that the industry knew these health claims were false:

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.⁵⁹

The most recent report of the Surgeon General, *Preventing Tobacco Use Among Youth and Young Adults*, released in March 2012, presents additional evidence that health claims by major tobacco companies, particularly those marketing light and low-tar cigarettes, may have increased youth initiation to cigarettes.⁶⁰ Moreover, despite the fact that the Tobacco Control Act now prohibits the use of the deceptive terms “light,” “mild” and “low-tar,” tobacco companies are using color-coding schemes to evade the ban and perpetuate the “safer

⁵⁵ Magazine advertisement, 1976.

⁵⁶ Tindle, HA, et al., “Cessation Among Smokers of ‘Light Cigarettes’: Results from the 2000 National Health Interview Survey,” *American Journal of Public Health* 96(8): 1498-504 (August 2006).

⁵⁷ 449 F. Supp.2d 1 at 430 (D.D.C. 2006), *aff’d in relevant part*, 566 F.3d 1095 at 1121 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

⁵⁸ *Id.* at 430.

⁵⁹ *Id.* at 430-31.

⁶⁰ HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (2012).

cigarette” deception.⁶¹ Lighter-colored packaging is now used for “light” brands, and terms like “gold” and “silver” have replaced “light” and “ultra-light”. For example, consumers who previously smoked Marlboro Lights were told that they could now purchase “Marlboro Gold” and “Marlboro Silver.”⁶² Philip Morris placed inserts on packs of Marlboro Lights reading “Your Marlboro Lights package is changing, but your cigarette stays the same” and directing customers to “in the future, ask for Marlboro in the gold pack.”⁶³

Even after the fraud of “light” and “low-tar” cigarettes was exposed, major tobacco companies continued to make baseless health claims for their products. For example, RJ Reynolds was found by a state court to have violated the provision in the Master Settlement Agreement of 1998 in which RJR and the other signatory tobacco companies agreed not to make material misrepresentations about the health consequences of their products, as well as a state anti-fraud statute. The court found that RJR had improperly made claims that its product, Eclipse, “compared to other cigarettes . . . may present less risk of cancer, chronic bronchitis, and possibly emphysema” and that such claims constituted material misrepresentations within the meaning of the agreement.⁶⁴

D. The RJR Petition Must be Seen as a Key Component of the Tobacco Industry’s Broad “Harm Reduction” Strategy

The RJR Petition is not only a continuation of the decades-old industry strategy of deception in marketing “safer” tobacco products, but it also must be seen as part of a broader industry campaign to promote smokeless tobacco in particular as a “harm reducing” product without having to make the scientific showings mandated by Sec. 911.

For example, RJR’s new website promising to “Transform Tobacco” embraces a “harm reduction” strategy based on the promotion of smokeless tobacco products as an alternative to cigarette smoking. Particularly in light of the claims on the website by RJR’s parent company, Reynolds American, Inc. (RAI), that “RAI’s operating companies are committed to engaging with the Food and Drug Administration on the issue of tobacco harm reduction and education,” the failure of RJR to file an application for its smokeless tobacco products to substantiate its claims according to the standards of Sec. 911 is notable.

Recently, tobacco companies have begun to encourage state health departments and state legislatures, including those in Oklahoma, Kansas and Indiana, to effectively circumvent

⁶¹ Connolly, GN & Hillel, AR, “Has the tobacco industry evaded the FDA’s ban on ‘Light’ cigarette descriptors?” *Tobacco Control* 0: 1-9 (2013). (pub. ahead of printing)

⁶² Duff Wilson, “Coded to Obey Law. Lights Become Marlboro Gold,” *New York Times* (February 18, 2010).

⁶³ Duff Wilson, “FDA seeks explanation of Marlboro Marketing,” *New York Times* (June 17, 2010).

⁶⁴ *State of Vermont v. R.J. Reynolds Tobacco Company*, 2010 Vt. Super. LEXIS 11 (Vt. Super. 2010).

FDA altogether by promoting smokeless tobacco as less harmful than smoking, even diverting tobacco prevention funding to this approach.

In April of 2012, Ronald Hein, on behalf of an RJR affiliate, RAI Services Company (“RAI Services”), gave testimony before a Kansas legislative committee supporting a resolution to direct the Kansas Department of Health and Environment to “research the science regarding tobacco harm reduction,” and asserting that smokers “can significantly reduce their healthcare risks by switching from smoking to other smokeless tobacco alternatives.”⁶⁵ Similarly, in September 2012, former Indiana Congressman Stephen Buyer, acknowledging that he is now a “paid consultant” to RAI, testified before the Health Finance Commission of the Indiana General Assembly in favor of “Harm Reduction Strategies” with respect to tobacco products and arguing – similar to RJR’s Petition – that warnings like the statutory warnings on smokeless tobacco products are misleading because smokeless tobacco products are far safer than cigarettes.⁶⁶ At no point in the testimony of Mr. Hein or Mr. Buyer did they acknowledge the existence of the federal statutory scheme established specifically to provide federal oversight and rigorous criteria before a manufacturer can make a health-related claim for any tobacco product. Nor did they explain why RJR has failed to use the statutory process under Sec. 911 to obtain regulatory review for such claims.

It is disingenuous for RJR, in its Petition, to offer the assurance that “[t]his petition . . . does not ask the Commissioner to embrace an overarching tobacco harm reduction policy,” insisting that the Petition concerns only “a misleading warning label statement”⁶⁷ According to the Petition, “[a]lthough we believe that sufficient scientific information exists to justify the inclusion of ST products in a harm-reduction framework, that is an issue for another day.”⁶⁸ A grant of RJR’s petition would constitute an endorsement of smokeless tobacco use by the FDA (and therefore the United States Government), as a “harm reduction” tobacco product. Of even greater significance, the FDA would have implicitly adopted a far-reaching “harm reduction” strategy completely outside the parameters of the statutory provision (Sec. 911) specifically designed to address such “harm reduction” issues. RJR says the broad “harm reduction” issue is one “for another day,” while conspicuously avoiding taking the very action contemplated by the Act to raise that issue: an application for approval of a “modified risk” claim under Sec. 911.

