



# PHILIP MORRIS

U.S.A.

CORPORATE HEADQUARTERS, RICHMOND, VIRGINIA 23261

JOHN R. NELSON  
PRESIDENT  
OPERATIONS AND TECHNOLOGY

P. O. Box 26603  
PHONE (804) 484-8120  
FAX (804) 484-8122

December 3, 2007

VIA FEDERAL EXPRESS

Rear Admiral Steven K. Galson, M.D., M.P.H.  
Acting Surgeon General  
United States Department of Health and Human Services  
5600 Fishers Lane  
Room 18-66  
Rockville, Maryland 20857

Dear Dr. Galson:

I write on a subject of great interest to Philip Morris USA Inc. PM USA is the largest manufacturer of cigarettes in the United States. In addition to manufacturing cigarettes, PM USA is currently test-marketing a low-nitrosamine smokeless tobacco ("LN-SLT") product in the Indianapolis area under the brand name "Taboka," and four versions of "Marlboro Snus," a LN-SLT product, in the Dallas/Fort Worth area. PM USA designed these LN-SLT products for adult smokers interested in a smokeless tobacco alternative to smoking. PM USA also recently announced the test-marketing of four varieties of Marlboro moist smokeless tobacco in metropolitan Atlanta. We are test-marketing all of our smokeless tobacco products without communicating any claims of reduced exposure or reduced risk relative to cigarette smoking.

Cigarette smokers and smokeless tobacco product users, as well as potential users of either product, rely on the messages of the U.S. Surgeon General and other public health authorities worldwide when deciding whether to use tobacco products. We post on the pmusa.com website information on public health messages related to health risks, addiction, quitting and similar topics related to cigarettes and smokeless tobacco products. We also link to the websites and publications of numerous government and public health authorities, including the U.S. Surgeon General's reports related to tobacco.

Given the unique role your office plays in providing to the public health information related to the risks of tobacco use, we think it is critically important that the public, and more specifically the approximately 45 million adults in the United States who continue to smoke

cigarettes, receive the most current, reliable science-based information from your office on the relative health risks of cigarettes and smokeless tobacco, particularly LN-SLT products.

Four years ago, former Surgeon General Richard Carmona told the House Subcommittee on Commerce, Trade, and Consumer Protection that "[t]here is no significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes."

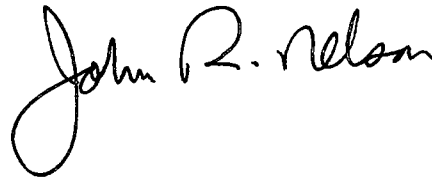
Today, while there are contrary views over what messages should be communicated to smokers, members of the scientific, medical, and public health communities in the United States and abroad have concluded in increasing numbers, based on new scientific studies and continued review of previous scientific data, that the health risks of using smokeless tobacco, particularly LN-SLT products, are substantially lower than the health risks of cigarette smoking with respect to lung cancer, chronic obstructive pulmonary disease, oral cancer, and other serious diseases.

The attached submission, prepared by PM USA and entitled "Relative Health Risks of Cigarettes and Low-Nitrosamine Smokeless Tobacco" supports the view that the relative health risks of LN-SLT products are far less than from cigarette smoking.

Accordingly, PM USA submits this letter respectfully requesting that the Office of the Surgeon General examine the available scientific evidence and communicate to the public the relative health risks from the use of LN-SLT products compared to the health risks from smoking cigarettes.

We would welcome the opportunity to meet with you and would be pleased to bring key members of our scientific staff to elaborate on questions you may have about this issue.

Sincerely,

A handwritten signature in black ink that reads "John R. Nelson". The signature is written in a cursive style with a large, looping initial "J".

# RELATIVE HEALTH RISKS OF CIGARETTES AND LOW-NITROSAMINE SMOKELESS TOBACCO

## Attachment to Letter to Acting Surgeon General Galson, dated December 3, 2007

Members of the scientific, medical, and public health communities in the United States and abroad have concluded, with increasing frequency, that the health risks of using smokeless tobacco, particularly low-nitrosamine smokeless tobacco (hereinafter “LN-SLT”) products, are substantially lower than the health risks of cigarette smoking with respect to lung cancer, chronic obstructive pulmonary disease, oral cancer, and other serious diseases. Philip Morris USA (“PM USA”) therefore respectfully requests that the Office of the Surgeon General examine the applicable science discussed below and communicate to the public the relative health risks from the use of LN-SLT products compared to the health risks from smoking cigarettes.

### **1. The Surgeon General’s 2003 Statements and the Need to Address Them**

Four years ago, former Surgeon General Richard Carmona told the House Subcommittee on Commerce, Trade, and Consumer Protection that he could not conclude that “the use of any tobacco product is a safer alternative to smoking.”<sup>1</sup> Speaking specifically about smokeless tobacco, the Surgeon General also remarked that “[t]here is no significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes.”<sup>2</sup> At the same time, he made clear that these views were not set in stone and agreed with the U.S. Institute of Medicine (“IOM”) that “it may be technically feasible to someday create a reduced harm tobacco product.”<sup>3</sup> Surgeon General Carmona emphasized that “[w]hen and if [a reduced harm tobacco product] is ever constructed, we would then have to take a look at the hard scientific data of that particular product.”<sup>4</sup>

It is appropriate for the Office of the Surgeon General to conduct this investigation at this time. The body of scientific evidence relating to the health risks of smokeless tobacco products – especially LN-SLT products – has expanded significantly since the Surgeon General’s testimony in 2003. LN-SLT products are smokeless tobacco products marketed for oral use that contain relatively low concentrations of a class of naturally-occurring tobacco carcinogens known as tobacco-specific nitrosamines (“TSNA”).<sup>5</sup> Snus, a type of moist snuff, is one example

---

<sup>1</sup> Statement of Richard H. Carmona, Surgeon General, before the House Subcommittee On Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, “Can Tobacco Cure Smoking, A Review of Tobacco Harm Reduction,” June 3, 2003, available online at <http://www.hhs.gov/asl/testify/t030603.html>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

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

<sup>5</sup> A team of U.S. public health researchers recently specified that to qualify as LN-SLT products, smokeless tobacco products “would at least meet the Gothiatek standard for production and manufacturing (www.gothiatek.com).” Levy, D.T., Mumford, E.A., Cummings, K.M., Gilpin, E.A., Giovino, G.A., Hyland, A., Swenor, D., Warner, K.E., Compton, C., 2006. “The potential impact of a low-nitrosamine smokeless tobacco

Footnote continued on next page

of a LN-SLT product.<sup>6</sup> Historically, snus was used predominantly in Sweden, but snus and other LN-SLT products are becoming increasingly available and popular in the U.S. Current evidence and scientific opinion support the evaluation of LN-SLT tobacco products as reduced-risk tobacco products, basing such review on scientific standards established by the IOM.

