

July 20, 2000

Secretary, Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-159
Washington, D.C. 20580

RE: 16 CFR Part 307

Dear Mr. Secretary:

This letter is in response to your Request for Comments Concerning Regulations Implementing the Comprehensive Smokeless Tobacco Health Education Act of 1986. We applaud the Federal Trade Commission's (FTC's) efforts in re-examining its regulatory mandate and thank you for the opportunity to comment on this important public health effort.

One of the goals of the Department of Health and Human Service (HHS) is to reduce death and disability resulting from tobacco use through programs of information, education and research. The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has been delegated the authority for implementing major components of the Department's tobacco and health program. OSH's mission is to lead and coordinate strategic efforts aimed at preventing tobacco use among youth, promoting smoking cessation among youth and adults, and protecting nonsmokers from environmental tobacco smoke.

Tobacco use is the single most preventable cause of death and disease in our society. Annually, tobacco use causes more than 430,000 deaths and costs the nation approximately \$50-\$73 billion in medical expenses alone. Many view smokeless tobacco as a safe substitute for cigarette smoking. However, oral use of smokeless tobacco represents a significant health risk which causes cancer and a number of noncancerous oral conditions and can lead to nicotine addiction and dependence.

Overall Recommendations

The current smokeless tobacco regulations were originally promulgated fourteen years ago. Since then, research has demonstrated the need for more conspicuous and harder hitting health messages to better arm consumers with health effects information. Therefore, we believe the statutory and regulatory authority for warning labels on tobacco packages and in advertisements in the US should be re-examined.

Although the current Notice and Request for Comments is limited by the FTC's current regulatory authority under the Comprehensive Smokeless Tobacco Health Education Act ("Smokeless Tobacco Act"), CDC would like to comment on the need for broader action to strengthen warnings on tobacco product labels and in advertisements. Research from consumer focus group studies (on both smokeless and smoked tobacco) in this country, Canada, Australia, and other countries leading in tobacco control regulation, suggest the need for both enhanced statutory authority in the U.S. and stronger and specific regulations related to warning placement, size, font, and other details under existing statutory authority.

Research and current regulatory trends in other countries suggest a need for new Congressional action in the U.S. to make warnings more effective, by authorizing: (1) new rotating health warnings that can be changed as necessary through administrative rule-making so they can remain current scientifically and so consumers will not become habituated to existing messages (2) states to regulate in this arena by removing the pre-emption provisions presently contained in the Smokeless Tobacco Act; (3) health "messages" that would include warnings but also allow for broader information, such as the benefits of quitting, as has been done in other countries; (4) content of new health messages that is direct, hard-hitting (such as those that relate tobacco use to specific diseases and disease outcomes) and unambiguous (such as the percentage of users who are likely to develop disease and the percentage of those who will die from it); and (5) use of graphic color depictions of tobacco-related disease, shown to be the most effective in terms of promoting recall and being perceived as likely to encourage cessation in Canadian and U.S. research; (6) the display of ingredient information and toxic constituent yields, as applicable, (using a range based on a specified testing method that takes into account smoker compensation) on packages to promote "informed consent", as is required of many other consumable products in the U.S., and in advertisements; and (7) a requirement for plain packaging, if constitutionally permissible, in order to eliminate any indirect promotion and appeal of hazardous tobacco products to U.S. youth.

CDC is aware that the above matters cannot be addressed in the current rule-making. However, present legal authority in the Smokeless Tobacco Act does allow the FTC to prescribe the precise placement locations, minimum warning size, and specified font color, size, and face of the present health warnings.

Issues for Comment

CDC responds to the specific issues raised in the Notice and Request for Comments as follows:

1. Effectiveness of the Warning Requirements: FTC Should Prescribe Strong Requirements for Warning Placement and Size, Format, and Font to Enhance The Warnings' Effectiveness

(a) warning placement

The warnings should appear, at minimum, on all of the main package panels, for example, on the top, bottom, and on what constitutes the front of the label on a canister and on the front and back of soft (pouch) packaging. This will prevent the warnings from being obscured or ignored simply by a turn of the package or carton during display. Warnings could also be required as package inserts, and should be required on all promotional materials, including displays. The warning should not be placed on any portion of the packaging that is removed or damaged by opening the container or package.