⁶⁵ Testimony re: HR 6026, House Federal and State Affairs Committee, Presented by Ronald R. Hein on behalf of RAI Services Company (April 26, 2012).

⁶⁶ Prepared Testimony by Stephen E. Buyer, Health Finance Committee, Indiana General Assembly, Hearing on HR 59, Tobacco harm reduction strategies to reduce smoking – attributable death and disease, September 19, 2012. Buyer also sought—unsuccessfully—to change federal law while he was a Member of Congress to mandate the reduced-risk warning for smokeless products.

⁶⁷ RJR Citizen Petition, *supra* note 5, at 5.

⁶⁸ *Id.*

Any doubt about the tobacco industry’s agenda behind the RJR Petition is removed by the comments in support of the Petition filed on behalf of Philip Morris USA Inc. (“Philip Morris”) by Altria Client Services Inc.⁶⁹ With a degree of candor missing from the RJR Petition itself, Philip Morris unabashedly urges the FDA to “encourage harm reduction,” asserting that “[t]he critical scientific knowledge needed to start down the path of harm reduction is available,”⁷⁰ but ignores the criteria and process set out in Sec. 911. According to Philip Morris, “[t]here is growing consensus that public health policies based solely on prevention and cessation, however, are not sufficient in the real world” because “[m]illions of adults are likely to continue using tobacco products, notwithstanding efforts by government, public health, and others to encourage them not to use tobacco at all.”⁷¹ Philip Morris has made clear what RJR seeks to obscure: that the RJR Petition is designed to facilitate the tobacco industry’s campaign to push all smokeless tobacco products as “harm reduction products” while evading the scheme carefully crafted by Congress to ensure that any “harm reduction” product claims be supported by rigorous science that includes consideration of the population impact of labeling and marketing a tobacco product as RJR seeks.

E. The Available Evidence Indicates that Revising the Statutory Smokeless Warnings to Include a Claim of Modified Risk Would Not Benefit Public Health

As noted, the RJR Petition makes no effort to offer scientific evidence supporting a population-wide public health benefit from promoting smokeless tobacco products as “harm reduction” products. Indeed, the available evidence suggests that using smokeless tobacco products as part of a “harm reduction” strategy likely would adversely affect public health. There is substantial evidence that, instead of causing smokers to quit smoking altogether and commence use of smokeless tobacco products as a smoking substitute, the marketing of smokeless tobacco products as “safer than cigarettes” is more likely to lead to greater initiation of tobacco products, including cigarettes, particularly among young people, as well as to encourage smokers to become high-risk “dual users” of cigarettes and smokeless tobacco products, rather than quitting smoking altogether using far safer nicotine replacement therapies and other cessation aids.

⁶⁹ Docket No. FDA-2011-P-0573 – Comments on Citizen Petition filed by R.J. Reynolds Tobacco Company, Altria Client Services (February 6, 2012).

⁷⁰ *Id.* at 9.

⁷¹ *Id.* at 2-3.

1. The Scientific Evidence Does Not Support the Premise that Smokers Would Switch to Exclusive Smokeless Tobacco Use

First, there is no strong evidence that the availability of smokeless tobacco products causes smokers to stop smoking and switch to smokeless tobacco products. The advocates of smokeless tobacco for harm reduction rely almost entirely on the experience with a specific smokeless tobacco product, Swedish Snus, in arguing for the likelihood that smokers will switch to smokeless products. Some studies have found that increased use of Snus among Swedish men is associated with a greater drop in smoking prevalence among men than among women. However, “[m]any have cautioned that the Swedish results could be a country-specific phenomenon due to unique historical and cultural factors associated with snus use.”⁷² There are many reasons why the Swedish experience may be inapplicable to the United States. For example, in Sweden, no advertising of cigarettes is allowed and no claims related to the relative risk of snus were permitted. Moreover, smokeless tobacco products sold in Sweden have significantly lower levels of toxicants than those sold in the United States and products that do not meet the Gothiatek standard have not been permitted to be sold in Sweden. Swedish snus has virtually no market in the United States and no such product standard applies. As a result, the products actually sold in the United States are far more likely to cause death and disease. Indeed, the Swedish experience has not been replicated elsewhere. In Norway, for example, the prevalence of smokeless tobacco use among males aged 16-24 years increased from 9 percent in 1985 to 21 percent in 2002, while the prevalence of cigarette smoking remained relatively constant.⁷³

Of greatest significance, the Swedish experience has not been replicated in the United States. One U.S. longitudinal study found that few male smokers stopped smoking and switched to smokeless tobacco (0.3% in one year) and few former smokers turned to smokeless tobacco (1.7%).⁷⁴ Instead, smokeless tobacco users were more likely to switch to cigarettes. The study further found that the quit rate for smokeless tobacco was three times higher than for smoking and that men, who are far more likely to be using smokeless tobacco, quit smoking at lower rates than women (11.7% vs. 12.4%). The study concluded that “smokeless tobacco is less useful for quitting smoking among U.S. smokers because in all likelihood they would quit smokeless tobacco before they quit cigarettes.”⁷⁵

⁷² Zhu, S-H, et al., “Quitting Cigarettes Completely or Switching to Smokeless: Do U.S. Data Replicate the Swedish Results?,” *Tobacco Control* 18: 82-87 (2009).

⁷³ Tomar, SL, et al., “Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm?,” *International Journal of Environmental Research and Public Health* 6: 10-24 (2009).

⁷⁴ Zhu, *supra*, note 72, at 85.

⁷⁵ *Id.* at 86.

