



**COMMENTS ON PETITION OF R.J. REYNOLDS TOBACCO COMPANY AND AMERICAN SNUFF COMPANY FOR RULEMAKING TO ADJUST STATUTORY SMOKELESS TOBACCO WARNING**

**DOCKET NO. FDA-2011-P-0573**

**Originally filed on November 9, 2012**

**Resubmitted on November 16, 2012 to add an additional supporting organization**

The undersigned organizations submit these comments on the Petition of R.J. Reynolds Tobacco Company (“RJR”) and the American Snuff Company (“ASC”), Reynolds American, Inc.’s smokeless tobacco subsidiary, requesting the Commissioner of Food and Drugs to initiate a rulemaking proceeding to alter the text of the statutorily-required smokeless tobacco (“ST”) product warning statement. The undersigned urge that the Petition be denied by the Food and Drug Administration (“FDA”).

Though presented as merely a request to FDA to modify one of the statutory product warnings on smokeless tobacco, in reality the RJR Petition is a transparent attempt to secure FDA’s support for their marketing of ST as a safer product than cigarettes, while evading the evidentiary requirements that Congress carefully constructed to ensure that such claims of reduced harm do not serve to increase tobacco use, cause more people to become addicted to tobacco, and die from tobacco-related disease. The Petition thus represents an attack on the integrity of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), the statute FDA is charged with enforcing, and should be treated as

such. The Petition is part and parcel of a broader industry campaign to circumvent the requirements of Section 911 of the Tobacco Control Act in order to promote ST as a “harm reducing” product, led by the two largest cigarette manufacturers – RJR and Philip Morris USA – who have entered the ST market and have every incentive to both expand the use of ST and to ensure that ST functions to protect and expand the market for cigarettes.

The fact is that the scientific evidence has not changed since Congress passed the Tobacco Control Act in 2009 and that the challenged statutory warning is accurate, not misleading and strongly supported by the overwhelming scientific evidence of the deadly effects of ST. Particularly given the continued efforts of the industry to market ST products in ways that appeal to young people, the current statutory warnings on ST are of paramount importance to public health. Indeed, revising the warnings as advocated by RJR would effectively convert those warnings into marketing tools for the tobacco industry and undermine the fundamental purpose of the statute.

### **THE PETITION IS A TRANSPARENT ATTEMPT TO EVADE THE STRICT STATUTORY STANDARDS FOR CLAIMS OF MODIFIED RISK**

#### **A. The Petition, on Its Face, Seeks to Persuade FDA to Sponsor a Claim of Modified Risk for Smokeless Tobacco Products Without Satisfying the Requirements of Section 911**

Despite RJR’s insistence that its Petition concerns only the need for a revision of an allegedly “misleading” statutory warning on ST products, in fact the Petition is a thinly-veiled effort to convince FDA to approve, and indeed sponsor, a claim of modified risk for smokeless tobacco without satisfying the rigorous statutory requirements for making such claims under Sec. 911 of the Tobacco Control Act.

Because the health harms of ST products are so serious and well-established, the Tobacco Control Act itself mandates, in Sec. 204, that ST manufacturers include, on a rotating basis on their product packages, four specific warning statements. The statute also requires manufacturers to rotate the four required warnings on their product advertising. The four statutory warnings are:

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.

The crux of RJR’s Petition is that the third statutory warning – “This product is not a safe alternative to cigarettes” – is misleading because, in RJR’s words, “it implies that ST 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.”<sup>1</sup> The Petition asks FDA to substitute this alternative

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<sup>1</sup> RJR Citizen Petition, at 4.

warning: “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”<sup>2</sup>

As discussed below, there is no basis for RJR’s contention that the statutory warning is misleading. However, before considering that issue, it is critical to understand that the Petition expressly and unambiguously asks FDA to allow, *indeed to require*, that a claim of modified risk be made with respect to ST products, in defiance of the statutory scheme established under Sec. 911 specifically to regulate such modified risk claims.