Most participants in recent, CDC-funded focus groups¹ could not remember specifics of smokeless tobacco labels or even if warning labels existed on smokeless tobacco products, indicating a need for specifications that will enhance the warnings' prominence. Nearly all parents and teens commented that the present warning labels were not at all noticeable. When handed cans of tobacco, nearly all needed to spend a good deal of time examining the cans until they found the warnings. Participants suggested that warnings be placed in multiple places, specifically the top of the smokeless tobacco can below the logo and possibly on the bottom as well, and indicated that warnings as a package insert, in addition to the outside package warnings, also could be very effective. Many teens noted that in order to open a can of tobacco, the user had to pull off the side label, which contained the warning. Therefore, after opening the product for the first time, the warning label was removed.

Although the interpretation of these findings is limited by the small number of participants, a 1990 study of 192 high school students also suggests the current warnings require enhancement. Fewer than one half of the students recalled seeing the warnings on a can of oral snuff and a pouch of chewing tobacco they viewed, and only 32.2% of those who recalled the warnings recalled the content of the warnings.²

A larger CDC-funded qualitative study on smoked tobacco products also arrived at similar findings regarding warnings on cigarette packs. A total of 2510 adolescents (age 11-18) participated in almost 400 focus groups in 12 states. In general, the participants reported that they would like the warnings to be more noticeable and provide information on how smoking affects young persons.³ Requiring the warning on the main package panels and as inserts would

¹ CDC Unpublished Study, Focus Groups on Smokeless Tobacco Warning Labels (Atlanta, GA, June 2000)

² Brubaker, RG, Mitby SK, Health risk warning labels on smokeless tobacco products: are they effective? *Addictive Behaviors* 1990; 15(2):115-8.

³ CDC Unpublished Study, Responses to Tobacco Control Policies Among Youths (Tobacco Control Network, 1990). The 3-year study, exploring youth reaction to several tobacco control policies, included participants from 12 states. Focus group discussions centered on awareness, knowledge, opinions, and behavior in response to laws and rules, price, cigarette ingredients, and warning labels. Participants reported also that they did not find warnings on the cigarette packs informative, impressive, or relevant, instead describing them as "vague", "stale", and "worn out". Participants reported that they

make the warnings more noticeable. Canada already has set the precedent for such warning placements.

(b) warning size

In order to match or exceed the example recently set by the Canadian government, CDC suggests that the FTC mandate that warnings occupy at least 50% of the panels on which they appear (see above). The recently enacted Canadian health message regulations, following extensive consumer research, set the standard as such on the basis of findings showing consumers perceived larger warnings as more likely to encourage them to stop or refrain from smoking.⁴ CDC's smokeless tobacco focus group findings suggest the need for larger warnings as well -- on seeing the actual labels on smokeless tobacco cans, participants mistook the warning label for ingredients or other neutral text because of the small font, placement, and coloring of the current warning label. Many commented that the expiration date on the bottom of the can was in larger font than the warning.

If a warning occupying 50% of the panel is required through rule-making, as suggested, this clearly will call for a larger font size than that presently deemed acceptable. The size of the font for the warning should exceed the size of any other type on the label to make it distinguishable from and more prominent than the other text. When presented with a labels in a variety of fonts, nearly all of the CDC's smokeless tobacco focus group participants (both parents and teens) picked the largest fonts available to them (size 13, 14, and 16--the largest given) as appropriate for warning labels. The font sizes chosen by the participants most closely matched the size of the product's logo. Some parents and teens recommended using a bigger font size than was given to them as a choice, noting that even size 16 was smaller than some of the other writing on the can.

