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Via Certified Mail #7005 1160 0004 8562 and E-mail: [Infoquality@samhsa.gov](mailto:Infoquality@samhsa.gov)

December 15, 2005

Mr. Mark Weber  
Director, Office of Communications  
Substance Abuse and Mental Health Services Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Request for Correction of Erroneous Information  
Under the Data Quality Act

Dear Mr. Weber:

The National Legal and Policy Center (NLPC) brings this information quality request for correction of erroneous information disseminated by the Substance Abuse and Mental Health Administration's (SAMHSA) National Clearinghouse for Alcohol and Drug Information (NCADI) concerning the relative risks of using smokeless tobacco compared to smoking cigarettes. The erroneous information violates the Data Quality Act (DQA),<sup>1</sup> the implementing guidelines issued by the Office of Management and Budget (OMB Guidelines),<sup>2</sup> the Department of Health and Human Services (HHS Guidelines),<sup>3</sup> and the Substance Abuse and Mental Health Services (SAMHSA Guidelines).<sup>4</sup>

<sup>1</sup> Pub. L. 106-554, amending Paperwork Reduction Act; 44 U.S.C. §§ 3501 et seq.

<sup>2</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002), available at [www.whitehouse.gov/omb/fedreg/reproducible2.pdf](http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf).

<sup>3</sup> Guidelines for Ensuring the Quality of Information Disseminated by HHS Agencies, available at [www.hhs.gov/infoquality](http://www.hhs.gov/infoquality).

<sup>4</sup> Guidelines for Ensuring the Quality of Information Disseminated to the Public, available at [www.hhs.gov/infoquality/Guidelines/SAMSHAinfo2.shtml](http://www.hhs.gov/infoquality/Guidelines/SAMSHAinfo2.shtml).

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## I. Overview

The erroneous information appears in a brochure produced by SAMHSA which can also be accessed on the Internet at <http://ncadi.samsha.gov/govpubs/phd633/>. A copy of the material cited is attached at Tab A.

The document, entitled "Tips for Teens: The Truth About Tobacco," (#PH323) and its corresponding web page, provide information regarding health risks associated with the use of tobacco.

Under the "Q & A" section, the following appears:

**Q. Isn't smokeless tobacco safer to use than cigarettes?**

**A. No. There is no safe form of tobacco.**

The answer goes on to describe health risks purported to occur from the use of smokeless tobacco but the initial response to the effect that smokeless tobacco is not safer than cigarettes is patently erroneous and is not supported by the weight of sound science. In fact, there is a substantial body of scientific consensus to the opposite: that the use of smokeless tobacco involves significantly less risks of adverse health effects than cigarette smoking.

The government's dissemination of this erroneous information has serious ramifications. No information is more important to consumers than information about health, and when a federal agency is the source of that information, the public believes it and relies upon it. If it is not accurate, it can do damage, both to the public health in general and to individuals who act, or fail to act, upon the misinformation.

The misinformation at issue here equates the relative risks of smokeless tobacco to that of cigarette smoking. It misleads consumers, and denies them the opportunity to make informed choices about the tobacco products they use, and the alternatives available for reducing their risks.

Moreover, when a substantially similar claim was made by the National Institute for Aging, a part of the National Institute for Health and – as with SAMHSA – part of the Department of Health and Human Services, the National Legal and Policy Center filed a formal request for correction of erroneous information under the Data Quality Act. The printed statement to which NLPC objected was:

**"Some people think smokeless tobacco (chewing tobacco and snuff), pipes, and cigars are safer than cigarettes. They are not."**

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The NLPC DQA complaint focused its objection to the portion of the statement which declared that smokeless tobacco was not safer than smoking cigarettes.

After a thorough review, the National Institute for Aging responded in a letter from Jane E. Shure, Director of the Office of Communications and Public Liaison dated June 29, 2004:

**“In response to your Request we carefully reviewed scientific literature on the subject of smokeless tobacco. Because NIA is committed to providing precise and scientifically accurate information we have decided to discard our existing inventory of *Smoking: It’s Never Too Late to Stop*. We will print a new edition that is a more current statement of evidence-based information. The updated language on smokeless tobacco will be immediately reflected on our web version.”**

Given the consequences of disseminating this erroneous information, SAMHSA should act quickly to correct the information. Further, it should take steps to notify consumers of the error so they do not continue to make decisions involving their health based on inaccurate information. Lingering misperceptions can only be corrected by such measures.