Recently, at the Third Triennial Conference of the National Association of Attorneys General, held on October 15-16, 2007, in Seattle, Washington, Dr. Terry F. Pechacek, Associate Director for Science, Office on Smoking and Health of the Centers for Disease Control and Prevention, stated that the Surgeon General had intended to testify only that smokeless tobacco products were not *safe* rather than *not safer*. These clarifying statements of Dr. Pechacek indicate further that it is appropriate for the Office of the Surgeon General to review the body of scientific evidence and clarify its position.

PM USA acknowledges, and discusses further below, that there is an ongoing debate within the public health community regarding whether smokers should be provided with scientifically accurate information about the health risks of using smokeless tobacco, particularly LN-SLT products, as compared to smoking cigarettes. PM USA believes, however, that cigarette smokers should receive accurate, up-to-date information on this profoundly important issue. The Surgeon General has long occupied a trusted position in American medicine and public health and has, for decades, taken a special interest in issues relating to tobacco and tobacco use. Since 1964, the Office of the Surgeon General has issued approximately thirty official reports on tobacco-related issues. A report has not been devoted to smokeless tobacco products, however, in more than 20 years. We believe the Surgeon General should act now to clarify the public health position on LN-SLT products.

## **2. LN-SLT Products and the Current U.S. Market**

PM USA is currently test-marketing a LN-SLT product in the Indianapolis area under the brand name “Taboka,” and four versions of “Marlboro Snus” in the Dallas/Fort Worth area.<sup>7</sup> PM USA designed Taboka and Marlboro Snus for adult smokers interested in smokeless tobacco

---

Footnote continued from previous page

product on cigarette smoking in the United States: Estimates of a panel of experts.” *Addictive Behaviors* 31: 1190-1200 (hereinafter “Levy et al., 2006”) at 1192. The Gothiatek<sup>®</sup> standard is a publicly-available quality standard developed by Swedish Match for the production and manufacturing of its snus products. Among other things, it imposes upper limits on the levels of tobacco-specific nitrosamines and other naturally-occurring tobacco constituents, including benzo[a]pyrene (BaP) and various metals. The maximum permissible limit for tobacco-specific nitrosamines is established at 5 mg/kg tobacco assuming 50% water content, or at 10 mg/kg tobacco on a dry weight basis. See <http://www.gothiatek.com>.

<sup>6</sup> See, e.g. Levy, D.T., Mumford, E.A., Cummings, K.M., Gilpin, E.A., Giovino, G.A., Hyland, A., Swenor, D., Warner, K.E., 2004. “The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts.” *Cancer, Epidemiology, Biomarkers & Prevention* 13: 2035-42, 2035 (hereinafter “Levy et al., 2004”); see also [www.en.wikipedia.org/wiki/snus](http://www.en.wikipedia.org/wiki/snus).

<sup>7</sup> PM USA also just recently announced the test marketing of four varieties of Marlboro moist smokeless tobacco in metropolitan Atlanta.

alternatives to smoking, and we are test-marketing these products without communicating claims of reduced exposure or reduced risk. Other manufacturers are also marketing snus products.

The fact that LN-SLT products are *already* on the market makes it all the more important for the Office of the Surgeon General to assess the current scientific evidence relating to the relative health risks of cigarettes and smokeless tobacco, focusing specifically on LN-SLT products such as snus.<sup>8</sup>

### **3. Scientific Evidence for LN-SLT Products as of 2003**

When the Surgeon General testified before a Congressional subcommittee in 2003, the review and analysis of the scientific evidence regarding LN-SLT products was significantly less extensive than it is today. But even then, some members of the public health community had concluded that some forms of smokeless tobacco were less hazardous than smoking.

For example, in 2001, the IOM issued a landmark, 600-page report entitled “Clearing the Smoke” (the “2001 IOM Report”), at the request of the U.S. Food & Drug Administration, in which the IOM observed that smokeless tobacco products pose lower overall risk than cigarettes:

[T]he overall risk is lower than for cigarette smoking, and some products, such as Swedish snus, may have no increased risk. It may be considered that such products could be used as PREPs for persons addicted to nicotine, but these products should undergo testing as PREPs using the guidelines and research agenda contained herein.”<sup>9</sup>

---

<sup>8</sup> Historical differences in TSNA content between U.S. domestic moist snuff and snus and have been attributed, at least in part, to differences in manufacturing processes – specifically, a fermentation process for U.S. moist snuff as compared to a pasteurization process used for Swedish-style snus. Several sources have reported that different manufacturing processes notwithstanding, the TSNA content of some U.S. domestic moist snuff products has been comparable to snus since at least the 1990s. Among others, a report issued in 1997 by the Swedish National Board of Health and Welfare concluded, “Recent data suggest that the differences [in TSNA levels reported in American and Swedish moist snuff] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks at least where TSNA content is concerned.” Ahlbom A., Olsson U.A., Pershagen G., 1997. Health hazards of moist snuff. *SoS Report* 11:3-29, at 7. See also Stratton, K., Shetty, P., Wallace, R., Bondurant, S., eds. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*. National Institutes of Health, Institute of Medicine (Washington, D.C.: National Academies Press 2001) (“2001 IOM Report”) at 300 (“Generally, the TSNA levels in both U.S. and Swedish products have decreased over the last decade secondary to changes in processing methods, and TSNA levels in certain U.S. brands of snuff have approached the Swedish variety”) (*citations omitted*); Meister, K., for the American Council on Science and Health, October 2006. “Helping Smokers Quit: A Role for Smokeless Tobacco?” (hereinafter “ACSH Report”) at 5 (“[T]he process of manufacturing modern moist snuff produces smaller amounts of cancer-causing nitrosamines than older methods did. Some moist snuff products may pose little or no oral cancer risk.”).

<sup>9</sup> 2001 IOM Report, *supra* n. 8, at 167. “PREP” is an acronym coined by the IOM to refer to tobacco products that may reduce the user’s exposure to tobacco toxins and potentially the risk of developing a disease caused by tobacco use.