The science supports the conclusion of the U.S. Public Health Service in the 2008 Update of its Clinical Practice Guidelines: “The use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective to helping smokers quit.”⁷⁶

2. There Is a Significant Risk that Promotion of Smokeless Tobacco as a Harm Reduction Strategy Would Lead to Greater, and More Dangerous, Dual Use

The available evidence suggests that it is far more likely that the promotion of smokeless tobacco products as “safer than cigarettes” would lead to increased, and more dangerous, dual use of smokeless tobacco and cigarettes than to substitution of smokeless tobacco products for cigarettes.

The evidence indicates that smokers in the U.S. use smokeless tobacco products in conjunction with smoking, rather than switching entirely. Dual use has become particularly common among young smokers. 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.⁷⁷ An analysis of data from four large U.S. nationally representative surveys found that “the prevalence of daily smoking is very high among male students in middle school and high school who use smokeless tobacco.”⁷⁸ For 12th grade males, the prevalence of smoking one-half pack of cigarettes or more per day was nearly five times greater among smokeless tobacco users than non-users.⁷⁹

Results from the Minnesota Adult Tobacco Survey show a significant increase in the prevalence of smokeless tobacco use and smokers using smokeless tobacco between 2007 and 2010.⁸⁰ Smokeless tobacco use by smokers doubled, whereas no similar increase was observed among former smokers or never smokers.⁸¹ These results indicate that the increase in smokeless tobacco use was largely due to current smokers using concurrently, not to smokers switching to smokeless tobacco.

A revealing study of a large group of U.S. Air Force airmen who had been forbidden to use tobacco during basic training showed little use of smokeless tobacco as a harm reduction

⁷⁶ Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline (May 2008), http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

⁷⁷ SAMHSA, *supra* note 21, at 5.

⁷⁸ Tomar, SL, “Patterns of Dual Use of Cigarettes and Smokeless Tobacco among U.S. Males: Findings from National Surveys,” *Tobacco Control* 19: 104-109 (2010).

⁷⁹ *Id.* at 105.

⁸⁰ Boyle, R, et al., “Concurrent Use of Cigarettes and Smokeless Tobacco in Minnesota,” *Journal of Environmental and Public Health* doi:10.1155/2012/593109 (2012).

⁸¹ *Id.* at 3.

strategy 12 months after basic training ended.⁸² The use of smokeless tobacco for harm reduction was rare, with only 0.9 percent of those who were smokers at the outset of basic training giving up cigarettes and switching to smokeless tobacco products. By contrast, 5.6 percent (or five times as many) smokers demonstrated harm escalation by initiating smokeless tobacco use in addition to maintaining their smoking habit.⁸³ The study also showed significant harm escalation among smokeless tobacco users, with 14 percent of smokeless tobacco users at the outset of basic training switching to cigarettes and another 14.5 percent of smokeless tobacco users becoming dual users.⁸⁴ These results suggest smokeless tobacco may well be a gateway to smoking.

The risk of greater dual use is particularly significant in light of evidence that dual users are less likely to quit than are exclusive smokers or exclusive smokeless tobacco users.⁸⁵ Moreover, as one study concluded, “Because the health risks associated with cigarettes and ST are different in some respects, and because their effects may be additive if not synergistic, the concomitant use of cigarettes and ST may increase the risk of tobacco-attributable death and disease relative to use of either product alone.”⁸⁶ This risk was borne out by a 2006 case-control study across 52 countries that found that smokers who also chewed tobacco had the highest increase in risk of heart attack compared to exclusive smokers or chew tobacco users.⁸⁷

3. Studies Show that Smokeless Tobacco Is a Gateway to Smoking

The studies discussed above suggest that smokeless tobacco products already function as a gateway to smoking, a deadly effect likely to be enhanced were smokeless tobacco to be promoted as a harm reduction product. As noted, the longitudinal study by Zhu, et al., found that it was more likely for smokeless tobacco users to switch to cigarettes than for smokers to switch to smokeless tobacco. The military cohort study by Klesges et al. also found significant harm escalation by smokeless tobacco users to cigarettes.

Other studies provide additional data pointing to smokeless tobacco as a gateway to smoking, particularly for young people. Using data from the 1989 and 1993 national Teenage

⁸² Klesges, RC, et al., “Tobacco Use Harm Reduction, Elimination, and Escalation in a Large Military Cohort,” *American Journal of Public Health* 100(12): 2487-2492 (December 2010).

⁸³ *Id.* at 2489.

⁸⁴ *Id.*

⁸⁵ Klesges, et al., *supra* note 82, at 2490 (“Importantly, dual users were less likely to become tobacco abstinent than were smokers or smokeless tobacco users”); Wetter, D, et al., “Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation,” *Preventive Medicine* 34: 638-648 (2002) (“Concomitant users were significantly less likely to quit using tobacco over the course of 4 years than were users of cigarettes or ST.”).

⁸⁶ Wetter, et al., *supra* note 85, at 647.

⁸⁷ Teo, K, et al., “Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: a case-control study,” *The Lancet*, 368: 647-658 (August 19, 2006).