Below is a fuller discussion of the grounds for this request. Pursuant to SAMHSA Guidelines, the following topics are addressed: (a) the reasons for believing the information is erroneous and fails to comply with OMB, HHS, and SAMHSA Guidelines; (b) recommendations as to what corrective actions should be taken; and (c) a description of how the requester is affected by the information error.

## **II. Why the Disseminated Information is Erroneous and Fails to Comply with Data Quality Guidelines**

### **A. The Disseminated Information is Contradicted by Sound Science**

The statement being challenged here is only the claim that use of smokeless tobacco is not less harmful than smoking cigarettes. No challenge is being made at this time to statements that smokeless tobacco is not safe.

There is no sound scientific research to support the challenged claim. In fact, there is a substantial body of scientific opinion that the health risks from using smokeless tobacco available in the United States today are dramatically less than from smoking cigarettes.

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Scientific research supports the following findings regarding the comparative health risks between cigarettes and smokeless tobacco products in the U.S. and Sweden:

- Although some studies show that smokeless tobacco products are not “safe,” “the overall risk is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk.”<sup>5</sup> In fact, a group of renowned scientists reported recently that they are confident that the evidence base supports a conclusion that, on average, “Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking.”<sup>6</sup>
- Swedish men, who prefer a form of moist snuff, called “snus” over cigarettes, experience Europe’s lowest risk of dying from a smoking-related disease, and benefit from Europe’s lowest rates of lung cancer, larynx cancer, oral cavity cancer and bladder cancer.<sup>7</sup>
- With respect to cardiovascular risks, the adverse effects of smokeless tobacco are much less than from cigarette smoking.<sup>8</sup>

<sup>5</sup> — Stratton K, Shetty P, Wallace R, Bondurant S (eds.) Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine. National Academy Press, Washington, D.C., 2001, at p. 434. See also Henningfield JE, Fagerström KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control* 2001; 10: 253-257; Johnson N. Tobacco use and oral cancer: A global perspective. *J Dent Educ* 2001; 65: 328-339; Fagerström KO, Ramström L. Can smokeless tobacco rid us of tobacco smoke? *Am J Med* 1998; 104: 501-503; Tobacco Advisory Group of the Royal College of Physicians of London, Protecting Smokers, Saving Lives: The Case for a Tobacco and Nicotine Regulatory Authority, 2002, at p. 5. Kozłowski L. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine & Tobacco Research* 2002; 4: (suppl 2): S55-S60.

<sup>6</sup> Bates C, Fagerström K, Jarvis M, Kunze M, McNeill A, Ramström L. European Union policy on smokeless tobacco. A statement in favor of evidence-based regulation for public health. February 2003, available at <http://www.ash.org.uk/html/regulation/html/eusmokeless.html>. The mortality risk of smokeless tobacco is viewed by some to be only about two percent that of cigarette smoking. See e.g., Rodu B, Cole P. Nicotine maintenance for inveterate smokers. *Technology* 1999; 6:17-21.

<sup>7</sup> See e.g., Wilson, C. My friend nicotine. *New Scientist* 2001; 10: 28-31; Cole P, Rodu B. Analytic Epidemiology: cancer causes. *Cancer: Principles & Practice of Oncology*. Lippincott Williams & Wilkins, Pennsylvania 2001: 241-252.

<sup>8</sup> See e.g., Huhtasaari F, Lundberg V, Eliasson M, Janlert U, Asplund K. Smokeless tobacco as a possible risk factor for myocardial infarction: A population-based study in middle-aged men. *J Am Coll Cardiol* 1999; 34: 1784-1790; Benowitz NL. Medical implications. In: Davis RM (ed). Smoking cessation: Alternative strategies. Session III: Implications of alternative treatment goals. In: *Tobacco Control* 1995; 4: (suppl 2): S44-S48; Bates C, “Harm Reduction and Smokeless Tobacco,” (presentation at the 3<sup>rd</sup> International Conference on Smokeless Tobacco, Stockholm, Sweden, September 2002).

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- Cigarette smoking harms non-users through exposure to second hand tobacco smoke, whereas smokeless tobacco eliminates such risks to others because it produces no second hand smoke.<sup>9</sup>

## **B. The Information Fails to Comply with the Data Quality Act and OMB, HHS and SAMHSA Guidelines**

The erroneous statements at issue here violate the general standards of objectivity and utility, as well as the higher standards of quality for “influential scientific information,” that are required by the guidelines of OMB, HHS and SAMHSA.