Having concluded that reducing the inherent health risks of tobacco products was feasible,<sup>10</sup> the 2001 IOM Report established a scientific standard for evaluating tobacco products for reduced risk (or reduced exposure). According to the report's Regulatory Principle 4, a reduced risk claim for a tobacco product is substantiated and should be permitted if a regulatory agency determines, based on scientific evidence:

(a) that the product substantially reduces exposure to one or more tobacco toxicants and

(b) *if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse effects,*

compared with whatever benchmark product the agency requires in the labelling.<sup>11</sup>

The IOM defined a “substantial reduction” in exposure as being “sufficiently large that independent scientific experts would anticipate finding a measurable reduction in morbidity and/or mortality in subsequent clinical or epidemiological studies.”<sup>12</sup>

Other members of the public health community reached similar conclusions. In 2002, the Royal College of Physicians the oldest medical organization in England, issued a report concluding that “the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product,” and that “[s]ome smokeless tobacco products . . . may offer substantial reductions in harm compared to smoking.”<sup>13</sup> Similarly, just months before the Surgeon General's testimony, a group of well-known European scientists and tobacco control advocates argued that smokeless tobacco can play an important role in reducing the harm of cigarette smoking, based in part on their conclusion that smokeless tobacco products are at least 90% less hazardous than cigarettes:

Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos - are *a very substantially less dangerous way to use tobacco than cigarettes*. Smokeless tobaccos are not associated with major lung diseases, including COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than

---

<sup>10</sup> *Id.* at 5 (“[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible”).

<sup>11</sup> *Id.* at 213-15 (emphasis added).

<sup>12</sup> *Id.*

<sup>13</sup> Royal College of Physicians of London, Tobacco Advisory Group of the Royal College of Physicians, 2002. “Protecting Smokers, Saving Lives” at 11, 28. The Royal College did not identify which types of smokeless tobacco products (LN-SLT products or other) may be less harmful than cigarettes.

for smoking. . . . These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the public health community has a moral obligation to explore this strategy.<sup>14</sup>

[W]e are confident that the evidence base suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking*. In a spectrum of risk, snus is *much closer* to [nicotine replacement therapies] than it is to cigarette smoking.<sup>15</sup>

Based on current evidence and scientific opinion today, LN-SLT tobacco products should be evaluated as reduced risk tobacco products based on the IOM standard.

#### **4. Scientific Evidence for LN-SLT Products since 2003**

Experts in the U.S. and abroad have continued to test and evaluate LN-SLT products from a variety of different perspectives, and the body of scientific evidence and analysis regarding these products is substantially greater today than it was when the Surgeon General testified in 2003. Based on this evidence, increasing numbers of experts in the scientific, medical, and public health communities have concluded that people who use LN-SLT products have a substantially lower risk of developing lung cancer, oral cancer, chronic obstructive pulmonary disease (“COPD”), and other serious diseases than people who smoke cigarettes. Recent evidence from U.S. and international researchers, respectively, is summarized below.<sup>16</sup>

---

<sup>14</sup> Bates, C., Fagerstrom, K., Jarvis, M., Kunze, M., McNeill, A., Ramstrom, L., 2003. “European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health” at 3 (emphasis original).

<sup>15</sup> *Id.* at 4 (emphasis original). *See also* Cummings, M.K., 2002. “Programs and policies to discourage the use of tobacco products.” *Oncogene* 21:7349-64, 7360 (hereinafter “Cummings, 2002”) (“[I]f all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as pretty minor compared to the difference in disease risk between smoked and smokeless products. Until smokers are given enough information to allow them to chose [sic] products because of lower health risk, then the status quo will likely remain.” (internal citations omitted)).

<sup>16</sup> In addition, PM USA has engaged the Life Sciences Research Office (LSRO) “to provide an independent, comprehensive evaluation of the science base necessary to determine if there is sufficient scientific evidence to characterize (1) the relative risks of using smokeless tobacco products compared to cigarette smoking and (2) the relative risks posed to users of various categories of smokeless tobacco products.” [http://www.lsro.org/dtr/dtr\\_home.html](http://www.lsro.org/dtr/dtr_home.html). While PM USA is providing the funds necessary to complete this project, it “will provide no input into the design or implementation of the study or the final recommendations.” *Id.*

a. **Evidence from U.S. Researchers**

i. **The Levy Studies (2004, 2006)**

A team of U.S. public health researchers (collectively, the “Research Team”) funded by the National Cancer Institute recently evaluated the health risks and usage patterns of LN-SLT products compared to cigarettes, focusing on published studies of smokeless tobacco use in the U.S. and snus smokeless tobacco use in Sweden.<sup>17</sup> The Research Team, which included experts in epidemiology, medicine, statistics, and economics,<sup>18</sup> described its methods, results, and conclusions in two peer-reviewed scientific publications, both of which are described below.

To aid in its task, the Research Team assembled two panels of experts – a panel of “experienced tobacco epidemiologists,”<sup>19</sup> and a panel of “experts in tobacco use.”<sup>20</sup> The Research Team used an iterative, consensus-building technique called a “modified Delphi approach” to arrive at the conclusion of each expert panel. Further to this approach, individual expert panelists reviewed the scientific literature and provided their preliminary conclusions to the Research Team, which in turn shared these conclusions anonymously with other members on the panel. Each expert was then invited to modify his or her prior conclusions based upon the additional information they received. This process was repeated until consensus was reached.<sup>21</sup>

▪ **Levy, 2004**

The first Levy study, published in late 2004, compared the long-term health risks of using LN-SLT products to the long-term health risks of both cigarette smoking and tobacco abstinence, focusing on premature total mortality, lung cancer, oral cancer, and heart disease.<sup>22</sup> To help evaluate the evidence, the Research Team selected a panel of nine experienced tobacco epidemiologists “based on their knowledge of the health risks associated with both smokeless

---

<sup>17</sup> Levy et al., 2004, *supra* n. 6 at 2037; Levy et al., 2006, *supra* n. 5, at 1194.

<sup>18</sup> The Research Team and their affiliations are as follows: David T. Levy (Pacific Institute for Research and Evaluation; Department of Economics, University of Baltimore); Elizabeth A. Mumford (Pacific Institute for Research and Evaluation); K. Michael Cummings (Roswell Park Cancer Institute); Elizabeth A. Gilpin (Cancer Prevention and Control Program, Cancer Center, University of California-San Diego); Gary Giovino (Roswell Park Cancer Institute Division of Cancer Prevention and Population Sciences and Department of Health Behavior); Andrew Hyland (Division of Cancer Prevention and Population Sciences, Roswell Park Cancer Institute); David Sweanor (Smoking and Health Action Foundation, Ottawa, Ontario, Canada); Kenneth E. Warner (Department of Health Management and Policy, School of Public Health, University of Michigan); Christine Compton (Pacific Institute for Research and Evaluation) (2006 study only).

<sup>19</sup> Levy et al., 2004, at 2035.

<sup>20</sup> Levy et al., 2006, at 1192.

<sup>21</sup> Levy et al., 2004, at 2036; Levy et al., 2006, at 1193-95. According to the authors, “[t]he Delphi process has been applied in numerous fields including health care and health policy since its development in the 1950s.” Levy et al., 2004, at 2036; *see also* Levy et al., 2006, at 1193.

