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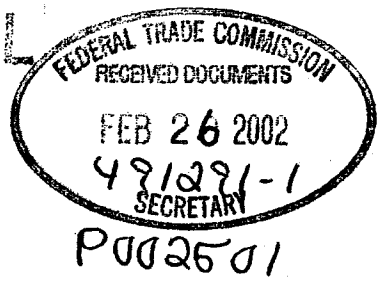

P002501

February 25, 2002

The Honorable Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Secretary Clark:

We are writing to ask the Federal Trade Commission (FTC) to reject the request submitted by the U.S. Smokeless Tobacco Company (USSTC), a subsidiary of the UST, Inc., dated February 5, 2002. In that request, USSTC asks the FTC to take the discretionary step of issuing an advisory opinion to permit USSTC and other smokeless tobacco manufacturers to claim in their advertisements that "the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes."

As its reason for why the FTC should act, USSTC argues that its request addresses "an issue of significant public interest". The public interest it discusses is the desire of the public health community to reduce the harm caused by cigarette smoking and USSTC's assertion that taking the requested action will in fact promote the public health.

Despite how USSTC framed its request, the breadth of what USSTC is requesting is enormous and the license it is seeking to make claims is broad and unrestricted. While USSTC says it is asking to be able to make a comparative health claim, its position paper, Attachment B, entitled "Smokeless Tobacco and Health," argues that "it is USSTC's position that smokeless tobacco *has not been shown to be a cause of any human disease.*" (Emphasis added). What USSTC is, in essence, requesting is that the Federal Trade Commission review, revise and overturn the scientific conclusions of the U.S. Surgeon General, the National Cancer Institute and every other major scientific and public health agency that has examined the health effects of smokeless tobacco.

USSTC's request also covers all smokeless tobacco products, no matter how they are processed, what kind of tobacco they include, what levels of nitrosamines they contain or how they might be formulated in the future. Further, USSTC's request is not limited to certain, narrowly defined marketing campaigns carefully tailored to reach addicted adult smokers. Indeed, representatives of USSTC have stated in various venues that if the FTC acted, it would be powerless to prevent USSTC from including these claims in ads like the recent USSTC ad for "Rooster" that appeared in *Rolling Stone* magazine under the slogan "Cock-A-Doodle Freakin Do", an ad clearly not aimed at switching adult smokers. USSTC may claim that its interest is in harm reduction for addicted adult smokers, but it wants the FTC's permission to disseminate these claims in ads whose primary appeal could be to young non-tobacco users.

We urge the FTC to deny USSTC's request for two reasons. First, the scientific judgments that USSTC is asking the FTC to make are more appropriately made by federal agencies charged with protecting the public health that also possess the expertise for and experience with evaluating all of the evidence of the health effects of smokeless tobacco products. As recently confirmed by the Institute of Medicine, claims for reduced harm should be subject to regulatory review by agencies with the expertise and authority to review relevant clinical, experimental, medical and epidemiological data and to conduct post-marketing surveillance and epidemiological surveys to properly evaluate health consequences (*Clearing the Smoke*, Institute of Medicine, May 2001).

Second, the FTC lacks the regulatory authority needed to take the reasonable steps necessary to ensure that any comparative health claims made by USSTC are not only truthful, but promote the public health. Under these circumstances the FTC should not take the discretionary action of

issuing an Advisory Opinion for the stated purpose of promoting the public health when it lacks authority to prevent USSTC's use of the Advisory Opinion to engage in actions which discourage smokers from quitting or encourage non-smokers to start using tobacco.

First, the authority and expertise to make scientific and medical decisions regarding the public health has been vested in the agencies of the Department of Health and Human Services (DHHS). For that reason, the FTC has historically deferred to HHS on scientific issues related to tobacco and the FTC should do so here.