If RJR’s requested “adjustment” to the statutory warning were to be adopted by FDA, all ST products would, in essence, be granted the status of “modified risk tobacco product” 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.” Section 911 goes on to define the term “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products” as a tobacco product meeting at least one of several specified conditions. Of particular importance here is the condition 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.”

It is difficult to imagine a more explicit representation of “lower risk” than RJR’s proposed “adjusted text.” Yet RJR has filed no application under Sec. 911 and makes no effort to comply with the rigorous standards for FDA approval of a modified risk product.

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

Under Sec. 911(g)(1), the burden is on the applicant to demonstrate that the product, “as it is actually used by consumers” will (1) “significantly reduce harm and risk of tobacco-related disease to individual tobacco users”; and (2) “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;

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<sup>2</sup> RJR Citizen Petition, at 1.

(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 the effects of the marketing of the product on initiation, use, cessation and relapse among the population as a whole. 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.<sup>3</sup> 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.”<sup>4</sup> The Draft Guidance then provides twelve pages of detailed discussion of the scientific evidence needed to inform each of these considerations.<sup>5</sup>

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 ST 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 ST products, marketed as lower risk than cigarettes, would cause non-users or lapsed users to begin tobacco use, whether ST products function as a “gateway” to smoking, particularly for young people, whether current smokers would switch to ST products, whether smokers would simply use ST as a “bridge product” in places that do not allow smoking rather than quitting, and other questions essential to evaluating the health impact of ST 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

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<sup>3</sup> Guidance for Industry, Modified Risk Tobacco Product Applications, *Draft Guidance*, Food and Drug Administration, Center for Tobacco Products (March 2012) (“Guidance for Industry”).

<sup>4</sup> Guidance for Industry, at 16-17.

<sup>5</sup> *Id.* at 17-29.

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.*)<sup>6</sup>

If RJR believes that marketing all ST products (RJR does not distinguish between ST products) as lower risk promotes the public health, it should file a Sec. 911 application as contemplated by the statute. It has failed to do so.

### **C. The Rigorous Sec. 911 Requirements as to Modified Risk Reflect the Congressional Response to the Tobacco Industry’s Long History of False and Baseless Claims of Reduced Risk from its Products**

The demanding standards under Sec. 911 reflect the recognition by Congress of the tobacco industry’s long and deadly history of making “reduced risk” and other health claims about its products either without scientific support, despite the industry’s own knowledge that the claims were false, and despite the industry’s recognition that the claims were likely to increase the number of youth who start 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.<sup>7</sup> Indeed, the current Petition should be viewed as the latest chapter in that tragic story, as RJR now seeks to enlist the FDA’s support in evading the provisions of the Act specifically enacted to prevent the industry from making unwarranted and deadly reduced risk claims.

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 such a 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.<sup>8</sup>

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.<sup>9</sup>

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<sup>6</sup> RJR Citizen Petition, at 4 (emphasis added).

<sup>7</sup> National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13 (November, 2001).

<sup>8</sup> Today approximately 99.5% of the U.S. cigarette market is made up of filtered cigarettes. Federal Trade Commission (FTC), *Cigarette Report for 2009 and 2010, 2012*, <http://ftc.gov/os/2012/09/120921cigarettereport.pdf>. Data for top five manufacturers only.

<sup>9</sup> National Cancer Institute, *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine*, Smoking and Tobacco Control Monograph No. 13 (November, 2001).

In 2001, the National Cancer Institute issued a Monograph entitled “Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine” (“Monograph 13”) citing internal tobacco company documents in concluding 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.<sup>10</sup> 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.<sup>11</sup> 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 quit or smoke True. I smoke True.”<sup>12</sup>

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.*<sup>13</sup> and furnished critical support for the Court’s conclusion that the defendant tobacco companies, including the Petitioner, 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.<sup>14</sup>

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.<sup>15</sup>

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.<sup>16</sup> Moreover, despite the fact that the Tobacco Control Act now prohibits the use of the deceptive terms “light,” “mild” and “low-tar,” tobacco

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Magazine advertisement, 1976.