<sup>22</sup> Citing a lack of data, the Research Team did not examine the health risks associated with switching from cigarettes to LN-SLT products or with using both concurrently. *See* Levy et al., 2004, at 2036.

tobacco and cigarette use.”<sup>23</sup> Following three rounds of evaluation and discussion, a consensus emerged that LN-SLT products pose substantially lower risk to the individual user than cigarettes:

In comparison with smoking, experts perceive *at least a 90% reduction* in the relative risk of LN-SLT use.<sup>24</sup>

The results show that, within the selected Health Panel of experts, there is consensus that LN-SLT products are less hazardous than conventional cigarette smoking *by a wide margin*.<sup>25</sup>

On the narrow question of the relative health risk of LN-SLT products, these results *clearly* indicate that experts perceive these products to be *far less dangerous* than conventional cigarettes. Based on the available published scientific literature as of 2003, there seems to be consensus that LN-SLT products *pose a substantially lower risk to the user* than do conventional cigarettes.<sup>26</sup>

The Research Team emphasized that these findings apply only to LN-SLT products and do not justify “blanket health claims” for all smokeless tobacco products.<sup>27</sup> Even so, it must be recognized that the epidemiological evidence relied upon by the Research Team in reaching its findings was not limited to snus smokeless tobacco use in Sweden, but included U.S. smokeless tobacco products as well.

▪ **Levy, 2006**

The second Levy study, published in early 2006, took the analysis a step further. The second study had the goal of “predict[ing] the impact on tobacco use in the US of a ‘harm

---

<sup>23</sup> Levy et al., 2004, at 2035-36. The members of this panel were as follows: Graham A. Colditz (Channing Laboratory, Boston, MA); Martin Jarvis (Health Behaviour Unit of Cancer Research UK, Department of Epidemiology and Public Health, University College London, London, United Kingdom); Michael Kunze (Institute of Social Medicine, University of Vienna, Vienna, Austria); Freddi Lewin (Department of Oncology, Huddinge University Hospital, Stockholm, Sweden); Jonathan M. Samet (Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD); Peter Shields (Cancer Genetics and Epidemiology, Lombardi Cancer Center, Georgetown University Medical Center, Washington, DC); Steven D. Stellman (Mailman School of Public Health, Department of Epidemiology, Columbia University, New York, NY); Michael Thun (Department of Epidemiology and Surveillance, American Cancer Society, Atlanta, GA); Deborah M. Winn (Epidemiology and Genetics Research Program, Division of Cancer Control and Population Sciences, NI). *Id.* at 2036, Table 1.

<sup>24</sup> *Id.* at 2035 (emphasis added).

<sup>25</sup> *Id.* at 2038 (emphasis added).

<sup>26</sup> *Id.* at 2039 (emphasis added).

<sup>27</sup> *Id.* As discussed above, the TSNA content of various U.S. domestic moist snuff products declined during the 1990s, becoming comparable to Swedish snus. *See supra* n. 8.

reduction’ policy that requires the smokeless tobacco product meet low nitrosamine standards, but could be marketed with a warning label consistent with the evidence of relative health risks.”<sup>28</sup> The Research Team assembled a panel of seven experts “based on their knowledge of the behavioral trends associated with both smokeless tobacco and cigarette use.”<sup>29</sup> Using existing statistics and various modeling techniques, the outside experts estimated overall rates of cigarette and smokeless tobacco use over a five-year period during which LN-SLT products were marketed in a hypothetical regulatory environment with a “warning label consistent with the evidence of relative health risks.”<sup>30</sup> The warning label statement selected was:

This product is addictive and may increase your risk of disease.  
This product is substantially less harmful than cigarettes, but  
abstaining from tobacco use altogether is the safest course of  
action.<sup>31</sup>

The experts reached consensus that the proposed scenario would reduce cigarette smoking and only modestly increase smokeless tobacco use at the population level. They predicted that when combined with the substantially lower health risks of LN-SLT products, the reduction in cigarette smoking and modest increase in smokeless tobacco use should result in an overall benefit to public health. Describing their conclusions, the Levy team observed:

In conclusion, the results from this study indicate that the  
introduction of a well regulated LN-SLT product is expected to  
reduce smoking and only modestly increase [smokeless tobacco]  
use in the United States. . . .

The results indicate that cigarette users would switch to smokeless  
with little change in overall tobacco use and with a limited degree  
of substitution of LN-SLT for cigarettes. If these results hold, the  
substantial reduction in health risks associated with LN-SLT use  
should yield a net public health benefit through reduced  
mortality.<sup>32</sup>

\* \* \*

---

<sup>28</sup> Levy et al., 2006, at 1190.

<sup>29</sup> *Id.* at 1192, 1194.

<sup>30</sup> *Id.* at 1190. Describing the hypothetical regulatory environment, the Levy team specified that “all [smokeless tobacco products] sold in the United States would be low-nitrosamines products meeting the *same* regulatory standards for manufacturing, handling, and sale as specified by the Food and Drug Administration, effective July 2005. The product (e.g., Ariva, Swedish snus) would at least meet the Gothiatek standard for production and manufacturing (www.gothiatek.com).” *Id.* at 1192. In addition, they assumed that other tobacco control policies would remain at their current 2005 levels. *Id.*

<sup>31</sup> *Id.* at 1197.

<sup>32</sup> *Id.* at 1199.

Standing alone, these two studies provide sufficient cause for the Office of the Surgeon General to determine that, based upon the science currently available, the health risks of serious disease from the use of LN-SLT products are substantially lower than the health risks of cigarettes. But, the Levy studies comprise a small fraction of a much larger body of scientific evidence and analysis.

***ii. The ACSH Report (2006)***

In October 2006, the American Council on Science and Health (ACSH)<sup>33</sup> issued a peer-reviewed report evaluating the scientific and public health basis for providing consumers with accurate and complete information on the relative benefits of smokeless tobacco products compared to cigarettes. The report found that “[t]he health risks associated with smokeless tobacco are much less extensive than those associated with cigarette smoking,” pointing out that “[o]verall, the use of smokeless tobacco confers only about 2% of the health risks of smoking.”<sup>34</sup> ACSH also concluded that LN-SLT products like snus are “the safest types” of smokeless tobacco products and have “negligible health risks” compared to cigarettes.<sup>35</sup>

Based on its analysis of the evidence, ACSH stated that to benefit the public health, “[g]overnment agencies and private health organizations should provide accurate and complete information about the health risks of tobacco, including information about the differential risks of different types of tobacco use.”<sup>36</sup> ACSH’s recommendation encompassed not only LN-SLT products, but other forms of smokeless tobacco as well.