On matters relating to the scientific determination of the health effects of tobacco products, the FTC has deferred to the various agencies with expertise in this area within the Department of Health and Human Services. It should do so here. For example, in 1985 the National Cancer Advisory Board (NCAB) issued a resolution in which it stated that the NCAB "considers the use of smokeless tobacco to pose a serious and increasing health risk." In September 1985 the International Agency for Research on Cancer (IARC) concluded, "In aggregate, there is sufficient evidence that oral tobacco use of smokeless tobacco is carcinogenic to humans." In January 1986 a NIH-NCI Consensus Development Conference reached a similar conclusion and later that year the Surgeon General's Advisory Committee concluded

> "AFTER A CAREFUL EXAMINATION OF THE RELEVANT EPIDEMIOLOGIC, EXPERIMENTAL, AND CLINICAL DATA, THE COMMITTEE CONCLUDES THAT THE ORAL USE OF SMOKELESS TOBACCO REPRESENTS A SIGNIFICANT HEALTH RISK. IT IS NOT A SAFE SUBSTITUTE FOR SMOKING CIGARETTES. IT CAN CAUSE CANCER AND A NUMBER OF NONCANCEROUS ORAL CONDITIONS AND CAN LEAD TO NICOTINE ADDICTION AND DEPENDENCE."

The PHS Advisory Committee also noted that snuff contained N'-nitrosamines at levels 100 times higher than permitted under federal regulations for all other ingested consumer products in the United States. Since 1986 the National Cancer Institute has twice issued scientific monographs on the health effects of smokeless tobacco products. The first was issued in 1989 and the second was issued in 1992. Both reinforced the conclusions of the Surgeon General.

Critically, for the purpose of the FTC's consideration of its role, each of these scientific inquiries examined relevant scientific information beyond the available epidemiological evidence. These inquiries looked at clinical and pathological effects, examinations of carcinogens in smokeless tobacco products, oncogens in tobacco-induced oral cancer, how these products are metabolized, animal data and other potentially relevant scientific data. The evaluations were complex and involved a broad range of scientific expertise. If there is a need to reevaluate the scientific evidence of the health effects of smokeless tobacco products, it should be done by agencies with the expertise and the public health mandate that is possessed only by these same agencies.

USSTC indicates that it is requesting this action because of its latest review of the epidemiological evidence. However, USSTC has never acknowledged that it agrees with the Surgeon General's conclusion that smokeless tobacco products can cause cancer. Having failed to convince the agencies vested with the authority and expertise to make these decisions, it is now coming to the FTC.

Second, USSTC's request to the FTC countermands the express intent of Congress.

Congress vested authority in the Secretary of Health and Human Services to examine the health effects of smokeless tobacco. The Comprehensive Smokeless Tobacco Health Education Act of 1986 identified the DHHS as the executive branch agency with responsibility for assessing and communicating the health risks associated with smokeless tobacco. The Act states, in relevant parts, "15 U.S.C., Chapter 70, Section 4401(a)(1) - *The Secretary of Health and Human Services shall* establish and carry out a program to inform the public of any dangers to human health

resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall –

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health."

The Congress was also clear about its position on the dangers associated with using smokeless tobacco. The warning labels required by Congress to appear on all smokeless tobacco products include statements that say, "This product may cause mouth cancer"; "This product may cause gum disease and tooth loss"; and, "This product is not a safe alternative to cigarettes." These mandatory labels represent the findings of Congress regarding smokeless tobacco products and are part of current law. Congress gave the FTC the authority to administer the legislatively mandated health warnings, not the authority to change or undermine them. The USSTC request could undermine the intent of Congress and could easily lead to confusion among tobacco users and potential tobacco users about whether smokeless tobacco should be considered an acceptable health risk, especially when compared with cigarettes.

Third, given the nature of USSTC's request, the Food and Drug Administration has the authority and is the most appropriate regulatory agency to address the public health issues raised by USSTC.

Although the Supreme Court held in *FDA v. Brown & Williamson*, 529 U.S. 120 (2000) that FDA does not have authority over traditional tobacco products, the Court's decision was limited to such products "as customarily marketed" and expressly recognized the FDA's "well-established" jurisdiction over tobacco products that bear health claims. 529 U.S. at 133. USSTC's request makes clear that it is seeking the FTC's stamp of approval to permit it to make comparative health claims. Having acknowledged that its rationale for its request is because of the asserted health impact of its products versus cigarettes, USSTC cannot now claim that the FDA lacks the authority to address the issues posed.

From the perspective of the undersigned major public health organizations, the FDA is the more appropriate agency to handle USSTC's request. It possesses both the scientific expertise necessary to address the health claims and the regulatory authority to ensure that whatever governmental action is taken is done in such a way to promote the public health. As it does in other areas of potentially shared responsibility, the FTC in this case should give great deference to a possible FDA scientific determination about how best to promote the public health in this instance.