Attitudes and Practices Survey, one study found that adolescent males who were smokeless tobacco-only users were more than three times as likely as never smokeless tobacco-users to become cigarette smokers within the following four years.⁸⁸ Severson et al. followed a cohort of adolescent boys in grades seven and nine who were smokeless tobacco-only users for two years. They found that initiation of weekly smoking in grades nine and eleven was significantly associated with baseline smokeless tobacco use, even after controlling for other risk factors.⁸⁹ The odds of being a weekly smoker after two years were more than 2.5 times greater for smokeless tobacco users than nonusers.⁹⁰ More than half (57.3%) of smokeless tobacco users later reported smoking cigarettes.⁹¹

Another study tracking the initiation of smoking in adolescents in grades seven and nine revealed that smokeless tobacco use was the strongest predictor of smoking two years later, even when controlling for other factors, such as parental, sibling and friend smoking, GPA and alcohol use.⁹² In a military cohort study of almost 8,000 young adult male Air Force recruits who had not smoked in the past year, both current and former smokeless tobacco users were more than twice as likely as never users to begin smoking.⁹³ A 2002 study found that “snuff use may be a gateway form of nicotine dosing among males in the United States that may lead to subsequent cigarette smoking.”⁹⁴ The study found that “the prevalence of smoking was substantially higher among men who had quit using snuff than among those who had never used snuff, suggesting that more than 40% of men who had been snuff users continued or initiated smoking.”⁹⁵

According to a review of the research, “the preponderance of evidence suggests that ST use is a predictor of cigarette smoking in the United States.”⁹⁶ There is every reason to believe that promotion of smokeless tobacco as a harm reducer will lead to greater smokeless tobacco use and, eventually, to a greater incidence of smoking, exactly the opposite effect predicted by advocates of smokeless tobacco products as harm reduction products.

⁸⁸ Tomar, S, et al., “Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience,” *Nicotine & Tobacco Research* 5(4): 561-569 (August 2003).

⁸⁹ Severson, H, et al., “Use of smokeless tobacco is a risk factor for cigarette smoking,” *Nicotine and Tobacco Research* 9(12): 1331-1337 (December 2007).

⁹⁰ *Id.* at 1335.

⁹¹ *Id.* at 1334.

⁹² Forrester, K, et al., “Predictors of smoking onset over two years,” *Nicotine and Tobacco Research*, 9(12): 1259-1267 (December 2007).

⁹³ Haddock, CK, et al., “Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males,” *Preventive Medicine* 32: 262-267 (2001).

⁹⁴ Tomar, S, “Snuff Use and Smoking in U.S. Men: Implications for Harm Reduction,” *American Journal of Preventive Medicine*, 23(3): 143-149 (October 2002).

⁹⁵ *Id.*

⁹⁶ Tomar, *supra* note 73, at 16.

4. The Promotion of Smokeless Tobacco by Major Cigarette Companies is Calculated to Keep People Smoking and Maintain Cigarette Sales

As noted above, both Reynolds and Philip Morris have acquired smokeless tobacco companies in recent years and have become dominant players in the smokeless tobacco market. These acquisitions profoundly changed the objectives of the smokeless tobacco companies. Whereas unaffiliated smokeless tobacco manufacturers were in competition with cigarette manufacturers for consumers of tobacco products, cigarette companies that own smokeless tobacco producers have every incentive to manipulate the promotion of smokeless tobacco products in ways that will ensure the profitability of the cigarette market. They have no incentive to promote smokeless tobacco in ways that reduce demand for cigarettes. The words, and the conduct, of the two leading cigarette manufacturers reflect this market reality.

In a November, 2012 presentation to investors, Daniel Delen, President and CEO of Reynolds American Inc. (“RAI”), the parent company of RJR, stated:

We have a little mantra inside of the company that we use, which we call the 80-90-90 . . . We spend about 80 percent of our resources in the combustible space. The combustible space is still 80 percent, 80-plus percent of our operating income. We spend the majority of our resources still in the combustible space. 90 percent of the organizational focus, the human resources inside the company, are actually focused on the combustible space. And despite a lot of these new innovations that you see coming out 90 percent of our R&D budgets are actually directed at the combustible category . . . That is the category that’s still going to deliver a lot of growth into the future . . . ”⁹⁷

For all the talk by RJR about pursuing “harm reduction” through smokeless tobacco products, Mr. Delen leaves no doubt that the company’s top priority is ensuring the growth of the cigarette market and that 90% of the organization’s assets are directed toward that objective.

The notion that the tobacco industry is genuinely interested in using smokeless tobacco to wean addicted smokers from cigarettes also is belied by how they use their marketing dollars. Tobacco companies spend almost \$8.5 billion annually marketing cigarettes and smokeless tobacco products. Of this amount, they spend 18 times more money to market cigarettes – which these companies say are their deadliest products – than to market smokeless tobacco, which they claim is far less harmful than cigarettes.⁹⁸

Cigarette manufacturers have developed new smokeless products, including moist snuff and snus brands, with promotion aimed at cigarette smokers. Several of these new brands

⁹⁷ Transcript from November 12, 2012 RAI Investor Day Presentation.

⁹⁸ FTC, *supra* note 27; FTC, *supra* note 51.

carry the names of popular cigarette brands (e.g. Camel Snus and Marlboro Snus). These products have been positioned in the market as “bridge products” to counter the impact of smoke-free laws that can be a powerful incentive for smokers to quit. Smokeless tobacco producers increasingly have used phrases in their marketing such as “when smoking isn’t an option”⁹⁹ and “tobacco pleasure to enjoy virtually anywhere,”¹⁰⁰ to tell smokers they can use smokeless tobacco when smoking is not allowed instead of quitting smoking altogether. Camel Snus marketing materials describe the product as “A tasty new tobacco pleasure for wherever,” and “You can Snus virtually anywhere, from work to bars to trains to your fussy friend’s party.”¹⁰¹ RJR currently is placing ads in airline magazines for Camel Snus, with an appeal to flyers who “can’t wait to get out of the cabin for a smoke” and encouraging them to “pack a tin on your next flight” and use Camel Snus “virtually anytime, anywhere.”¹⁰² Philip Morris has conducted an advertising campaign that explicitly urges dual use by highlighting to consumers that its smokeless tobacco product foilpack “rides perfectly alongside your smokes. Just slip one in your pocket, head out and you’re good to go almost anywhere anytime.”¹⁰³

A review of internal tobacco industry documents showed that “tobacco manufacturers, including cigarette and [smokeless tobacco] companies, have developed and targeted new [smokeless tobacco] products to exploit cigarette smokers.”¹⁰⁴

Cigarette manufacturers were initially focused on developing alternative smokeless products for smokers who would otherwise quit because of the changes in the cigarette market. Over time, the cigarette companies appear to have focused their efforts on products designed to augment cigarette use when smoking is not possible, thus offsetting regulatory strategies such as clean indoor air laws.¹⁰⁵

Indeed, in 2003, RJR (which acquired American Snuff in 2006) said this about positioning smokeless tobacco products for success: “There is a need to clearly position the product as a *situational* substitute for cigarettes, rather than a replacement. Communication of secondary

⁹⁹ Marlboro Snus direct mail advertisement, 2010, accessed October 18, 2012 from <http://www.trinketsandtrash.org/detail.php?artifactid=6184>.