### **1. Objectivity Standard**

All three guidelines require objectivity in both “presentation and substance.”<sup>10</sup> This means information must be presented in an “accurate, clear, complete and unbiased manner,”<sup>11</sup> and must be based on “accurate, reliable and unbiased” information.<sup>12</sup> In addition, HHS Guidelines provide that information in a “scientific context” must have supporting data that has been generated and analyzed “using sound statistical and research methods.”<sup>13</sup> Further, the misinformation contained in the SAMHSA web page does not cite specific studies or evidence on which it relies. As a result, there is no way to verify the accuracy of the statements. This is especially troublesome in light of OMB’s recent emphasis on the importance of peer reviews.<sup>14</sup> The OMB Bulletin on Peer Review and Information Quality proposes that peer reviews be conducted for the “most important scientific information regarding regulatory policy.”<sup>15</sup>

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<sup>9</sup> Shiffman S, Gitchell J, Warner K, Slade J, Henningfield J, Pinney J. Tobacco harm reduction: Conceptual structure and nomenclature for analysis and research. *Nicotine & Tobacco Research* 2002; S113-S129.

<sup>10</sup> See e.g., OMB Guidelines, V.3., 67 Fed. Reg. at 8459.

<sup>11</sup> *Id.* at V.3.a.

<sup>12</sup> *Id.* at V.3.b.

<sup>13</sup> HHS Guidelines, Part 1.D.2.c.

<sup>14</sup> See Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (Sept. 15, 2003)[hereinafter OMB Bulletin].

<sup>15</sup> *Id.* at 54026.

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The statements at issue here qualify as “most important scientific information” for two reasons. First, they are “influential,” as discussed below. Second, they relate to the agency’s position on smokeless tobacco generally which impact the decisions of the millions of adults who wish to quit smoking cigarettes. As discussed above, there is a growing scientific consensus that smokeless tobacco is significantly less hazardous than cigarettes. Peer review of any evidence to the contrary would demonstrate that the information contained in the “AGE Page” is incorrect and adversely impacts those who view it.

SAMHSA’s statements published in the document and on the web site about the comparative risks of smoking and smokeless tobacco fail these tests of objectivity. As discussed above, the information is neither accurate nor presented in a clear, accurate and complete manner. The information is contradicted by reliable scientific opinion, and the manner of presentation is misleading to consumers.

## 2. Utility Standard

All three guidelines require that disseminated information be useful to its intended users, including the public. In the case at hand, the erroneous information is not only not useful for this purpose, it is harmful to members of the public who rely on this misinformation to make decisions that are ultimately deleterious to their health.

## 3. Standard for “Influential Scientific Information”

Under the OMB Guidelines, the information at issue here must meet a higher standard of quality for information, because it falls into the category of “influential scientific information.”<sup>16</sup>

<sup>17</sup> Similarly, in its Guidelines, SAMHSA states that it “will ensure that disseminated information meets the standards of quality set forth in the OMB, HHS and SAMHSA guidelines. It is SAMHSA’s policy to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public.”<sup>18</sup> The statements at issue here constitute, “influential scientific information” because private individuals will rely on these statements - made by a government agency focused on public health - as they make choices about the comparative health risks of smoking cigarettes versus using smokeless tobacco.

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<sup>16</sup> *Id.* At V.3.b. ii. The standard requires “a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.”

<sup>17</sup> *Id.* at V.9. “‘Influential’, when used in the phrase ‘influential scientific ... information’ means that the agency can reasonably determine that dissemination of the information will have ... a substantial impact on important private sector decisions.”

<sup>18</sup> SAMHSA Guidelines for Ensuring the Quality of Information Disseminated to the Public, at I

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This higher standard applies to information which the agency can reasonably determine will have a clear and substantial impact on important public policies or important private sector decisions, *or will have important consequences for specific health practices.*

The statement challenged here, which appears in a publication and on a web site designed to offer recommendations about public health, falls squarely into the category of "Recommendations about Health Practices." It also has "important consequences for specific health practices," since its very aim is to influence consumers to make health-related decisions about their use of tobacco products. This is exactly the kind of influential public health information that the Guidelines require be supported by rigorous scientific standards. SAMHSA has fallen far short of meeting such standards.