Fourth, the FTC should take into consideration the potential that a decision by it to grant USSTC's request could have significant negative health consequences.

USSTC wants the ability to make health claims for its products without any regulatory control of the content or yield of its products. There is also nothing in USSTC's request that would prevent it from using claims it was authorized to make for its most hazardous products in ads placed in locations that experts have concluded have the greatest impact on children. It has happened before with tragic consequences.

In the early 1980's USSTC introduced new products and an aggressive marketing campaign, a part of which included statements that directly or indirectly stated and/or implied that these products were not only cool, they were safer than cigarettes. Public health experts and the Surgeon General concluded that the rise in smokeless tobacco use among young people that

followed was at least in part attributable to the "new and innovative marketing strategies" by the tobacco industry. *See for example,* Hearing on the Health Effects of Smokeless Tobacco – H.R. 760, H.R. 2950 and S. 3078 before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, July 26, 1985, Serial Number 99-41; U.S Department of Health and Human Services, Public Health Service, National Institutes of Health, *Smokeless Tobacco or Health: An International Perspective*, (1992)

As Surgeon General Antonia Novello noted:

> Paradoxically, it was the heightened awareness of smoking hazards in the 1970's and early 1980's that prompted some people, looking for a safe alternative to cigarettes, to begin using a product that the industry labeled "smokeless" tobacco. Early advertising campaigns pitched these products as a safe alternative because they did not contain the major health-threatening ingredient of cigarettes – smoke. Millions of consumers succumbed to this faulty logic, and the use of spit tobacco (chewing tobacco and snuff, or ST) spread rapidly, particularly among young adult and adolescent males,...".

Smokeless Tobacco or Health: An International Perspective at x, xi.

A review of USSTC's marketing subsequent to the 1998 Agreement between UST and 46 states reveals the continued use of themes and images that experts agree appeal to young people as well as the placement of those ads in locations, including magazines and convenience stores, with very high youth readership and exposure.

Conclusion

If USSTC is serious about its harm reduction interests, it will take those concerns to the appropriate public health agencies, including the Surgeon General, the National Cancer Institute and the Food and Drug Administration. Together, these agencies have the expertise to evaluate the health effects of smokeless tobacco products and to develop mechanisms for ensuring that any health claims actually reduce the number of people who die from tobacco rather than just increasing the number of people who are at risk.

The undersigned organizations represent a broad segment of the public health community concerned about the impact of tobacco in our society. We urge the FTC to deny USSTC's request that it issue an advisory opinion in this matter.

Matthew L. Myers, President
Campaign for Tobacco-Free Kids

On behalf of:
American Academy of Otolaryngology -- Head & Neck Surgery
American Academy of Family Physicians
American Cancer Society
American College of Chest Physicians
American Dental Association
American Heart Association
American Lung Association
American Public Health Association
American Society of Clinical Oncology
American Veterans Committee
Campaign for Tobacco-Free Kids

The General Federation of Women's Clubs
National Association of Local Boards of Health
National Center for Health Education
National Latino Council on Alcohol and Tobacco Prevention
Oncology Nursing Society
Oral Health America -- National Spit Tobacco Education Program
Partnership for Prevention
Pharmacy Council on Tobacco Dependence
Union of American Hebrew Congregations
WomenHeart the National Coalition for Women with Heart Disease

Alaska Division of Public Health
Greater Knoxville Coalition on Smoking OR Health
Indiana Tobacco Prevention and Cessation
John P. McGovern Museum of Health and Medical Science, Houston, TX
Maryland State Council on Cancer Control
Milford, CT Health Department
Minnesota Department of Health
North Dakota Tobacco Policy Initiative
Ohio Department of Health
Ohio Osteopathic Association
Ohio Psychological Association
Oklahoma Alliance on Health or Tobacco
Oklahoma Nurses Association
Oklahoma State Medical Association
Partnership for a Healthy Oklahoma
Rose State College, Health Science Division, Midwest City, OK
South Doyle Student Coalition Against Tobacco, Knoxville, TN
University of Cincinnati's Wellness Center