***iii. The Kozlowski Papers***

Dr. Lynn T. Kozlowski has also written extensively about the comparative risks of snus and cigarettes.<sup>37</sup> A well-known tobacco and health researcher, Dr. Kozlowski concluded that “Smokeless tobacco (SLT), for example, is substantially safer than cigarettes.”<sup>38</sup> With respect to snus specifically, Dr. Kozlowski stated:

---

<sup>33</sup> On its website, ACSH describes itself as “a not for profit organization led by a voluntary board of more than 350 leading physicians and scientists from prominent hospitals and universities.” The organization also emphasizes that its “work is not only peer-reviewed by these leading independent scientists, but ACSH reports are then further reviewed and published by mainstream medical and scientific journals with no connection to ACSH.” See <http://www.acsh.org/about/pageID.86/default.asp>.

<sup>34</sup> ACSH Report, *supra* n. 8, at 5.

<sup>35</sup> *Id.* at 1.

<sup>36</sup> *Id.* at 8. ACSH similarly recommended that “[m]anufacturers of tobacco products should acknowledge that “smokeless tobacco use is much less hazardous than cigarette smoking.” *Id.* (emphasis added).

<sup>37</sup> In addition to his writings, Dr. Kozlowski has made available an audio “dialogue” relating to the comparative risks of LN-SLT products and cigarettes. See <http://tc.bmj.com/cgi/content/full/12/1/34/DC1>.

<sup>38</sup> See Kozlowski L.T. & Edwards, B.O., 2005. “Not Safe is Not Enough: Smokers Have a Right to Know More Than There is No Safe Tobacco Product.” *Tobacco Control* 14 (Suppl. II) 113-117, 115.

Snus is not safe, but, on the basis of toxicological principles (no smoke toxins from smoke exposure to the lung) and current epidemiological knowledge, snus is significantly less dangerous to individual users than cigarettes.

[B]ased on current evidence, smokers have a right to information on snus . . . and medicinal nicotine as harm reduction options that would reduce substantially the risk to death to individuals.<sup>39</sup>

In a more recent article, Dr. Kozlowski notes that there is “considerable scientific consensus that smokeless tobacco products as sold in the United States, although not safe, are less dangerous than cigarettes to physical health.”<sup>40</sup> Dr. Kozlowski also notes that the public health community continues to debate whether that information should be communicated to smokers to help reduce population harm.<sup>41</sup>

Dr. Kozlowski also addresses evidence of risk reduction specifically among individuals who switch from cigarettes to smokeless tobacco products or continue to use both:<sup>42</sup>

One critique notes there is little research on the risk levels of various patterns of dual use of smokeless tobacco and cigarettes. While strictly true, it is also true that well-established dose-response principles should apply. Sequential “dual” use (moving completely off cigarettes to smokeless tobacco) will probably show reduction in smoking-caused diseases -- as a function of duration of smoking and daily dose of smoking. Substituting only a few cigarettes a day with smokeless tobacco is unlikely to reduce significantly tobacco harm. The longer and more one has smoked, the less likely a reduction in smoking-caused diseases will take place. For some problems the health damage may already have

---

<sup>39</sup> See Kozlowski, L.T., 2002. “Harm Reduction, Public Health, and Human Rights: Smokers Have a Right to Be Informed of Significant Harm Reduction Options.” *Nicotine & Tobacco Research* S55-S60, S55-S56. In addition, in 2005, a group of U.S. scientists, supported by funding from Swedish Match, published a peer-reviewed paper that identified and analyzed epidemiological studies that provide quantitative risk estimates of Swedish snus and cigarette smoking within the same population. Consistent with other studies and reports, they found that that “health risks associated with snus are lower than those associated with smoking,” reporting reduced risk for lung cancer, oral cancer, gastric cancer, and in three of four studies for cardiovascular disease. See Roth, H.D., Roth, A.B., X. Liu, 2005. “Health Risks of Smoking Compared to Swedish Snus.” *Inhalation Toxicology* 17:741-48, 747.

<sup>40</sup> See Kozlowski, L.T., 2007. “Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use: Policy Perspective for Tobacco-Risk Reduction.” *American Journal of Preventive Medicine* 33 (6S): S379.

<sup>41</sup> *Id.*

<sup>42</sup> See.e.g. Hatsukami, D.K., Ebbert, J.O., Feuer, R.M., Stepanov, I., and Hecht, S.S., 2007. “Changing Smokeless Tobacco Products: New Tobacco-Delivery Systems.” *American Journal of Preventive Medicine* 33 (6S): S372-73 & Tomar, S.L. 2007. “Epidemiologic Perspectives on Smokeless Tobacco Marketing and Population Harm.” *American Journal of Preventive Medicine* 33(6S): S389-90.

been done (e.g. cancer), and it will take years for the problem to appear, even if the individual has stopped all tobacco use.<sup>43</sup>

Of course, to the extent that concerns remain over “dual use,” such concerns are best addressed by communicating to smokeless tobacco product users appropriate qualifications on claims regarding the comparative safety of smokeless tobacco products and cigarettes.

**b. Evidence from International Researchers**

**i. The New Zealand Health Assessment (2007)**

In February 2007, New Zealand health researchers published a systematic review of the health effects of LN-SLT products, focusing on epidemiological studies of Swedish snus.<sup>44</sup> They reported, among other things, that the evidence suggests that these products pose “significantly less” risk than cigarette smoking for a variety of diseases:

The evidence from this review suggests that the harm of using snus, relative to non tobacco use, is significantly less than found for smoking with respect to cancers of the head, neck and gastro-intestinal region, and cardiovascular disease events.<sup>45</sup>

**ii. The Gartner Study (2007)**

In May 2007, Australian health researchers published a study that modeled the health impact of legalizing snus in Australia, where it is currently banned.<sup>46</sup> They concluded that “Individual smokers who switched to snus instead of continuing to smoke and new tobacco users who only used snus rather than smoking would achieve *large health gains* compared to smokers.”<sup>47</sup> They also predicted, as did the Levy Research Team in 2006, that snus would likely provide a net benefit to the public health.<sup>48</sup>

**iii. The Luo Study (2007)**

In May 2007, a team of international researchers affiliated with Sweden’s Karolinska Institute, the International Agency for Research on Cancer, and other institutions published an

---

<sup>43</sup> Kozlowski, *supra* n. 40, at S383. (footnote omitted).

<sup>44</sup> Broadstock, M., 2007. New Zealand Health Technology Assessment, Department of Public Health and General Practice, Christchurch School of Medicine and Health Science, Christchurch, New Zealand. “Systematic review of the health effects of modified smokeless tobacco products.”

<sup>45</sup> *Id.* at 82.

<sup>46</sup> Gartner, C.E., Hall, W.D., Vos, T., Bertram, M.Y., Wallace, A.L., Lim, S.S., 2007. “Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study.” *Lancet* (published online May 10, 2007).

<sup>47</sup> *Id.* at 3 (emphasis added).