<sup>13</sup> 449 F. Supp.2d 1 (D.D.C. 2006), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

<sup>14</sup> *Id.* at 430.

<sup>15</sup> *Id.* at 430-31.

<sup>16</sup> HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General* (2012).

companies are using color-coding schemes to evade the ban and perpetuate the “safer cigarette” deception. 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”.<sup>17</sup> Philip Morris placed notes 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.”<sup>18</sup>

Even after the fraud of “light” and “low-tar” cigarettes was exposed, major tobacco companies continued to make baseless health claims for their products. In fact, the Petitioner here – RJ Reynolds – was found by a state court to have violated the provision in the Master Settlement Agreement in which the signatory companies agreed not to make material misrepresentations about the health consequences of their products, as well as a state anti-fraud statute, by making claims that its product Eclipse, “compared to other cigarettes . . . may present less risk of cancer, chronic bronchitis, and possibly emphysema.”<sup>19</sup>

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 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 debacles like the marketing of filtered and low-tar cigarettes. FDA must be highly sensitive to, and must proactively respond against, any attempt to evade the Sec. 911 standards.

#### **D. The 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. Recently, tobacco companies have begun to encourage state health departments and state legislatures, including those in Oklahoma, Kansas and Indiana, to effectively circumvent FDA altogether by getting the

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<sup>17</sup> Duff Wilson, “Coded to Obey Law. Lights Become Marlboro Gold,” New York Times, Feb. 18, 2010.

<sup>18</sup> Duff Wilson, “FDA seeks explanation of Marlboro Marketing,” New York Times, June 17, 2010.

<sup>19</sup> *State of Vermont v. R.J. Reynolds Tobacco Company*, 2010 Vt. Super. LEXIS 11 (Vt. Super. 2010).

states to promote smokeless tobacco as less harmful than smoking, even diverting tobacco prevention funding to this approach.

RJR or its affiliates have been part of this industry effort to enlist the states to promote ST products as part of a “harm reduction” strategy. In April of this year, Ronald Hein, on behalf of an RJR affiliate, RAI Services Company (“RAI”), 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.”<sup>20</sup> Similarly, in September of this year, 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 ST products are misleading because ST products are far safer than cigarettes.<sup>21</sup> At no point in the testimony of Mr. Hein or Mr. Buyer do 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. At no point do they explain why RJR has failed to use the statutory process under Sec. 911 to obtain regulatory review for such claims.

It is beyond 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 . . .”<sup>22</sup> 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.”<sup>23</sup> It is undeniable, however, that should RJR succeed in convincing FDA to adopt its suggested warning language, it will have achieved FDA’s endorsement of ST 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.

Any remaining doubt about the real industry agenda behind the RJR Petition should be alleviated by the comments in support of the Petition filed on behalf of Philip Morris USA Inc. (“Philip Morris”) by Altria Client Services Inc.<sup>24</sup> Showing 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

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<sup>20</sup> Testimony re: HR 6026, House Federal and State Affairs Committee, Presented by Ronald R. Hein on behalf of RAI Services Company, April 26, 2012.

<sup>21</sup> 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.

<sup>22</sup> RJR Citizen Petition, at 5.

<sup>23</sup> *Id.*

<sup>24</sup> Docket No. FDA-2011-P-0573 – Comments on Citizen Petition filed by R.J. Reynolds Tobacco Company, Altria Client Services, February 6, 2012.



reduction is available,”<sup>25</sup> but ignores the criteria and process set out in Section 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.”<sup>26</sup> 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 ST products as “harm reducers” while nullifying the scheme carefully crafted by Congress to ensure that any “harm reduction” product claims be supported by science and carefully consider the population impact of how the product is labeled and marketed.