(c) warning format

Current regulations deem the warning statement to be of sufficient contrast with the rest of the package if it is printed in a color that is clearly visible against the background on which the warning appears. However, participants in the CDC's smokeless tobacco focus groups noted how difficult the label was to find in that it blended into the rest of the smokeless tobacco packaging and was hardly noticeable. They found that the label was especially difficult to find because it was not part of a standard format. According to participants, not only did these labels not stand out from the rest of products' packaging, they also were not standard with each other.

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The FTC regulations should specify not only the font size, but also the precise colors and shades of colors of the type of the warning, its background, and its contrast in relation to the remainder

would like to see warnings that are direct, realistic, factual, and strong (e.g. that warnings should avoid the use of "may").

⁴ Effects of increasing the area occupied by health warnings on cigarette packages. Les Etudes de Marche Createc, 1999.

of the package. Parents and teens suggested having a standard-looking, bright warning label that would catch consumers' attention rather than having it resemble the rest of the text on the packaging. Some parents recommended using standard symbols to demarcate the warnings, such as a red, upside-down triangle with "Danger" in the center, a circle with a slash diagonally cutting across it (as in "Do not use"), or a skull and crossbones so that they are more easily recognizable.

Similarly, in tobacco product advertisements and other promotional materials, precise warning placement, format and font requirements should be prescribed, within the limitations of the statutorily prescribed circle and arrow format required for advertisements. Both parents and teens in the CDC's smokeless tobacco focus groups thought that the warning label on the display advertisement shown to them was not very noticeable. They thought the font was too small and the gray background indistinguishable from the rest of the advertisement. Many did not read the warning at first glance.

2. Enforceability of the Warning Requirements: FTC Should Replace the "Safe Harbor Approach" with Specified Requirements

The FTC should prescribe precise, measurable requirements for the warning labels in order to remove any subjectivity about what is considered "prominent", "legible", and "conspicuous". The examples cited above, as well as the examples cited by the FTC related to dispensers and can rolls, clearly demonstrate the failure of the "safe harbor approach". Specifically prescribed requirements will remove any ambiguity as to what is required so that manufacturers will know what is expected of them and enforcers will know, without having to use any subjective judgement, what constitutes a violation.

3. Warnings on Smokeless Tobacco Dispensers

The FTC should require dispensers to carry the warning label on all main panels to avoid the exact problem noted and ensure its visibility to purchasers and potential purchasers. If the warning were required only on the principal display panel, there would be nothing preventing another object from being placed in front of the principal display panel as well. At the very least, however, all dispensers should be required to carry the warning label on its primary panel in a manner (font size, color, and placement) that ensure that it is legible to purchasers across a reasonable distance, such as 5 feet.

4. Warnings on Multi-Can Packages

The FTC should clarify that the larger warning size requirement applies to any number of can rolls wrapped for sale as a single unit for display. Larger font sizes should be required on the overwrap if the warning label on any individual can is not visible. Display of tobacco products is

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a form of promoting the product and, thus, large warnings should appear so that consumers can exercise informed consent in a more meaningful way both before deciding whether to purchase

the product and, once purchased, whether to continue using it.

5. Costs and Benefits of Suggested Changes

In considering any costs to manufacturers, costs to consumers and society of tobacco use also must be weighed. These costs include not only direct financial burdens on the individual and government in terms of significant health care expenditures, but also indirect costs such as lost productivity and human suffering. Each year 6.5 to 12 percent of U.S. health care expenditures are devoted to treating smoking-attributable illness, or between \$279 to \$380 per adult. In addition, as a consequence of the 430,000 annual smoking-attributable deaths, each year individuals and society lose more than 5.7 million potential life years and approximately \$50 billion in lifetime future earnings. More prominent and conspicuous warnings will promote consumer education and knowledge of the risks of tobacco use and will help consumers make a more informed judgment about using this dangerous and deadly product.

Thank you for considering these comments. We look forward to seeing the FTC take action on this important health issue.

Sincerely yours,

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Director
Office on Smoking and Health
National Center for Chronic Disease
Prevention and Health Promotion