Congress of the United States

Washington, DC 20515

June 4, 2002

The Honorable Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20850

Dear Secretary Clark:

On February 5, 2002, the U.S. Smokeless Tobacco Company (UST) asked FTC to issue an advisory opinion that would allow the company to market smokeless tobacco products with the claim that "many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes."[1] We are writing to urge you to reject this request. Emerging research indicates that smokeless tobacco acts as a "gateway drug," often leading teenage boys and young men to start smoking cigarettes. Allowing UST to increase the attractiveness of smokeless products by making health claims could therefore backfire, resulting in an increase -- not a decrease -- in smoking rates. The FTC's issuance of such an advisory opinion would also conflict with several provisions in federal statutes and consensus among experts that any health claims be considered only in the context of tobacco regulation.

Smokeless Tobacco: Gateway to Smoking

UST's justification for requesting the advisory opinion is a potential health benefit that might result from smokers switching to smokeless tobacco products. Undermining this potential benefit, however, are three serious potential drawbacks. First, as noted by the Institute of Medicine, some smokers who would have quit altogether may instead take up "safer" smokeless products.[2] Because smokeless tobacco causes many serious illnesses including oral cancer, these individuals will be worse off for having switched instead of quit.[3] Second, health claims for smokeless tobacco products may increase their attractiveness to nonsmokers.[4] Some of these consumers may take up smokeless tobacco and suffer the consequences. Third, as more nonsmokers begin to use smokeless tobacco, more will become addicted to nicotine and may transition to smoking.

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[1]Letter from Daniel C. Schwartz to the Honorable Donald S. Clark (Feb. 5, 2002).

[2]Institute of Medicine, *Clearing the Smoke,* 78 (2001).

[3]Institute of Medicine, *Clearing the Smoke,* 426-429 (2001).

[4]Institute of Medicine, *Clearing the Smoke,* 73-74 (2001).

A growing body of evidence suggests that smokeless tobacco acts as a "gateway drug" to cigarette use. Studies in the late 1980s first suggested that children who use smokeless tobacco frequently developed into cigarette smokers.[5] More recently, researchers have found two- and three-fold increases in smoking rates among teenage boys and young men who began as smokeless tobacco users compared to non-users. Dr. C. Keith Haddock and colleagues reported in *Preventive Medicine* last year that in a population of 7,865 male Air Force recruits, smokeless tobacco users were 233% more likely to be smoking at the end of a year than non-users.[6] The study concluded that use of smokeless products "appears to be an important predictor of smoking initiation among young adult males."

We have also become aware of a study that is slated for publication in *Nicotine & Tobacco Research* by Dr. Scott Tomar of the University of Florida College of Dentistry. Dr. Tomar previously worked in the Division of Oral Health at the Centers for Disease Control and Prevention. According to presentations of his research at scientific conferences, Dr. Tomar has found a strong association between use of smokeless tobacco and eventual smoking.[7] According to his results, 48% of boys ages 11 to 19 who regularly used smokeless tobacco were smokers four years later, compared to just 15% of boys who did not use smokeless tobacco. Dr. Tomar has also found that 44% of men ages 18 to 34 who used smokeless tobacco in the past were daily smokers at the time of a national survey, compared to just 22% of men who never used smokeless tobacco.

Separately, Dr. Tomar determined that very few smokers switched to smokeless tobacco products. Dr. Tomar concluded that the "availability of snuff may be responsible for increasing the rate of smoking initiation but may have little effect on quitting smoking."[8] These research findings illustrate the danger of allowing health claims for smokeless tobacco. In short, such claims could be counterproductive, increasing the use of a "gateway drug" to cigarettes.

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[5]A. Peterson, P. Marek, S. Mann, *Initiation and Use of Smokeless Tobacco in Relation to Smoking*, NCI Monographs, 63-9 (Volume 8, 1989).

[6]C. Haddock et al., *Evidence that Smokeless Tobacco Use Is a Gateway for Smoking Initiation in Young Adult Males*, Preventive Medicine, 262-7 (March 2001).

[7]Scott Tomar, *Is Smokeless Tobacco Use a Risk Factor for Cigarette Smoking?*, Presented at the 30th Annual Meeting of the American Association for Dental Research in Chicago, Illinois (Mar. 8, 2001).

[8]Scott Tomar, *Is Smokeless Tobacco Use a Risk Factor for Cigarette Smoking?*, Presented at the 30th Annual Meeting of the American Association for Dental Research in Chicago, Illinois (Mar. 8, 2001).