¹⁰⁰ Accessed October 18, 2012 at <http://www.trinketsandtrash.org/detail.php?artifactid=6684>.

¹⁰¹ Carpenter, CM, et al., “Developing smokeless tobacco products for smokers: an examination of tobacco industry documents,” *Tobacco Control* 18:54-59 (2009).

¹⁰² US Airways magazine, 2011, accessed October 18, 2012 from <http://www.trinketandtrash.org/detail.php?artifactid=7029>.

¹⁰³ Marlboro Snus direct mail advertisement, 2009, accessed October 18, 2012 from <http://www.trinketsandtrash.org/detail.php?artifactid=6358>.

¹⁰⁴ Carpenter, *supra* note 101, at 57.

¹⁰⁵ *Id.*

benefits (e.g. no odor, no second-hand smoke) may help smokers rationalize the use of a product they would rather not admit they need.”¹⁰⁶

Thus, it is hardly surprising to see an upsurge in dual use of smokeless tobacco and cigarettes. Nor is it surprising to see that smokeless tobacco is not being used as a substitute for smoking. A 2011 study based on U.S. consumer survey data showed that two-thirds (67.7%) of dual users reported using smokeless tobacco in places where they couldn’t smoke, and the majority (75.1%) did not think smokeless tobacco would help them quit smoking. Dual users reported more often than smokers that they would never quit.¹⁰⁷ The use of smokeless tobacco to ensure that smokers remain addicted to cigarettes is in the interest of the major cigarette manufacturers and has been the central focus of their promotion of smokeless tobacco.

5. Rather than Misusing the Warning Label Provisions of the TCA to Sponsor Modified Risk Claims for Deadly Smokeless Tobacco Products, FDA’s Regulatory Policy Should Maximize the Effectiveness of Cessation Products Proven to be Safe and Effective

Instead of allowing the misuse of the warning label provisions of Sec. 204 and 205 to sponsor modified risk claims for deadly smokeless tobacco products in derogation of the strict requirements of Sec. 911, FDA should direct its regulatory policy toward the far safer alternative of maximizing the use and impact of nicotine reduction therapies already found to be “safe and effective.”

The intent of Congress that FDA explore ways to expand the use of approved NRTs and other cessation products is clear from Sec. 918 of the FDCA, which directs FDA to consider the use of fast track authority with respect to approval of cessation products, as well to consider approval of the extended use of NRTs, as well as the approval of additional indications for NRTs, such as for craving relief or relapse prevention. Sec. 918 also requires FDA to submit to Congress a report examining how best to regulate, promote, and encourage the development of innovative products to treat tobacco dependence in a manner that best protects public health. Pursuant to Sec. 918, FDA’s Center for Drug Evaluation and Research (CDER) recently convened a public hearing, and accepted written comments, on various issues raised by Sec. 918.¹⁰⁸

We commend FDA for commencing the Sec. 918 proceeding and urge the agency to explore every available alternative for maximizing the use of products already approved for the

¹⁰⁶ R.J. Reynolds, “Project MARS, Hard Tobacco” (2003), Bates No. 532800973/1084 (emphasis in original). Carpenter, *supra* note 101, at 56.

¹⁰⁷ McClave-Regan, A, et al., “Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users,’” *Tobacco Control* 20: 239-242 (2011).

¹⁰⁸ 77 Fed. Reg. 70955 (November 28, 2012).

treatment of tobacco dependence. As noted by several commenters in that proceeding, with the passage of the TCA and creation of the Center for Tobacco Products, FDA through the Center for Tobacco Products and CDER, now has the authority to regulate tobacco and all other nicotine products in all their forms.¹⁰⁹ FDA can best serve public health by establishing a regulatory scheme that will both reduce the use of tobacco products that addict and kill, while increasing the availability, effectiveness and use of nicotine and other products that can help people quit using tobacco products that cause death and disease. This would apply FDA resources consistent with the statutory scheme established by Congress—a scheme designed to ensure that industry claims of “safer” tobacco products are scientifically sound.

F. FDA Sponsorship of Modified Risk Claims Through Revision of the Statutory Smokeless Tobacco Warnings Would be Inconsistent with the Intent of Congress

The text of the smokeless tobacco warning provisions of the TCA, and the legislative history of the statute, along with previous Congressional consideration of warning labels on smokeless tobacco, show that Congress could not have intended that Sec. 205(a) be the basis for FDA to sponsor modified risk claims for smokeless tobacco.

1. The Text of Sec. 205(a) Provides No Support for Its Use to Make Modified Risk Claims

Although it relies on Sec. 205(a) of the TCA as the basis for revising the statutory smokeless tobacco warnings to make a claim of modified risk, the RJR Petition never quotes the entirety of the relevant text. Read in its entirety, the pertinent language does not support the use of a warning label to make a modified risk claim.

Sec. 205(a) reads:

AUTHORITY TO REVISE WARNING LABEL STATEMENTS. The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

¹⁰⁹ See e.g. Comments of Campaign for Tobacco-Free Kids responding to request comments on Actions Related to Nicotine Replacement Therapies and Smoking-Cessation Products; Report to Congress on Innovative Products and Treatments for Tobacco Dependence (January 16, 2013) at 2.