If RJR or Philip Morris has persuasive evidence supporting a claim of “harm reduction” for ST products, then it should be subject to the exacting scrutiny dictated by Sec. 911, requiring a searching inquiry into the impact on “the health of the population as a whole.” There is strong reason to doubt that the available scientific evidence would be sufficient to meet the Sec. 911 standards. The 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation concluded, “the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.”<sup>27</sup> Another survey of the scientific literature found: “There is little evidence that ST use is effective for smoking cessation; or that ST is an effective nicotine maintenance product. In addition, the available evidence suggests that ST use may be a gateway to smoking initiation in the United States.”<sup>28</sup> The authors concluded that “there is a real danger of potential unintended adverse consequences of promoting ST for harm reduction,” with the greatest concern being “that broader promotion of ST would result in an increase in ST initiation and simply add to or increase cigarette smoking among adolescents and young adults, as apparently was the case in Norway.”<sup>29</sup>

These concerns are accentuated by recent trends in the marketing of ST products to counter the impact of smoke-free laws that result in many smokers quitting. In recent years, ST producers increasingly have used phrases in their marketing such as, “when smoking isn’t an option”<sup>30</sup> and “tobacco pleasure to enjoy virtually anywhere,”<sup>31</sup> to tell smokers that they can use ST where and when smoking is not allowed, instead of quitting. Philip Morris has conducted an advertising campaign that explicitly urges dual use by highlighting to consumers that its smokeless product foilpack “rides perfectly alongside your smokes. Just slip one in your pocket, head out and you’re good to go almost anywhere anytime.”<sup>32</sup> Petitioner RJR currently is placing ads in airline magazines for its smokeless product Camel SNUS, with an express appeal to flyers

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<sup>25</sup> *Id.* at 9.

<sup>26</sup> *Id.* at 2-3.

<sup>27</sup> Fiore, M.C., et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline, May 2008.

<sup>28</sup> Scott L. Tomar et al., *Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm from Cigarette Smoking?*, *Int. J. Environ. Res. Public Health* 2009, 6, 16.

<sup>29</sup> *Id.* at 16-17.

<sup>30</sup> Marlboro Snus direct mail advertisement, 2010, accessed October 18, 2012 from <http://www.trinketsandtrash.org/detail.php?artifactid=6184>.

<sup>31</sup> Accessed October 18, 2012 at <http://www.trinketsandtrash.org/detail.php?artifactid=6684>.

<sup>32</sup> Marlboro Snus direct mail advertisement, 2009, accessed October 18, 2012 from <http://www.trinketsandtrash.org/detail.php?artifactid=6358>.

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.”<sup>33</sup>

Particularly given the entry into the ST market by cigarette manufacturers RJR and Philip Morris, this kind of marketing can be expected to intensify, as these companies have every incentive to promote ST as an alternative product to individuals seriously contemplating quitting tobacco use altogether. In some instances, ST products are even marketed with cigarettes, reinforcing the message that ST is a bridge to use between cigarettes where smoking is no longer allowed.

Given the current marketing strategy of the tobacco industry, the companies’ professed commitment to a true harm reduction approach that will encourage smokers to quit should be treated with extreme skepticism. Tobacco companies spend almost \$8.5 billion annually marketing cigarettes and ST products.<sup>34</sup> Currently 18 times more money is spent to market cigarettes, the products these companies claim are most deadly, than to market ST, which they claim is 98% less harmful than cigarettes. Any sincere commitment to harm reduction by the tobacco companies would dictate a reversal of those marketing priorities.

## **THE CHALLENGED STATUTORY WARNING IS NOT MISLEADING AND THE STATUTORY LANGUAGE DOES NOT SUPPORT RJR’S PETITION**

### **A. The Statutory Warning is Accurate, Not Misleading and Supported by the Scientific Evidence**

RJR’s argument that FDA should commence a rulemaking to consider whether to use its authority under Sec. 204 of the Act to “adjust” the statutory warning on ST products is based on a misreading of the warning itself.

