



July 6, 2000

Robert Pitofsky  
Secretary  
Federal Trade Commission  
Room H-159  
600 Pennsylvania Avenue, N.W.  
Washington, DC 20580

Dear Mr. Pitofsky:

These comments concern regulations implementing the Comprehensive Smokeless Tobacco Health Education Act of 1986, 16 CFR Part 307.

Oral Health America is a 501 (c )(3) organization that is dedicated to the protection and promotion of oral health. Since 1991, it has supported the National Spit Tobacco Education Program because of its deep concern that smokeless/spit tobacco is a risk to health including oral health, that its use is addictive, and that the public is not well aware that it is not a safe alternative to smoking. Oral Health America is deeply concerned that, since the early 1970s, patterns of use have shifted remarkably from primarily older persons to primarily youths and young adults because of a massive increase in smokeless tobacco industry advertising and promotion that has targeted children and youths. A strong warning is needed to offset the virtual total industry control of the public's knowledge and attitudes in regard to smokeless tobacco.

#### A. Background Information

In general, current labels are much too weak. First, printed warnings should be able to be read at arms length by an individual with less than average eyesight, that is 30 inches, on any single or multiple bound package; the warning label should be no less than 50 percent of the point size of the brand name. Second, warnings should include the statement that smokeless tobacco is highly addictive. This was clearly stated in the 1986 report to the Surgeon General, *The Health Consequences of Using Smokeless Tobacco* and demonstrated more expansively in the 1988 Surgeon General's Report to Congress, *Nicotine Addiction*. Recent literature and tobacco industry documents confirm that nicotine is addictive and the reason individuals who want to quit find it so difficult to do so. Third, the public needs graphic images that communicate in ways that words cannot. Canadian government plans to show photographs of tobacco-induced damage from tobacco use should be replicated on tobacco package advisories to the U.S. public.

Research findings since 1986 reaffirm the correctness of the three statements required in the Smokeless Tobacco Act of 1986. The most recent statement in support of the statement, WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER, is in the 9<sup>th</sup> Edition, Report on Carcinogens prepared by the National Toxicology Program and released May 15, 2000 by the National Institute of Environmental Health Sciences, DHHS. The statement, THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS has been long established, especially in regard to the focal loss of periodontal structures. Its use also causes tobacco-induced white and red lesions, and other oral conditions. The statement, WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES may have greater importance in the future since studies are beginning to be published that show associations between use and cardiovascular and other life-threatening diseases. An example is G. Bolinder's findings in Sweden that, after 12 years, cardiovascular death rates among smokeless tobacco users were double that of a comparable tobacco-free

population. Another important statement still missing is a warning about the addiction potential and the especially dangerous combination of using both smokeless tobacco and alcohol.

B. Issues for comment:

1. Oral Health America commends the FTC for amending its smokeless tobacco regulations on March 20, 1991, 56 FR 11662.\1\ requiring warnings on utilitarian items, and subsequent technical requirements to counter industry efforts to evade the letter and spirit of the regulations. Oral Health America agrees that special advertising, such as on motor racing vehicles should carry **prominent** warnings. We urge fairness in “prominence” because regulations narrowly defined by size, color, contrast, type of image, and so on are often easily manipulated by the smokeless tobacco industry to make such warnings ineffective.

2. Safe harbor: No special favor be provided an industry that markets a product that is highly addictive, that carries serious risk to health, and is made attractive to children and youths, nor, given its record, should the industry ever be trusted to be self-regulating in any respect.

3. Dispensers: Rules should be stated so that no labeling and advertising should be visible without the warning also visible, indeed “prominent.”

4. Can rolls: The point type of warnings or number of cans in a package is irrelevant. Any package of one or more cans or other containers must have a warning label visible wherever the product label can be seen. The label should be sufficiently large to be read at arms length by an individual with weak eyesight.

C. Responses to specific questions:

1. The regulations are needed more than ever. Experience is showing that people learn from receiving a message multiple times, via many sources, and in many environments. The effectiveness of warning labels cannot be measured in isolation, but contribute to the development of public knowledge. However, the degree of contribution is a function of the forcefulness and attractiveness of the message. Past labeling requirements have been too weak. Even so, the industry acknowledges warning labels as a real threat or it would not have been trying so hard to diminish, hide, and remove them.

2. The upward trends in sales during the past 2 decades and shift to a youth market suggests that purchasers, potential purchasers, and the public have not been inconvenienced in the slightest by relevant FTC regulations. Some potential purchasers may have been cautioned, but more likely, messages have benefited users who are in the process of making a decision to quit or making a quit attempt by reinforcing their commitment. Warning labels can better benefit purchasers, potential purchasers and the public by becoming a more effective communication method. See #7 below.