It is apparent that this language was intended to enable FDA to make adjustments to the statutory warnings in order to enhance the impact and effective communication of messages conveying the grave health risks of smokeless tobacco, not to convert the statutory warnings into claims of modified risk for smokeless tobacco. Thus, for example, the agency is given the authority to require color graphics to more effectively communicate the health risks of smokeless tobacco. It also is significant that the language gives FDA the authority only to *increase* the area occupied by the warnings; no authority is given to *decrease* it. The text speaks to FDA's authority to revise the warnings to enhance public understanding of the "*risks* associated with the use of smokeless tobacco products" (emphasis supplied), not of the benefits of using smokeless tobacco versus other tobacco products. Indeed, the language of modified risk RJR seeks to add – "this product presents substantially lower risks to health than cigarettes"—is not a "warning" at all, but rather a recommendation for use. It is simply implausible on the face of Sec. 205(a) that Congress intended the warning label provisions of the statute to be the basis for a claim of modified risk, particularly given the rigorous pathway and standards established in Sec. 911 to address precisely those kinds of claims.

2. The Legislative History of the TCA, and the History of Congress' Consideration of Smokeless Tobacco Warnings, Do Not Support the Use of Smokeless Tobacco Warning Labels to Make Claims of Modified Risk

Three of the four current statutory smokeless tobacco warnings, including the warning "This product is not a safe alternative to cigarettes," originated with Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (STA), under which the Federal Trade Commission had authority over enforcement of the smokeless tobacco warnings. Section 204 of the TCA amended Section 3 of the STA to add a fourth warning about the addictiveness of smokeless tobacco, and to specify the format for the warnings on packaging and advertisements.

While Congress was considering comprehensive tobacco control legislation, it heard repeated testimony from proponents of smokeless tobacco contending that smokeless tobacco causes less harm to health than cigarettes, as well as suggestions that the warning labels be revised just as RJR does in its Petition. However, Congress opted, in the TCA, to retain the "no safe alternative" warning and to reject proposals to convert the warning to a claim of modified risk. Indeed, in the TCA, Congress added a warning about addictiveness, a statutory change at odds with a legislative intent to allow the FDA to alter the warnings to state that smokeless tobacco is "safer" than other products.

The operative text of Sections 204 and 205 of the TCA closely parallels the analogous provisions in S. 1415, the 1998 tobacco control legislation introduced by Senator John McCain

(R-Ariz.). The 1998 Senate Commerce, Science, and Transportation Committee report on S. 1415 stated that the purpose of defining the warning label format was to provide “new *more emphatic* warnings for smokeless tobacco labels, packaging and advertising.”¹¹⁰ Section 204 of the TCA only slightly modified Section 303 of S. 1415, including increasing the area that the warning must occupy on smokeless tobacco packaging from 25% to 30%, thus making the warnings even more noticeable than proposed in S. 1415.

Sec. 205 of the TCA, granting FDA authority to revise the warning labels, was based on Sec. 304 of S. 1415. Notably, Sec. 205 gave FDA express authority to increase the warning label area on the package from 30% to 50%, and to accompany the text with color graphics, authority not expressly given in S. 1415. Thus, the current statutory language is stronger than its predecessor legislation, which itself was described by a Senate Committee as providing for “more emphatic” warnings.

During the period of Congressional consideration of comprehensive tobacco control legislation following the 1998 McCain bill and leading to the enactment of the TCA in 2009, there were extensive hearings at which Members of Congress, smokeless tobacco-sponsored researchers, industry representatives, and others, testified and submitted voluminous evidence about the issue of smokeless tobacco as a reduced risk product. On numerous occasions, both witnesses at Congressional hearings and Members of Congress urged changes in the statutory warnings.

On June 3, 2003, there were hearings in two different House Committees on the issue. The House Committee on Energy and Commerce convened a hearing on the subject, “Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction.”¹¹¹ Smokeless tobacco was the central focus of this hearing. In his opening statement, Rep. Cliff Stearns (R-Fl.), Chairman of the Subcommittee on Commerce, Trade and Consumer Protection, claimed “there is an increasing amount of research suggesting that some tobacco products are less harmful than others,” suggesting that for smokers “who can’t seem to quit smoking, switching to a less hazardous product could save lives.”¹¹² Several witnesses, including Dr. Brad Rodu, a researcher supported by the smokeless tobacco industry, and Richard Verheij, Chairman of U.S. Smokeless Tobacco, testified in support of smokeless tobacco as a harm reduction product. The proposal to alter the smokeless tobacco warnings to make a modified risk claim was specifically discussed during the hearing, with Rep. Gene Green (D-Tx.) opposing the idea because:

¹¹⁰ S. Rep. No. 105-180 (May 1, 1998), at 36 (emphasis added).

¹¹¹ “Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction,” Hearings before House Committee on Energy and Commerce, No. 108-31 (June 3, 2003).

¹¹² *Id.* at 2.

These warnings all send the same message. Smokeless tobacco is hazardous to your health. For the FTC to consider a label effectively promoting smokeless tobacco as a lower risk alternative to cigarette smoking, however, sends a very different message. . . Not only is this message mixed. It also is based on questionable science.¹¹³

Surgeon General Richard Carmona also spoke to the warnings issue:

I cannot recommend the use of smokeless tobacco products because there is no scientific evidence that smokeless tobacco products are both safe and effective aids to quitting smoking. Smokers who have taken the courageous step of trying to quit should not trade one carcinogenic product for another, but instead could use Food and Drug Administration approved methods, such as nicotine gum, nicotine patches or counseling.¹¹⁴