### **III. Recommended Corrective Action**

#### **A. Correction of Erroneous Information**

The SAMHSA's publication and web site (Tab A) should be revised in the following ways:

- The current question – if it remains as written ("Isn't smokeless tobacco safer to use than cigarettes?") must be answered "Yes."
- A new paragraph should be added with the heading: "Smokeless Tobacco is Significantly Less Hazardous than Smoking." In the text that follows the heading, accurate information should be provided about the risks of smokeless tobacco, including the relative risks of smokeless tobacco compared to smoking. Text along the following lines should be included: "The use of smokeless tobacco available in the United States today involves significantly less risk of adverse health effects than cigarette smoking. Those who do not or cannot quit smoking, and for whom nicotine replacement therapy is not a satisfactory solution, should consider switching completely from smoking cigarettes to using smokeless tobacco as a harm reduction alternative."

It is not sufficient simply to rewrite the text of the document to omit any reference to the relative risks of smokeless tobacco compared to cigarettes. This would do nothing to correct the misimpressions about the relative risks of smokeless tobacco created by the erroneous text. Such corrective action is needed where the misleading information affects individual adult decisions which could have a significant impact on their health.

#### **B. Public Notice of Correction**

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Given the potential adverse consequences of widely disseminating erroneous information about the relative risks of tobacco products, and the difficulty of identifying those members of the public who received the information, this is a case where SAMHSA should issue a press release to correct the error. In addition, the SAMHSA should provide notice of the error and correction on the home page of its web site for a sufficient period of time to reach those repeat visitors to the site who may have received the erroneous information.

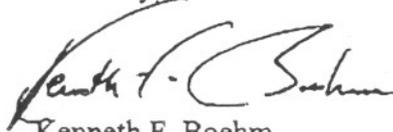
#### **IV. Requester is Adversely Affected by the Information Error**

The National Legal and Policy Center (NLPC) has demonstrated a long commitment to promoting open, accountable and ethical practices related to health care policy. NLPC was one of the groups which successfully challenged the illegal secrecy of President Clinton's Health Care Task Force in federal court in 1993. In 1996, NLPC filed more than 650 Freedom of Information Act requests with the Food and Drug Administration. The information obtained regarding improprieties at the FDA was covered in a nationwide Associated Press article and the FDA Commissioner announced his intended resignation shortly after the AP story ran.<sup>19</sup> NLPC seeks to add reason and balance to debates about public health issues and to bring common sense views on these issues to the public.

The SAMHSA's dissemination of erroneous information about the relative risks of smokeless tobacco, which contributes to widespread public misperceptions about such risks, adversely affects the efforts of the National Legal and Policy Center (a) to ensure that the public receives common sense views on smokeless tobacco, based on reliable scientific evidence, and (b) to encourage debate in the public health community on the use of smokeless tobacco as a harm reduction alternative to smoking cigarettes.

We appreciate your consideration of this request. We believe it raises issues of significant public interest and deserves your prompt attention and careful consideration.

Sincerely,



Kenneth F. Boehm  
Chairman

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<sup>19</sup> "Study Shows FDA Chief's Expenses Were Padded," *The Washington Times*, Associated Press, Saturday, Nov. 2, 1996, page A3

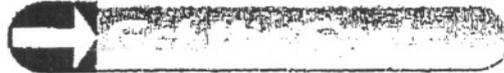
 Add to Cart

# TIPS FOR TEENS

The Truth About

## Tips for Teens: The Truth About Tobacco

### **Slang -- Cigarettes: Smokes, Cigs, Butts. Smokeless Tobacco: Chew, Dip, Spit Tobacco, Snuff**



**Tobacco damages your health.** Smoking is the most common cause of lung cancer. Smoking is also a leading cause of cancer of the mouth, throat, bladder, pancreas, and kidney. Smokeless tobacco can cause mouth cancer, tooth loss, and other health problems.

**Tobacco affects your body's development.** Smoking is particularly harmful for teens because your body is still growing and changing. The 200 known poisons in cigarette smoke affect your normal development and can cause life-threatening diseases, such as chronic bronchitis, heart disease, and stroke.

**Tobacco is addictive.** Cigarettes contain nicotine—a powerfully addictive substance. Three-quarters of young people who use tobacco daily continue to do so because they find it hard to quit.

**Tobacco can kill you.** Smoking is the leading preventable cause of death in this country. More than 400,000 Americans die from tobacco-related causes each year, and most of them began using tobacco before the age of 18.