<sup>48</sup> *Id.* at 1.

epidemiological analysis of tobacco use in 270,000 Swedish male construction workers during the period 1978-1992.<sup>49</sup> Their analysis focused on three cancer types – oral, lung, and pancreatic cancers – in cigarette smokers, snus users who never smoked, and never-users of any type of tobacco. The “main finding” of this study, as described by the authors, was an “increased risk of pancreatic cancer in never-smoking snus users compared with never-users of any tobacco, with some evidence for a dose response association. We did not detect any excess risk for cancer of the oral cavity or lung.”<sup>50</sup>

The results of this study also demonstrated significant reductions in risk for these diseases in snus users compared to cigarette smokers. These reductions are evident in the following graph, which appeared in a companion article published in the same scientific journal by two U.S. public health researchers, Drs. Jonathan Foulds and Lynn Kozlowski:

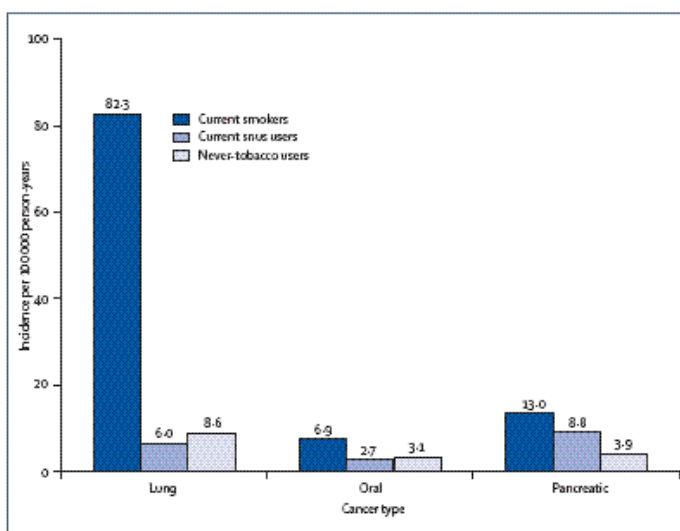


Figure: Age-adjusted incidence rates for three cancers (by 2004) as function of tobacco-use status in male Swedish construction workers at recruitment (1978-92). Redrawn from data in tables 2 and 3.<sup>4</sup>

Drs. Foulds and Kozlowski concluded, based on these and other data, that the risks “for all the major smoking-caused diseases” (including pancreatic cancer) are lower with snus than with smoking.<sup>51</sup>

<sup>49</sup> Luo, J., Ye, W., Zendehdel, K., Adami, J., Adami, H-O, Boffetta, P., Nyren, O., 2007. “Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung, and pancreas in male construction workers: a retrospective co-hort study.” *Lancet* (published online May 10, 2007).

<sup>50</sup> *Id.* at 3.

<sup>51</sup> Foulds, J. & Kozlowski, L., 2007. “Snus – what should the public-health response be?” *Lancet* (published online May 10, 2007) at 1.

iv. *The SCENIHR Preliminary Report (2007)*

In July 2007, the Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”) of the European Commission released for public comment a preliminary report entitled “Health Effects of Smokeless Tobacco Products.”<sup>52</sup> SCENIHR is one of several scientific committees that advises the European Commission’s Health & Consumer Protection Directorate-General, which is responsible for keeping up-to-date various laws established by the European Union (E.U.) relating to the safety of food and other products, consumer rights, and the protection of public health. E.U. law currently bans snus (and many other types of smokeless tobacco products) from the market in all member countries other than Sweden. In light of recent developments, the Directorate-General asked SCENIHR for its assessment of “the health effects of smokeless tobacco products (STP) with particular attention to tobacco for oral use, moist snuff, which is called ‘snus’ in Sweden.”<sup>53</sup>

Like recent scientific and public health reports which precede it, SCENIHR’s preliminary report found that the overall health risks of smokeless tobacco, particularly snus, are “clearly” and “substantially” less than the overall health risks of cigarettes.

Overall therefore, in relation to the risks of the above major smoking related diseases, and with the exception of use in pregnancy, STP and particularly snus are clearly less hazardous, or substantially less hazardous, than cigarette smoking. This conclusion is also reached by the only systematic review of the evidence from studies that allow direct comparison of relative risks of smoking and smokeless in the same populations (Roth et al. 2005). The magnitude of the overall reduction in hazard is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for pancreatic cancer at least 30%, for oral and other GI cancer at least 50% and probably more, and for lung cancer and chronic obstructive pulmonary disease, possibly 100%. A recent study using a modified Delphi approach (judgement [*sic*] by a panel of experts) to estimate the relative hazard of snus concluded that the product was likely to be approximately 90% less harmful than smoking (Levy et al. 2004b).<sup>54</sup>

Indeed, SCENIHR found the evidence so compelling that it described its findings regarding the disease risk of smokeless tobacco products as “undeniable”:

---

<sup>52</sup> European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), “Health Effects of Smokeless Tobacco Products Preliminary Report,” approved for public consultation at the 19<sup>th</sup> plenary on 21-22 June 2007. The preliminary report is open for public comment until September 28, 2007.

<sup>53</sup> *Id.* at 9.

<sup>54</sup> *Id.* at 107.

It is undeniable that for an individual substitution of tobacco smoking by the use of moist snuff would decrease the incidence of tobacco related diseases.<sup>55</sup>

The only increased risk for snus relative to cigarette smoking occurred during pregnancy. SCENIHR cited a 2003 study which found that the use of cigarettes or snus during pregnancy increased the risks of preterm delivery and other complications compared to non-users of tobacco. In this study, which was based on data from Sweden, maternal use of snus during pregnancy increased these risks to a greater extent than smoking cigarettes, although cigarette smoking led to a greater reduction in birthweight than using snus.<sup>56</sup> Evaluating this study and others, SCENIHR concluded that “the data on reproductive effects in relation to oral tobacco use during pregnancy are too sparse to allow conclusions.”<sup>57</sup>

v. *The Royal College of Physicians Report (2007)*

In October 2007, the Tobacco Advisory Group of the Royal College of Physicians (“RCP”) issued a report entitled “Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit.”<sup>58</sup> RCP is an independent professional membership organization in the U.K. established in 1518 “representing over 22,000 Fellows and Members worldwide” which “aims to ensure high quality care for patients by promoting the highest standards of medical practice. It provides and sets standards in clinical practice and education and training, conducts assessments and examinations, quality assures external audit programmes, supports doctors in their practice of medicine, and advises the Government, public and the profession on health care issues.”<sup>59</sup>

Consistent with several other recent scientific and public health reports, the RCP report found that the health risks of smokeless tobacco, especially LN-SLT products like snus, are “considerably” and “substantially” less than the overall health risks of cigarettes:

The health risks of smokeless tobacco are considerably lower than those associated with combustible tobacco products as it is largely the combustion process that makes tobacco use so deadly . . . . The major benefits of smokeless tobacco products over combustible products are the virtual absence of respiratory risks, and potentially

---

<sup>55</sup> *Id.* at 13.