The challenged warning reads simply: “WARNING: This product is not a safe alternative to cigarettes.” RJR concedes that the warning is true. Indeed, according to RJR, “. . . it is indisputable that quitting is the only safe alternative to using any tobacco product . . .”<sup>35</sup> It argues, however, that the warning “is a misleading comparison because it implies that ST 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.”<sup>36</sup>

Contrary to RJR’s reading, the challenged warning in no sense implies that ST products and cigarettes present equal risks to users. The warning represents only that the hazards of ST products and cigarettes are both sufficiently serious that neither can be considered “safe,” a proposition that RJR itself does not deny. The warning simply does not address the issue of

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<sup>33</sup> US Airways magazine, 2011, accessed October 18, 2012 from <http://www.trinketandtrash.org/detail.php?artifactid=7029>.

<sup>34</sup> FTC, *Cigarette Report for 2009 and 2010, 2012*, <http://ftc.gov/os/2012/09/120921cigarettereport.pdf>. FTC, *Smokeless Tobacco Report for 2009 and 2010, 2012*, <http://ftc.gov/os/2012/09/120921tobaccoreport.pdf>. Data for top five manufacturers only.

<sup>35</sup> RJR Citizen Petition, at 5.

<sup>36</sup> *Id.* at 4.

whether ST products are, in any sense, “safer” than cigarettes. Only by imagining that the current warning says something it clearly does not say is RJR able to manufacture a pretext for inviting FDA to give its imprimatur to the industry’s strategy of promoting ST as a modified risk product.

It is revealing that RJR does not challenge the truth of the other three statutory warnings on ST:

WARNING: This product can cause mouth cancer.

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

WARNING: Smokeless tobacco is addictive.

If these warnings are true and not misleading, and ST truly is an addictive product that causes serious disease, then *ipso facto* it is true and not misleading to warn that ST “is not a safe alternative to cigarettes.”

The scientific evidence overwhelmingly supports the proposition that ST is not a safe alternative to cigarettes and provides compelling support for the continued public health need for the statutory warning. The Surgeon General’s landmark report on ST concluded, based on “a careful examination of the relevant epidemiologic, experimental, and clinical data” that “the oral use of smokeless tobacco represents a significant health risk. It is not a safe substitute for smoking cigarettes. It can cause cancer and a number of non-cancerous oral conditions and can lead to nicotine addiction and dependence.”<sup>37</sup> According to the U.S. National Cancer Institute, “[t]he bioassay data strongly support the epidemiological observation that ST is carcinogenic to humans. Twenty-eight carcinogens have been identified in chewing tobacco and snuff.”<sup>38</sup> The National Toxicology Program of the U.S. Public Health Service found that “[t]he oral use of smokeless tobacco is known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans which indicate a causal relationship between exposure to smokeless tobacco and human cancer.”<sup>39</sup> The World Health Organization reports “conclusive evidence that certain smokeless tobacco products increase risk of oral cancer, specifically . . . smokeless tobacco in the United States.”<sup>40</sup>

The continued public health importance of the statutory warnings on ST is further underscored by the significant and increasing use of these products by young people. While youth smokeless tobacco use declined from 1997 to 2003, recent national surveys show that ST use has increased more recently among youth. The Youth Risk Behavior Survey found that in 2011, 12.8 % of high school boys currently use smokeless tobacco products.<sup>41</sup> The incidence of

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<sup>37</sup> 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.

<sup>38</sup> National Institutes of Health (NIH), National Cancer Institute (NCI), *Smoking and Tobacco Control Monograph 1: Smokeless Tobacco or Health: An international Perspective*, September 1992.

<sup>39</sup> U.S. Department of Health and Human Services (HHS), Public Health Service, National Toxicology Program, *Report on Carcinogens, Eleventh Edition*, January 31, 2005.

<sup>40</sup> World Health Organization, Scientific Advisory Committee on Tobacco Product Regulation, *Scientific Advisory Committee on Tobacco Product Regulation Recommendation on Smokeless Tobacco Products*, 2003.