On the same day, the House Committee on Government Reform convened a hearing on a similar topic, “Potential Reduced Exposure/Risk Tobacco Products: An Examination of the Possible Public Health Impact and Regulatory Challenges,” which included testimony from the National Cancer Institute, the Institute of Medicine, the FTC and smokeless tobacco and cigarette industry executives.¹¹⁵ During that hearing, Richard Verheij of UST again testified, raising the question, “what obligation does the Federal Government and the public health community have to communicate to adult smokers who are not quitting that . . . smokeless tobacco is significantly less harmful?”¹¹⁶ Dr. Dorothy Hatsukami, of the University of Minnesota Medical School, cautioned the Committee that even though “individuals may show a reduction in tobacco toxin exposure...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.”¹¹⁷

Congressional consideration of smokeless tobacco as a harm reduction product continued in 2007 during Senate hearings on S. 625, the tobacco control bill introduced in the 110th Congress to give FDA authority to regulate tobacco.¹¹⁸ That hearing featured specific testimony objecting to a larger warning label stating “This product is not a safe alternative to cigarettes,” because it does not inform smokers “that smokeless tobacco products pose fewer morbidity and mortality risks than cigarettes,”¹¹⁹ exactly the argument RJR makes in its Petition.

¹¹³ *Id.* at 29.

¹¹⁴ *Id.* at 41.

¹¹⁵ “Potential Reduced Exposure/Risk Tobacco Products: An Examination of the Possible Public Health Impact and Regulatory Challenges,” Hearings before the House Committee on Government Reform (June 3, 2003).

¹¹⁶ *Id.* at 315.

¹¹⁷ *Id.* at 126.

¹¹⁸ “The Need for FDA Regulation of Tobacco,” Hearings before the Senate Committee on Health, Education, Labor and Pensions (February 27, 2007).

¹¹⁹ *Id.* at 129 (written testimony of Bill Godshall).

Indeed, the hearing record contains a proposal by two of the witnesses that the current warning be replaced with a warning similar to that proposed by RJR: “Warning: Smokeless tobacco use has risks, but cigarette smoking is far more dangerous.”¹²⁰

Several months later, the issue again was addressed in House hearings on “The Family Smoking Prevention and Tobacco Control Act.”¹²¹ For example, then-Rep. Buyer (R-Ind.) endorsed the idea of “moving people from cigarettes to smokeless tobacco as a harm reduction strategy.”¹²² In response to a question from Rep. Buyer about whether smokeless tobacco should be considered a safer alternative to smoking, Professor Richard Bonnie of the University of Virginia School of Law expressed skepticism about the idea that a regulatory agency should “be in the position of basically announcing to the public that our overall goal is to encourage people to use a smokeless tobacco, as an example.”¹²³

Thus, throughout years of consideration of various proposals to regulate tobacco, Congress heard vigorous debate on the general issue of whether smokeless tobacco should be promoted as a safer product than cigarettes and whether the smokeless tobacco warnings should communicate a harm reduction message. Specific proposals were made to alter the smokeless tobacco warnings to communicate the message now sought by the Petition.

Years of Congressional consideration culminated in final consideration of the bill that became the Tobacco Control Act. In the House, that bill was H.R. 1256, sponsored by Rep. Henry Waxman (D-Cal.). Rep. Buyer offered a substitute amendment to the underlying bill that he entitled the “Youth Prevention and Tobacco Harm Reduction Act.”¹²⁴ The Buyer substitute would have altered the smokeless tobacco warning labels to delete the current warning that the smokeless tobacco product “is not a safe alternative to cigarettes” and to substitute this language: “WARNING: This product has significantly lower risks for diseases associated with cigarettes,”¹²⁵ language substantially similar to that now sought by RJR.

Rep. Waxman opposed the Buyer substitute on the Floor of the House and argued strongly against its revision of the smokeless tobacco warning labels:

There’s no evidence to support this approach. He is basing his assumption that current smokers will use smokeless tobacco to quit, but there’s no evidence to support this assumption. . . Rather than have smokers quit, it’s just as likely that smokeless tobacco

¹²⁰ *Id.* at 148 (article by Rodu/Godshall).

¹²¹ “The Family Smoking Prevention and Tobacco Control Act,” Hearings before the House Subcommittee on Health of the Committee on Energy and Commerce (October 3, 2007).

¹²² *Id.* at 26-27.

¹²³ *Id.* at 52.

¹²⁴ 155 Cong. Rec. H4344 (April 1, 2009).

¹²⁵ *Id.* at H4357.

can be used to introduce youth to tobacco use and to discourage smokers from quitting.¹²⁶

Rep. Waxman further emphasized that his bill specifically addressed the issue of harm reduction through provisions [now Sec. 911] that ensure that any claims of reduced harm are supported by science:

The substitute fails to protect consumers from false and misleading claims about reduced harm. It would allow tobacco companies to market products as safer or posing less risk without providing scientific evidence that those claims are actually true . . . Our bill would allow products to be marketed as less hazardous only when those claims are based on sound science and only when the health of the entire population is considered.¹²⁷

On April 2, 2009, the Buyer substitute was rejected by the House by a 284-142 margin.¹²⁸

During Senate consideration of S. 1247, the Senate version of the Tobacco Control Act that mirrored H.R. 1256, Senator Burr (R-NC) offered a substitute amendment (S. Amend. 1246) that would have deleted the then-existing smokeless tobacco warnings and substituted only two statutory warnings – that “Smokeless tobacco is addictive” and that it is “lower risk than cigarettes.”¹²⁹ The Senate rejected the Burr substitute by a vote of 60-36.¹³⁰

Therefore, after a decade of consideration that included extensive debate about smokeless tobacco as a “harm reduction” product and the impact of the long-time statutory warning that smokeless tobacco “is not a safe alternative to cigarettes,” both the House and the Senate affirmatively and decisively rejected legislation that would have mandated warning text indistinguishable from that advocated by RJR. Instead, Congress reaffirmed the existing warning and established separate rules and rigorous standards in Section 911 to ensure that modified risk claims be supported by solid science. Nothing in the history of congressional consideration of harm reduction, or in the specific legislative history of the Tobacco Control Act, suggests that it was the intent of Congress to have FDA, through its authority to revise the statutory smokeless tobacco warning labels, promulgate modified risk claims by placing them on smokeless tobacco labels and advertising. Through the enactment of Section 911, Congress placed that burden squarely on a tobacco product manufacturer that seeks to market a product while making such claims.