3. Oral Health America is not qualified to respond to this issue.

4. Regulations should include a specific statement that FTC regulations do not preempt any stronger municipal, county or state regulations, laws or enforcement method that provide for more effective public education, limitations on use, restrictions on the promotion and sale to individuals less than legal age for purchase, or other public health tobacco control measure.

5. Oral Health America is not aware of any scientifically sound demonstration of burden or cost to any small or large retail business subject to the regulations. Smokeless tobacco products are commonly only one of hundreds of products offered at retail stores. More effective regulations would bring gradual social change, not precipitous changes in demand because most users are addicted to nicotine containing products.

Requirements for Disclosure on the Label:

6. The smokeless tobacco industry believes that its advertising and promotion is effective or it wouldn't constantly make huge investments in it. However, multiple channels are used including sponsored events and other promotional methods, advertising, product labels and product placement. Single factors, such as

labels, are difficult to independently assess. At the moment, the warning labels seem to be ineffective as evidenced by the huge increase in product sales since the required labels have been in place. Although warning messages are truthful, their presentation format is a whisper overwhelmed by a shout of product advertising and promotion intensity and the size, color, imagery and placement on product packages.

#### Requirements for Disclosure on the Label:

7. Effectiveness is a matter of degree. Ideally, warnings should be the same size, use images of adverse health consequences, and be located in the same sites as product words and images. To be fair, warnings should be tombstone type where the industry uses a tombstone description of its products. Where the industry uses color and imagery in a certain placement, the warnings should also use strong contrasting colors and imagery. The tobacco industry conducts market research so knows what size, color, typeface, and placement is conspicuous and attractive. It is only just that truthful messages should receive at least parity with ephemeral product imagery. We recommend a 1 to 1 relationship to avoid the swamp of technical regulations that reduce warnings to ineffective communication means, but the warning label should be no less than 50 percent of the point size of the brand name.

#### Enforceability of the Regulations:

8. We do not understand “safe harbors” nor expect that most of the public, including merchants and clerks do. Storeowners and service personnel should be accountable for smokeless tobacco sales by ensuring that all customers are of legal age to purchase the product. “Sting” operations and other compliance checks should be allowed. There should be a specific statement that municipal, county and state enforcement mechanisms that hold sellers of smokeless tobacco products accountable must not be preempted by less stringent or less effective FTC requirements. Penalties for sales to individuals who are less than legal age should include the suspension or revocation of licenses to sell tobacco products. Of course, this implies that sales should only be from licensed merchants as is required for merchants of liquor and other psychoactive substances.

We are deeply concerned that product placement is often easily available to children and youths, in proximity to candy and gum displays, and in locations that permit theft by children and youths. We strongly urge that regulations require that all smokeless tobacco products be displayed behind sales counters where children and youths cannot steal them, and where adults cannot collect the product as a self-service item. Smokeless tobacco product placement should be required to be together with other tobacco products. Such displays should not be near candy and gum displays, and never in an area that is not in view or out of the full and immediate control of service personnel.

#### Smokeless Tobacco Dispensers:

9. Requiring that a warning label be visible on a product dispense would be fair and consistent. Its intention is to educate the public. If the product name can be seen, the warning label should be simultaneously seen and in print large enough and in a format that can be read at 30” or about arms length. The warning label should be no less than 50 percent of the point size of the brand name.

#### Can Rolls:

10. Any smokeless tobacco can or roll of cans should display a highly visible warning. The regulation should simply read, “one or more cans.” The tobacco industry proposed “two can roll” exception is clearly a ploy to gain a loophole to the spirit and letter of the law that the public be informed about scientifically established adverse health consequences that may result from product use. If the product name can be seen, the warning label should be simultaneously seen and in print large enough and in a format that can be read at 30” or about arms length. The warning label should be no less than 50 percent of the point size of the brand name.

11. If possible through regulation rather than legislation, a warning should be added that smokeless tobacco use is addictive. We have heard anecdotal reports that parents, especially parents in disadvantaged

populations, use such products to treat teething children or as a candy, not recognizing nicotine's potential for addiction. Certainly youths either do not understand or underestimate the addictive potential of using smokeless tobacco.

12. We do not have cost information. However, we recognize that money not spent on smokeless tobacco does not disappear, but is available for other personal expenditures and investments. Also, long-term social costs associated with lost productivity and treating smokeless tobacco-related health problems are a direct benefit to those who avoid smokeless tobacco use and public resources needed to pay for avoidable costs.

13. We make no recommendation about requirements for tobacco companies to report their plans for rotating, displaying, and distributing health warnings on their packages and advertising. Since our primary concern is about the ability of warning labels to effectively communicate and to complement truthful public health messages via other channels, we support either longer or shorter rotation cycles as determined by marketing and behavioral research to be most effective.

Thank you for your attention to these recommendations. Best wishes as you, in accord with Comprehensive Smokeless Tobacco Health Education Act of 1986, endeavor to effectively inform the public about risks to health and well being associated with the use of smokeless tobacco.

Sincerely,

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