<sup>41</sup> U.S. Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance – United States, 2011,” *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 61 (SS-4), June 8, 2012.

use among high school boys was particularly high in certain states, including Kentucky (28.1%), Oklahoma (23.8%) and West Virginia (25.5%).<sup>42</sup> According to the 2011 Monitoring the Future survey, the incidence of ST use among 12<sup>th</sup> graders increased 36% from 2006 to 2011. Among 10<sup>th</sup> graders, there was a 34.7% increase in ST incidence from 2004 to 2010.<sup>43</sup> Youth prevalence data show that cigarette smoking and smokeless tobacco use declined between 1997 and 2003, but as youth smokeless use has increased since then, the youth smoking decline has stalled.<sup>44</sup> This suggests smokeless is *not* substituting for smoking (thus refuting a key contention of the proponents of ST as a “reduced harm” product), but rather is adding to the number of tobacco users. Indeed, large numbers of youth are using both kinds of products. 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 smoking cigarettes in the past month.<sup>45</sup>

The fact is that U.S. smokeless tobacco companies have a history of creating new products that appeal to kids and marketing them aggressively to children. Tobacco industry documents show that U.S. Smokeless Tobacco Company (“UST,” now a subsidiary of Altria, the parent company of Philip Morris) had a specific strategy to “graduate” new, young smokeless tobacco users from candy-flavored or fruit-flavored starter products in pouches to more potent varieties. Following this strategy, between 1983 and 1984, UST introduced Skoal Bandits and Skoal Long Cut as its beginner strength products, later adding flavoring to these products to increase their appeal to youth. A former UST sales representative explained that “Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”<sup>46</sup> According to UST’s 2005 Annual Report, flavored products (which now include such flavors as apple, peach, vanilla, berry blend and citrus blend) account for over 11% of all moist snuff sales.<sup>47</sup> Smokeless tobacco companies continue to advertise products in magazines that appeal to youth. For example, although RJR stopped running magazine ads for its main cigarette brands in 2008, it has continued to place magazine ads for its Camel smokeless tobacco products in *Rolling Stone*, *Sports Illustrated*, and other youth-friendly magazines.

The fact that major cigarette companies have now entered the ST market intensifies the concern about the promotion of ST products to kids. The two largest cigarette manufacturers, Petitioner RJR and its ally in pursuing this Petition, Philip Morris, are producing their own ST products under their well-known cigarette brand names, which are the most popular cigarette brands among youth. In the landmark ruling in *United States v. Philip Morris*, the District Court found the evidence “clear and convincing – and beyond any reasonable doubt” – that RJR, Philip Morris and the other industry defendants “have marketed to young people twenty-one and under while consistently, publicly and falsely, denying that they do so.”<sup>48</sup> The fact that these companies have now entered the ST market, and are selling products that themselves have

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<sup>42</sup> *Id.*

<sup>43</sup> Johnston LD, et al., *Monitoring the Future national survey results on drug use, 1975-2011, Volume I: Secondary school students*, Institute for Social Research, University of Michigan, 2012.

<sup>44</sup> U.S. Centers for Disease Control, “Youth Risk Behavior Surveillance – United States, 2009,” *MMWR Surveillance Summaries* 59(SS-5), June 4, 2010.

<sup>45</sup> SAMHSA, *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*, Office of Applied Studies, March 5, 2009.

<sup>46</sup> Freedman, A.M., “How a Tobacco Giant Doctors Snuff Brands to Boost Their Kick,” *Wall Street Journal*, October 26, 1994.

<sup>47</sup> UST, 2005 Annual Report & 2006 Proxy.

<sup>48</sup> *United States v. Philip Morris*, *supra* at 691 .

historically been marketed to children,<sup>49</sup> suggests that strong warnings on ST products are needed now more than ever.

### **B. The Statutory Language Provides No Support for the RJR Petition**

Despite the fact that Congress found ST products so dangerous as to mandate four specific warnings for those products, the RJR Petition maintains that Congress nevertheless intended that Sec. 205(a) of the Tobacco Control Act functions to allow ST producers to make a claim of modified risk. Such a view of the statutory scheme is implausible on its face, is unsupported by the text of Sec. 205(a), and ignores the fact that the same statute set out a specific mechanism for evaluating modified risk claims, Section 911.