¹²⁶ *Id.* at H4368.

¹²⁷ *Id.*

¹²⁸ 155 Cong. Rec. H4412 (April 2, 2009).

¹²⁹ 155 Cong. Rec. S6092 (June 3, 2009).

¹³⁰ 155 Cong. Rec. S6347 (June 9, 2009).

IV. WE WOULD ENCOURAGE AN INQUIRY ADDRESSING WHETHER THE EXISTING WARNING LABELS ON SMOKELESS TOBACCO ARE STILL EFFECTIVE IN ENSURING PUBLIC UNDERSTANDING OF THE HEALTH RISKS OF SMOKELESS TOBACCO OR WHETHER THEY ARE WEARING OUT AND CHANGES ARE NEEDED TO ENHANCE THAT UNDERSTANDING

Given the serious health risks of smokeless tobacco, the growth in its use, particularly by young people, and the scientific evidence that indicates that the impact of warning labels can wear out if not rotated periodically, FDA should assess the effectiveness of the current statutory warnings in achieving the intent of Congress that the public understand and fully appreciate the health hazards of smokeless tobacco. As part of that inquiry, FDA should disclose to the public any research it has done on the impact and effectiveness of the current smokeless tobacco warnings and on possible revisions to the text and format of the warnings.

Such an inquiry should consider, among others, these kinds of questions:

- (1) Whether prospective and actual users of smokeless tobacco (particularly young people) are aware of the current warnings;
- (2) Whether the public, and specifically prospective and actual users of smokeless tobacco (particularly young people), are well informed about the health risks of smokeless tobacco;
- (3) Whether new warnings should be added concerning the risk of diseases other than mouth cancer and gum disease, in light of evidence that smokeless tobacco has been associated with cancer of the esophagus, pharynx, larynx, stomach and pancreas;
- (4) Whether the required warning label area should be increased, as specifically permitted by Sec. 205;
- (5) Whether adjustments in the format, type size, etc. would enhance the effective communication of the health risks;
- (6) Whether color graphics should accompany the text to enhance the communicative power of the text.

In addition to commencing such an inquiry, FDA should test and evaluate the effectiveness of the smokeless tobacco warnings on a continuing basis. FDA should establish a system of on-going, systematic testing to detect evidence of diminishing effectiveness and be prepared to make changes in the warnings as needed. This is

particularly important as science demonstrates that the effect of specific consumer warnings diminishes over time and that warnings go “stale” if not updated and refreshed periodically.¹³¹ Specifically, the salience of health warnings decreases and the frequency with which users notice, read and think about the warnings lessens, with repeated exposure.¹³² In one study, researchers found that a majority of those surveyed believed that warning labels that had been in use for five years were already stale and had lost much of their impact.¹³³

Furthermore, a large body of research on the effectiveness of cigarette warning labels confirms that warning labels that are larger, appear on the front of the package and contain a clear, direct and accurate message about the dangers of tobacco use, including messages about specific health effects, are the most effective.¹³⁴ Warnings with color pictures are more effective than text-only warnings.¹³⁵ Studies show that cigarette warning labels with these characteristics are noticed more, are an important source of health information and increase knowledge about tobacco use harms and perceptions of risk.¹³⁶ In order to ensure that the smokeless tobacco warnings are as effective as possible, FDA should assess whether the specific characteristics of the smokeless tobacco warnings, such as their size, format and content need to be adjusted to enhance their impact.

Without such a system of continuous monitoring and testing, FDA cannot fulfill the mandate of Sec. 205 that changes in the warnings be made as necessary to ensure that the public understands, on an on-going basis, the risks associated with the use of smokeless tobacco products.

¹³¹ Hammond, D, “Health warning messages on tobacco products: a review,” *Tobacco Control* [epub ahead of print] (May 23, 2011).

¹³² Health Canada, *Health Warning Testing: Final Report*, Prepared by Environics Research Group (1999). See also, Informa Market Research Co. Ltd., Focus group research on new health warnings on tobacco packages (1999); Hammond, D, et al., “Measures to evaluate the effectiveness of tobacco product labeling policies,” in: *IARC Handbook II: Evaluating the Effectiveness of Population Based Tobacco Control*, International Agency for Research on Cancer (2007). Institute of Medicine, *Ending the Tobacco Epidemic, A Blueprint for the Nation* (2007). Ference R, Hammond G, Fong D, Warning Labels, C-3.

¹³³ Mahood, G, “Warnings that tell the truth: breaking new ground in Canada,” *Tobacco Control* 8(4): 356-361 (1999).

¹³⁴ Hammond, D, *Tobacco Labeling & Packaging Toolkit, A Guide to FCTC Article 11* (February 2009). Hammond, *supra* note 131.

¹³⁵ Hammond, 2009, *supra* note 134.

¹³⁶ Hammond, *supra* note 131.

Sincerely,

Campaign for Tobacco-Free Kids
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Academy of General Dentistry
American Academy of Family Physicians
American Academy of Pediatrics
American Association for Cancer Research
American Association for Respiratory Care
American College of Preventive Medicine
American Dental Association
American Psychological Association
American Public Health Association
American Thoracic Society
Association of Women's Health, Obstetric and Neonatal Nurses
Cancer Prevention and Treatment Fund
Community Anti-Drug Coalitions of America
Legacy
National Association of City and County Health Officials
National Latino Alliance for Health Equity
Oncology Nursing Society
Partnership for Prevention
Society for Cardiovascular Angiography and Interventions
Tobacco Control Legal Consortium