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REC'D NIH 3/17/04

March 16, 2004

Office of Communications
ATTN: Information Quality
National Institute on Aging
Building 31, Room 5C-27
9000 Rockville Pike
Bethesda, MD 20892

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

Dear Sir or Madam:

This is to request correction of erroneous information disseminated by the National Institute on Aging (NIA) concerning the relative risks of using smokeless tobacco compared to smoking cigarettes. The erroneous information violates the Data Quality Act (DQA),¹ and the implementing guidelines issued by the Office of Management and Budget ("OMB Guidelines"),² the Department of Health and Human Services ("HHS Guidelines")³ and the National Institutes of Health ("NIH Guidelines").⁴

I. Overview

The erroneous information appears in an health information publication of the NIA, which also can be accessed on the Internet at <http://www.niapublications.org/engagepages/smoking.asp>. A copy of the relevant information at this website is attached at Tab A. The document, entitled "Smoking: It's Never Too Late to Stop," and its corresponding web page, provide information about the

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

² 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.

³ Guidelines for Ensuring the Quality of Information Disseminated by HHS Agencies, available at www.hhs.gov/infoquality.

⁴ Guidelines for Ensuring the Quality of Information Disseminated to the Public, available at www.hhs.gov/infoquality/NIHinfo2.htm.

risks of smoking and how to quit. The document is part of a series of NIA "Age Pages" which provide "[i]nformation on health topics for older people."⁵ Under the heading, "Breaking the Habit," the publication provides advice on how to quit smoking, including the use of nicotine replacement therapies that "provide nicotine to the body without the harmful substances found in tobacco smoke." Following this advice is the heading, "Cigars, Chewing Tobacco, and Snuff Are Not Safer," which is followed by text that begins: "Some people think smokeless tobacco (chewing tobacco and snuff), pipes, and cigars are safer than cigarettes. They are not."

The heading and text are erroneous, at least with respect to smokeless tobacco. As developed more fully below, the statement that smokeless tobacco is not safer than cigarettes 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.

The adverse impact on consumers can be especially great in this instance. This NIA publication specifically targets adult smokers who want to stop smoking. This is a sizeable audience, with some 50 million smokers in this country, many of whom are unwilling or unable to quit. The misinformation about the comparative health risks of cigarettes and smokeless tobacco published by NIA discourages switching to smokeless tobacco, even though by doing so smokers could reduce significantly their health risks.

Given the consequences of disseminating this erroneous information, NIA 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.

⁵ See National Institute on Aging, Health Information Publications, at <http://www.niapublications.org>.

Below is a fuller discussion of the grounds for this request. Pursuant to NIH Guidelines, the following topics are addressed: (a) the reasons for believing the information is erroneous and fails to comply with OMB, HHS, and NIH 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 statements being challenged here are only those about the claim that use of smokeless tobacco is not less harmful than is 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 claims. 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.

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.”⁶ In fact, a group of renowned scientists reported last year that they are confident that the evidence base supports a conclusion that, on average, “Scandinavian or American smokeless tobaccos are at least 90% less

⁶ 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. Kozlowski 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.

hazardous than cigarette smoking.”⁷

- 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.⁸
- With respect to cardiovascular risks, the adverse effects of smokeless tobacco are much less than from cigarette smoking.⁹
- 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.¹⁰

B. The Information Fails to Comply with the Data Quality Act and OMB, HHS and NIH 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 NIH.

⁷ 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.

⁸ 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.

⁹ 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 3rd International Conference on Smokeless Tobacco, Stockholm, Sweden, September 2002).

¹⁰ 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.

1. Objectivity Standard

All three guidelines require objectivity in both “presentation and substance.”¹¹ This means information must be presented in an “accurate, clear, complete and unbiased manner,”¹² and must be based on “accurate, reliable and unbiased” information.¹³ 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.”¹⁴

Further, the misinformation contained in the NIA “Age 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.¹⁵ The OMB Bulletin on Peer Review and Information Quality proposes that peer reviews be conducted for the “most important scientific information regarding regulatory policy.”¹⁶ 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 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.

NIA’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

¹¹ See e.g., OMB Guidelines, V.3., 67 Fed. Reg. at 8459.

¹² *Id.* at V.3.a.

¹³ *Id.* at V.3.b.

¹⁴ HHS Guidelines, Part 1.D.2.c.

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

¹⁶ *Id.* at 54026.

All three guidelines require that disseminated information be useful to its intended users, including the public.¹⁷ NIA's "Age Pages" provide "information on health topics to older people."¹⁸ 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."^{19, 20} Similarly, in its Guidelines, NIH states that it is "committed to applying rigorous scientific standards to ensure the accuracy, reliability, and reproducibility of research results" with respect to such information.²¹ The statements at issue here constitute, "influential scientific information" because private individuals will rely on these statements - made by a government agency focused on the health of adults - as they make choices about the comparative health risks of smoking cigarettes versus using smokeless tobacco.

Under NIH Guidelines, 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.*"²² Among the specific types of information identified as potentially influential: "NIH Recommendations about Health Practice or Medical Treatment."²³

¹⁷ See e.g., OMB Guidelines, V.2., 67 Fed. Reg. at 8459.

¹⁸ See National Institute on Aging, Health Information Publications, Age Pages at <http://www.niapublications.org>.

¹⁹ *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."

²⁰ *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."

²¹ NIH Guidelines, VII (first unnumbered paragraph).

²² *Id.* (emphasis added).

²³ *Id.* at VII (fourth unnumbered paragraph).

The statements challenged here, which appear in a publication and on a web site designed to offer recommendations about how to stop smoking, fall 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. NIA has fallen far short of meeting such standards.

III. Recommended Corrective Action

A. Correction of Erroneous Information

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

- The current heading: "Cigars, Chewing Tobacco, and Snuff Are Not Safer" should be rewritten to exclude Chewing Tobacco and Snuff. The text following the heading should omit all references to smokeless tobacco.
- 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

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 NIA should issue a press release to correct the error – a measure contemplated in its Guidelines to correct widely disseminated errors.²⁴ In addition, the NIA 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 the 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.²⁵ 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 NIA'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.

²⁴ *Id.* at VI.3.

²⁵ "Study Shows FDA Chief's Expenses Were Padded," *The Washington Times*, Associated Press, Saturday, Nov. 2, 1996, page A3

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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,

A handwritten signature in black ink, appearing to read "Kenneth F. Boehm". The signature is written in a cursive style with a large, sweeping initial "K".

Kenneth F. Boehm
Chairman