**Know the law.** It is illegal for anyone under 18 to buy cigarettes, smokeless tobacco, or tobacco-related products.

**Stay Informed.** Addiction to tobacco is hard to control. More than 90 percent of teens who use tobacco daily experience at least one symptom of withdrawal when they try to quit.

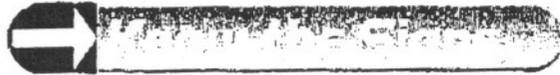
**Keep your edge.** The poisons in cigarettes can affect your appearance. Smoking can dry your skin out and cause wrinkles. Some research even relates smoking to premature gray hair and hair loss.

**Be aware.** It can be hard to play sports if you use tobacco. Smoking causes shortness of breath and dizziness, and chewing tobacco causes dehydration.

**Think of others.** Smoking puts the health of your friends and family at risk. Approximately 3,000 nonsmokers die of lung cancer each year from breathing other peoples' smoke.

**Get the facts.** Each day more than 3,000 people under age 18 become regular smokers. That's more than 1 million teens per year. Roughly one-third of them will eventually die from a tobacco-related disease.

**Look around you.** Even though a lot of teens use tobacco, most don't. According to a 1998 study, less than 20 percent of teens are regular smokers. In fact, 64 percent of 12- to 17-year-olds have never even tried a cigarette.



How can you tell if a friend is using tobacco? Sometimes it's tough to tell. But there are signs you can look for. If your friend has one or more of the following signs, he or she may be regularly using tobacco:

- Wheezing
- Coughing
- Bad breath
- Smelly hair and clothes
- Yellow-stained teeth and fingers
- Frequent colds
- Decreased senses of smell and taste
- Difficulty keeping up with sports and athletic activities
- Bleeding gums (smokeless tobacco)
- Frequent mouth sores (smokeless tobacco)

What can you do to help someone who is using tobacco? Be a real friend. Encourage your friend to quit. For information and referrals, call the National Clearinghouse for Alcohol and Drug Information at 800-729-6686.

## Q&A

**Q.** Doesn't smoking help you relax?

**A.** No. Smoking can actually increase feelings of stress and nervousness. Break the cycle: Use drug-free strategies to calm your nerves like exercise and talking to your friends.

**Q.** Isn't smokeless tobacco safer to use than cigarettes?

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

**Q.** Isn't smoking sexy?

**A.** Only if you think bad breath, smelly hair, yellow fingers, and coughing are sexy. Advertisements often portray smoking as glamorous and sophisticated, but think carefully about who created these ads and why.

## Info

To learn more about tobacco, or obtain referrals to programs in your community, contact:

SAMHSA's National Clearinghouse for Alcohol and Drug Information  
800-729-6686  
TDD 800-487-4889

linea gratis en español 877-767-8432  
Web site: [ncadi.samhsa.gov](http://ncadi.samhsa.gov)

Curious about the TV ads of the National Youth Anti-Drug Media Campaign? Check out the Web site at <http://www.freevibe.com> or visit the Office of National Drug Control Policy Web site at <http://www.whitehousedrugpolicy.gov>.

The bottom line: If you know someone who is using tobacco, urge him or her to quit. If you are using it-stop! The longer you ignore the real facts, the more chances you take with your health and well-being.

It's never too late. Talk to your parents, a doctor, a counselor, a teacher, or another adult you trust.

Do it today!

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## Footnotes

1. U.S. Centers for Disease Control and Prevention (CDC). "Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users -- United States, 1993," *Morbidity and Mortality Weekly Report (MMWR)*. 43(41):745-750, October 21, 1994.
  2. Ibid.
  3. Mosely, J.G., and Gibbs, A.C. "Premature grey hair and hair loss among smokers: a new opportunity for health education?" *British Medical Journal*. 313(7072):1616, December 21, 1996.
  4. *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders Fact Sheet*. EPA, 1992.
  5. CDC. "Incidence of Initiation of Cigarette Smoking--United States 1965-1996," *MMWR*. 47(39):837-840, October, 9 1998.
- See also, Pierce, J.P., et. al., "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *Journal of the American Medical Association*, Vol. 261, No. 1, 1989.
6. CDC. "Projected Smoking-Related Deaths Among Youth--United States," *MMWR*. 45(44):971-974, November 8, 1996.
  7. 1998 National Household Survey on Drug Abuse. Substance Abuse and Mental Health Services Administration (SAMHSA), 1998.
  8. CDC. Oral Cancer Background Papers-Working Draft. August 7-9, 1996.