<sup>56</sup> *Id.* at 107.

<sup>57</sup> *Id.* at 100. SCENIHR also considered the overall public health impact of permitting snus to be marketed in E.U. countries where it is currently banned. It found that the public health impact might be beneficial or adverse, depending on factors such as the effect of snus on reducing smoking prevalence in the E.U. and the manner in which snus is marketed. *Id.* at 107-10.

<sup>58</sup> Royal College of Physicians, “Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit.” A report by the Tobacco Advisory Group of the Royal College of Physicians. October 2007 (hereinafter “RCP Report”).

<sup>59</sup> Royal College of Physicians, The College, <http://www.rcplondon.ac.uk/college/>.

lower cardiovascular risks due to the absence of the gaseous components in smoke.”<sup>60</sup>

[S]mokeless tobacco products, and particularly the low nitrosamine products, are substantially less hazardous than smoked tobacco.”<sup>61</sup>

The RCP report “examine[d] the evidence for an association between smokeless tobacco and specific types of disease”<sup>62</sup> and compared such health effects with those of cigarette smoking, determining that the major health risks for smokeless tobacco – particularly snus – are lower, and in most cases much lower, relative to cigarettes:

[I]t is very clear that, for most of the major health effects of tobacco, smoking is many times more dangerous than smokeless tobacco use. Perhaps the main exceptions are pre-eclampsia, because other components in tobacco smoke appear to have a mild preventive effect, and cardiovascular disease, in which the risks from smoking, although certainly greater than those from smokeless use, may be in a similar range of risk.<sup>63</sup>

On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential for harm to health . . . . [I]n relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favourable.<sup>64</sup>

Based on these findings, RCP concluded that “[s]mokeless tobacco . . . has potential application as a lower hazard alternative to cigarette smoking” and, in particular, “[l]ow nitrosamine smokeless tobacco products may have a positive role to play in a coordinated and regulated harm reduction strategy which maximises public health benefit . . . .”<sup>65</sup>

## **5. The U.S. Public Health Community: Re-evaluating Positions and Recent Perspectives**

In the face of increasing scientific evidence, many members of the public health community who *previously* stated that smokeless tobacco products were no less dangerous than cigarettes have re-evaluated their position and no longer hold this view. Until June 2002, for example, the website of the Centers for Disease Control and Prevention (“CDC”) asked the

---

<sup>60</sup> RCP Report at 18.

<sup>61</sup> *Id.* at 221.

<sup>62</sup> *Id.* at 145.

<sup>63</sup> *Id.* at 156.

<sup>64</sup> *Id.* at 161, 237

<sup>65</sup> *Id.* at 161, 230, 238, 241.

question “Is smokeless tobacco safer than cigarettes?”, and answered it: “NO WAY! It’s true that many people think smokeless tobacco . . . isn’t as bad as cigarettes . . . . Very Wrong!”<sup>66</sup> After re-evaluating the available scientific evidence, the CDC subsequently revised its website to its current form, which states that smokeless tobacco is not safe but does not compare it with cigarette smoking.<sup>67</sup> Similarly, in early 2006, the Substance Abuse and Mental Health Services Administration (SAMHSA) removed from its website a conclusion that smokeless tobacco was not “safer to use than cigarettes.”<sup>68</sup>

Within the last few years, the American Cancer Society (ACS) also changed its position regarding the risk of smokeless tobacco products relative to cigarettes. As of December 2004, the ACS website stated that “Some people believe that using smokeless tobacco is safer than smoking. This is not true.” ACS subsequently revised its website, replacing the word “safer” with “safe,” and eliminating any comparison with cigarette smoking.<sup>69</sup> To this day, rather than addressing the comparative risk question directly, the ACS website states only that “some people” suggest that smokers should switch to smokeless tobacco products, while “most medical experts recommend quitting use of all tobacco products.”<sup>70</sup> However, in August 2006, the *New York Times* quoted the ACS director of cancer science and trends as stating that pouches of smokeless tobacco products “may be less harmful than other smokeless tobacco products and cigarettes.”<sup>71</sup> And, in March 2007, the *Wall Street Journal* quoted Dr. Michael Thun, the ACS

---

<sup>66</sup> See L.T. Kozlowski & R.J. O’Connor, *Apply Federal Research Rules on Deception to Misleading Health Information: An Example on Smokeless Tobacco and Cigarettes*, Public Health Reports, 118:187-192 (2003).

<sup>67</sup> See *id.*; see also The Surgeon General’s Report for Kids About Smoking, available at: <http://www.cdc.gov/TOBACCO/SGR/sgr4kids/smokless.htm> (“Is smokeless tobacco safe?” NO WAY! It’s true that many people think smokeless tobacco . . . is safe . . . . Very Wrong!”).

<sup>68</sup> Until early 2006, a page on SAMHSA’s website answered the question “Isn’t smokeless tobacco safer to use than cigarettes?” by stating “No. There is no safe form of tobacco.” Following a “request for correction” under the Data Quality Act filed by the National Legal and Policy Center on December 12, 2005, SAMHSA removed the material altogether from its website and no longer addresses the health risk of smokeless tobacco versus cigarettes. See ACSH Report, at 7; Letter from Kenneth Boehm, Chairman, National Legal and Policy Center, to Mark Weber (SAMHSA) regarding Request for Correction of Erroneous Information Under the Data Quality Act, December 12, 2005, available at <http://aspe.hhs.gov/infoQuality/request&response/26a.shtml>.

Under similar circumstances, the National Institute on Aging (NIA) contained a statement on its website that smokeless tobacco was “not safer” than cigarettes, but changed it in 2004 to read simply that smokeless tobacco is not “safe” following another request for correction under the Data Quality Act by the National Legal & Policy Center. See ACSH Report, at 7.

<sup>69</sup> See Jacob Sullum, *Safer Alternative*, Reason Online, Dec. 28, 2004.

<sup>70</sup> See “Quitting Spit and Other Forms of Oral Tobacco,” [http://www.cancer.org/docroot/PED/content/PED\\_10\\_13X\\_Quitting\\_Smokeless\\_Tobacco.asp?sitearea=](http://www.cancer.org/docroot/PED/content/PED_10_13X_Quitting_Smokeless_Tobacco.asp?sitearea=), accessed May 19, 2007.

