

Department of Pathology
Oral Pathology

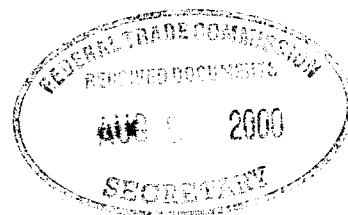
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OFFICE OF THE CHAIRMAN

August 2, 2000

Mr. Robert Pitofsky
Chairman
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580



Re: 16 CFR Part 307

Dear Mr. Pitofsky,

I am a Professor in the Department of Pathology at the University of Alabama at Birmingham and a Senior Scientist at the UAB Comprehensive Cancer Center. I have 21 years of teaching and research experience with diseases of the mouth, including the health effects of smokeless tobacco (ST) use and of cigarette smoking. My research has also focused on the differential health risks of various forms of tobacco use.

In consideration of the Commission's review of its ST trade regulation rule, I wish to bring to the Commission's attention that there is an inadequate scientific rationale for the following warnings.

Warning: This product may cause gum disease and tooth loss.

This warning was first mandated by the Comprehensive Smokeless Tobacco Health Education Act of 1986. However, at that time there was no pre-existing scientific evidence that smokeless tobacco use is an independent risk factor for either gum (periodontal) disease or tooth loss. Furthermore, no further evidence regarding smokeless tobacco use as a cause of gum disease and tooth loss has been published in the medical/scientific literature in the past 14 years. On the other hand, an intensive and very detailed study published in 1992 in an NIH Tobacco Control Monograph concluded that "Missing teeth, previous caries experience, levels of plaque and gingivitis, pocket depths, and occurrence of severe forms of periodontitis were **not** related to smokeless tobacco use." (emphasis added)(1).

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Warning: This product is not a safe alternative to cigarettes

The only established consequential health risk of ST use is oral cancer. The relative risk of oral cancer in long-term smokeless tobacco users (compared with nonusers of tobacco) is about four; this number has been documented in several studies that are cited frequently by critics of smokeless tobacco use (2,3,4).

By comparing the risks of oral cancer from smokeless tobacco use with the diverse risks from smoking, our research group has established in peer-reviewed research that ST use is 98% safer than smoking (5,6). Nothing has been published that contradicts the results of this research.

Although ST is a considerably safer alternative than cigarettes, it is not an absolutely safe product. However, it would be inconsistent for the Commission to apply a standard of absolute safety to ST products when no such standards are applied to any other consumer products. The establishment of comparative safety standards might obligate the Commission to oversee unnecessary warnings such as "Beer is not a safe alternative to distilled liquor" or "Automobiles are not a safe alternative to motorcycles."

Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 for the express purpose of educating the public about the adverse health effects of ST use. This mission remains severely compromised by inadequate scientific documentation of the warnings discussed above. The warnings are now 14 years old, and it can be contended that as written they are factually incorrect.

I believe that an investigation by the Commission will fully substantiate the concerns expressed in this letter. Although the content of the warnings may remain primarily the

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responsibility of Congress, I would hope that the Commission has an interest in ensuring that they are accurate and supported by adequate scientific documentation.

Sincerely,



Brad Rodu, DDS
Professor

Senior Scientist
Comprehensive Cancer Center

References

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2. Winn DM, Blot WJ, Shy CM, Pickle LW, Toledo A, Fraumeni JF. Snuff dipping and oral cancer among women in the southeastern United States. *New England Journal of Medicine* 304: 745-749, 1981.
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6. Rodu B, Cole P. Tobacco-related mortality. *Nature* 370: 184, 1994.