It is revealing that the RJR Petition never quotes the entirety of Sec. 205(a). Rather, it pulls statutory language out of context to create the misimpression that Sec. 205(a) can be used to transform the challenged statutory warning into a modified risk claim. According to RJR, Sec. 205(a) gives FDA the authority “to ‘adjust’ by rulemaking the text of any label statement ‘if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.’”

Actually, the relevant language of Sec. 205 (a) reads, in its entirety:

**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.

Read without RJR’s misleading editing, 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 ST, not to convert the statutory warnings into claims of modified risk for ST. Thus, for example, the agency is given the authority to require color graphics to more effectively communicate the health risks of ST. It is certainly 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 science has not changed since Congress enacted the Tobacco Control Act. The scientific conclusions of the Surgeon General, the National Cancer Institute, the US Public Health Service, and the American Cancer Society have not changed. Nothing in the language of Sec.

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<sup>49</sup> In the last several years, cigarette companies have introduced a number of new smokeless products that have the potential to dramatically increase the popularity of ST, particularly among kids. Most notable are the snus products, which are small, teabag-like pouches containing tobacco and other flavorings that users place between their upper gum and lip. RJR’s Camel Snus are now sold nationally in a variety of flavors. Because these products do not require spitting, their use can be easily concealed. One high school student admitted using Camel Snus during class, saying, “It’s easy, it’s super-discreet . . . and none of the teachers will ever know what I’m doing.” Nelson, L., “If you think Snus is a safe alternative to smoking, think again,” *Kansas City Star*, October 31, 2007.

205(a), read in context, suggests that Congress intended to effectively nullify Sec. 911 by authorizing FDA, at the urging of the tobacco industry, to sanction modified risk claims as “adjustments” to the warnings mandated by the statute.

In short, RJR’s Petition invites FDA to give a reading to the statute that sets one of its key provisions at war with another. FDA should decline the invitation.

## CONCLUSION

In enacting the Tobacco Control Act, Congress found that “[t]obacco use is the foremost preventable cause of premature death in America,” causing over 400,000 deaths in the United States each year and inflicting chronic illnesses on over eight million Americans. Congress also recognized that because “the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.”

Congress was keenly aware of the dangers of unsupported or false claims by the industry that certain tobacco products offer less dangerous alternatives to smoking, finding that such “reduced risk” claims “can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk.”

Congress determined that the “only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products” is for FDA to review industry claims of reduced harm in advance and “to require that the evidence relied on to support claims be fully verified.”

The RJR Petition in effect asks FDA to commence a rulemaking proceeding to create an avenue for the industry to defy Congressional intent, and the structure and language of the statute, by marketing smokeless tobacco products as “harm reduction” products without the rigorous scientific support Congress specifically required in Sec. 911. FDA must protect the integrity of the statute it is charged with the responsibility of enforcing, reject RJR’s baseless attack on the current statutory warnings on ST products, and deny the Petition in its entirety.

Sincerely,

American Academy of Family Physicians  
American Academy of Otolaryngology—Head  
and Neck Surgery  
American Academy of Pediatrics  
American Association for Cancer Research  
American Association for Respiratory Care  
American Cancer Society Cancer Action  
Network  
American College of Preventative Medicine  
American Heart Association  
American Lung Association  
American Medical Association  
American Public Health Association

American Society of Clinical Oncology  
American Thoracic Society  
Association of Reproductive Health  
Professionals  
Association of State and Territorial Health  
Officials  
Campaign for Tobacco-Free Kids  
Cancer Prevention and Treatment Fund  
ChangeLab Solutions  
General Board of Church and Society of the  
United Methodist Church  
Islamic Society of North America  
Legacy

Lung Cancer Alliance  
National Assembly on School-Based Health Care  
National Association of County and City Health  
Officials  
Oncology Nursing Society

Partnership for Prevention  
Tobacco Control Legal Consortium  
Wellness Council of West Virginia  
West Virginia Division of Tobacco Prevention