Federal Statutes

The scientific concerns raised above provide ample justification for FTC to refuse to issue the advisory opinion requested by UST at this time. Several provisions in federal statutes provide additional reasons why FTC should deny UST's request.

First, under the Food, Drug, and Cosmetic Act, Congress authorized the Food and Drug Administration to consider exactly the sorts of claims desired by UST. While the 2000 Supreme Court decision in *FDA v. Brown & Williamson* struck down the agency's authority over tobacco products as customarily marketed, it recognized FDA's ability to regulate those products if they make health claims. The message that smokeless tobacco poses "less risk of adverse health effects" is a health claim on its face. If smokeless tobacco manufacturers wish to advertise their addictive product as a healthier alternative to smoking, they must submit their claims to FDA. FDA would then have the ability to oversee the impact of any labeling and advertising changes.

Second, under the Comprehensive Smokeless Tobacco Health Education Act of 1986, Congress charged the Secretary of Health and Human Services with the responsibility to "establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products."[9] The intent of this legislation was to vest authority over the assessment of the harms of these products with a health agency with the history and expertise to do so. This authority should not be usurped by FTC through an order allowing manufacturers to make comparative health claims. Had Congress intended for FTC to make such scientific judgements in parallel with HHS, it would have expressly given the agency such authority.

Third, under the Comprehensive Smokeless Tobacco Health Education Act of 1986, Congress mandated a series of rotating warnings on smokeless tobacco products. One of these warnings states, "This product is not a safe alternative to cigarettes."[10] FTC should not permit a marketing claim that directly contradicts this message. Congress chose the wording because of a consensus among expert groups and government health officials that marketing of smokeless tobacco as an alternative to smoking would undermine the public health. As will be discussed below, this consensus remains intact today. FTC would be acting outside of its authority to undermine this clear language from Congress.

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[9] 15 U.S.C. 4401.

[10] 15 U.S.C. 4402.

Health Agencies and Expert Panels

Leading health agencies and expert panels would not support UST's request to FTC. The National Cancer Institute's web site flatly states that smokeless tobacco is not an acceptable alternative to smoking :

> * Is smokeless tobacco a good substitute for cigarettes?
> As long ago as 1986, the Surgeon General concluded that the use of smokeless tobacco "is not a safe substitute for smoking cigarettes. It can cause cancer and a number of noncancerous conditions and can lead to nicotine addiction and dependence."
> * What about using smokeless tobacco to quit cigarettes?
> Because of the addictive properties and documented health risks associated with smokeless tobacco, it should not be used to quit cigarettes.[11]

In 2001, the Massachusetts Tobacco Control Program (MTCP) uncovered evidence that undermines much of the safety data presented by UST, which is based on Swedish snuff. In June 2001, the MTCP tested UST's brands of smokeless tobacco against Swedish varieties and found that UST's brands had far higher levels of nitrosamines, which are linked to cancer.[12] The MTCP has also determined that UST is aggressively advertising its smokeless tobacco products in youth-oriented magazines including *Sports Illustrated*, *Hot Rod*, and *Rolling Stone*.[13]

Last year, the Institute of Medicine (IOM) issued an exhaustive study of tobacco regulation.[14] The IOM reviewed the research that is the basis of UST's petition and recommended that comparative claims only be allowed after further research is completed and only when there is authority to assure that the marketing of smokeless tobacco as less dangerous than cigarettes does not do more harm than good.

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[11]National Cancer Institute, Questions and Answers About Smokeless Tobacco and Cancer, http://cis.nci.nih.gov/fact/3_63.htm (Accessed May 16, 2002).

[12]Gregory N. Connolly and Howard Saxner, *Informational Update: Research on Tobacco Specific Nitrosamines in Oral Snuff*, Massachusetts Department of Public Health (Aug. 21, 2001).

[13]Massachusetts Department of Public Health, *Smokeless Tobacco Advertising Expenditures Before and After the Smokeless Tobacco Master Settlement Agreement* (May 2002).

[14]Institute of Medicine, *Clearing the Smoke* (2001).

Conclusion

We urge you to decline UST's request for an advisory opinion that would allow health claims to be made for smokeless tobacco. It could lead to more smoking, is in clear violation of congressional intent as expressed in several statutes, and conflicts with the most recent and credible expert recommendations.

Sincerely,

Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
U.S. House of Representatives

Richard J. Durbin
Chairman
Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia
United States Senate