<sup>71</sup> Jane L. Levere, *No Smoke, No Foul? Critics Disagree*, N.Y. Times, Aug. 9, 2006. The ACS official, who did not specify which forms of smokeless tobacco “may be less harmful,” went on to argue that the suggestion that cigarette smokers switch to smokeless tobacco products is “a very tempting argument, but it is a Pandora’s box. There’s a lot we don’t know about. The products could encourage people to continue smoking who ordinarily would have quit.”

vice president of epidemiology, as saying “There’s *no question* that switching to spit tobacco and quitting tobacco altogether are both *far less lethal* than continuing to smoke.”<sup>72</sup>

These individuals and public health organizations are not alone. Within the last several years, many other well-known members of the public health community have acknowledged that the risks of smokeless tobacco products, especially LN-SLT products, are far lower than the risks of cigarette smoking.<sup>73</sup> For instance, referring to these products in 2005, Dr. Gary Giovino, the director of Tobacco Research Program at Roswell Park Cancer Institute, remarked that “If everybody who smoked used these instead, there would be less disease.”<sup>74</sup> Dr. Neal Benowitz, a professor and researcher at the University of California - San Francisco, similarly concluded that “If someone can’t quit smoking, *there is no question* that smokeless is much safer.”<sup>75</sup>

It must be acknowledged, however, that some members of the public health community adamantly oppose the notion of providing smokers with scientifically accurate information about the health risks of LN-SLT and other smokeless tobacco products as compared to cigarettes. This debate does not concern whether these products pose lower risk to the individual than cigarette smoking. Rather, it relates to whether communicating that information to consumers might increase the overall level of tobacco use in the population as a whole by, for example, causing people who do not currently use tobacco products to start, or by causing cigarette smokers to switch to smokeless tobacco products instead of quitting tobacco use altogether. Concerns have also been expressed that smokeless tobacco products may function as a “gateway” to future cigarette smoking,<sup>76</sup> or, for current smokers, undermine smoking cessation by providing smokers with a means to obtain nicotine when they cannot smoke. Speaking to these issues, the ACSH Report concluded:

---

<sup>72</sup> K. Helliker, *The Case for Smokeless Tobacco*, Wall St. Journal, March 27, 2007 (emphasis added).

<sup>73</sup> This is not to say that LN-SLT products or other forms of smokeless tobacco are regarded as “safe.” Indeed, epidemiological evidence recently published by ACS and CDC scientists reported that cigarette smokers who switched to smokeless tobacco had a higher disease risk than cigarette smokers who quit using tobacco entirely. See Henley, S.G., Connell, C.G., Richter, P., Husten, C., Pechachek, T., Calle, E.E., Thun, M.J., 2007. “Tobacco-related disease mortality among men who switched from cigarettes to spit tobacco.” *Tobacco Control* 16:22-28. This study did not compare the risks of switching to the risks of continuing to smoke, but its co-author Dr. Thun recently observed, as noted in the text above, that switching to smokeless tobacco is “far less lethal than continuing to smoke.” See *supra* n. 72 and accompanying text. Even so, it is appropriate to continue to remind smokers that “abstaining from tobacco use altogether is the safest course of action.”

<sup>74</sup> Valerie Retiman, *Cigarette stand-ins: a safer addiction?* Seattle Times, June 30, 2004.

<sup>75</sup> *Id.* (emphasis added).

<sup>76</sup> Some members of the public health community have expressed the concern that snus (and other forms of smokeless tobacco) might serve as a “gateway” to cigarette smoking; others, citing the experience of Sweden, maintain that “To the extent there is a ‘gateway’ it appears not to lead *to* smoking, but *away* from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe.” See, e.g., Bates et al., 2003, *supra* n. 14, at 2 (emphasis added); ACSH Report, *supra* n. 8, at 6 (“Concerns have been expressed that the use of smokeless tobacco might serve as a gateway to the much more dangerous habit of cigarette smoking, but the Swedish experience doesn’t support this idea. Studies of men in Sweden have indicated that the use of snus is more likely to lead to quitting smoking than starting it. Snus users were less likely than nonusers to start smoking, and snus was the most commonly used smoking cessation aid.”).

Some government and health organizations and health professionals may be reluctant to tell people that smokeless tobacco use is less dangerous than cigarette smoking out of concern that this information might prompt nonusers of tobacco to start using smokeless tobacco. However, *the overall public health impact of any increase in smokeless tobacco use is extremely unlikely to outweigh the beneficial effect of cigarette smokers switching to smokeless tobacco, since it would require 50 people to start using smokeless tobacco to equal the degree of health risk associated with one person smoking.*<sup>77</sup>

This conclusion is bolstered by the results of the Levy studies described above, which predicted “a net public health benefit through reduced mortality” as a result of reduced cigarette smoking, notwithstanding the potential for a “modest” increase in smokeless tobacco use.<sup>78</sup>

## **6. Conclusion**

The scientific evidence and analysis relating to LN-SLT products has developed and evolved substantially since 2003, when former Surgeon General Carmona stated that there was “no significant scientific evidence that suggests smokeless tobacco is a safer alternative to cigarettes.” In fact, based on today’s evidence, many scientists, doctors, and public health officials have publicly concluded that smokeless tobacco products, particularly LN-SLT products, are far less hazardous than cigarettes. Recent studies, however, show that the vast majority of smokers continue to believe that cigarette smoking is no more harmful than using smokeless tobacco. Indeed, in a survey of 2,028 U.S. smokers published in 2005, only 10.7% responded that smokeless products are less hazardous than cigarettes.<sup>79</sup> As noted by the public health scientists who reported this finding:

Here, smokers are *misinformed* in the opposite direction. Epidemiologic data suggest that SLT products sold in the United States are significantly less dangerous than cigarettes. Reservations remain about promoting SLT products for harm reduction in the United States, given the wide range of toxic constituents from brand to brand and concerns about marketing to youth. But smokers are clearly more apt to believe that cigarette-like products, with modest potential to reduce risk at best, are safer than SLT, which actually holds much greater potential for

---

<sup>77</sup> ACSH Report, *supra* n. 8, at 7.

<sup>78</sup> Levy et al., 2006, *supra* n. 5, at 1199.

<sup>79</sup> O’Connor, R.J., Hyland, A., Giovino, G.A., Fong, G.T., Cummings, K.M., 2005. “Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products.” *American Journal of Preventive Medicine* 29(2):85-89, 89. *See also* Cummings, 2002, *supra* n. 16, at 7360 (“Amazingly, many smokers don’t perceive much difference in health risks between smokeless tobacco products, nicotine medications and cigarettes.”).

reductions in risk. In short, this U.S. national sample of adult smokers holds beliefs about the relative harm reduction potential of modified cigarettes and SLT that are *contrary to the available scientific evidence*.<sup>80</sup>

This submission supports the view that the health risks of serious disease from the use of LN-SLT products are substantially lower than the health risks from smoking cigarettes. PM USA therefore respectfully requests that the Office of the Surgeon General examine the scientific evidence described above and communicate to the public the relative health risks from the use of LN-SLT products compared to the health risks from smoking cigarettes.

---

<sup>80</sup> *Id.* (emphasis added).