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**DRAFT**

December 9, 1997

Office of the Secretary  
Room 159  
Federal Trade Commission  
6th Street and Pennsylvania Ave. N.W.  
Washington D.C. 20580

**Re: FTC Cigarette Testing Methodology: FTC File No. P944509**

Dear Commissioners:

The Society for Research on Nicotine and Tobacco would like to comment on the proposed revision to the FTC method for determining tar, nicotine and carbon monoxide yields of cigarettes. The Society for Research on Nicotine and Tobacco (SRNT) is an international organization of scientists and public health professionals whose research and efforts are focused on studying the pathophysiology, prevention and treatment of tobacco-related diseases, including nicotine addiction. The SRNT membership includes many of the researchers around the world who have contributed to our current understanding of the relationship between yields determined by the current FTC cigarette testing method and human exposure to tobacco toxins. SRNT offers the following comments:

General Comments:

1. SRNT commends FTC's goal of providing smokers with more useful information about the cigarettes they smoke. We agree that the current system of testing yields of cigarettes is severely flawed. Standard test yields do not reflect actual human exposures. As a result many smokers are misled into thinking they are smoking brands that will significantly reduce the health risks of smoking, when for the most commonly smoked brands there is no persuasive evidence that risks are reduced as a function of tar and nicotine yield differentials.
2. SRNT is concerned however that FTC's proposed rule could adversely affect public health. In particular, the failure of the proposal to provide information about how

much tar, nicotine and carbon monoxide the consumer would obtain when cigarette vent holes are blocked, and the proposed simplification of labels such as "low tar" and "ultra light", as well as other deficiencies described in our comments, would result in a rule that while better than the old rule, would still provide less than optimal guidance to the smoker about the cigarettes he or she smokes

3. In the absence of substantial revisions of the proposed rule, it may be preferable to simply inform the public that the present rating system seriously underestimates exposure to tar and nicotine and forbid acknowledgment of the FTC in cigarette advertisements.
4. Research shows that smokers are generally unaware that tar and nicotine information is to be found in advertising. Generic cigarettes are often not advertised at all. As a consumer information system, the current FTC approach is ineffective. We suggest that the Food and Drug Administration take over testing of cigarettes, develop a dose-rating system based more closely on actual human exposures, and make new provisions for the labeling of cigarettes.
5. Regardless of whether a new testing procedure is implemented, we recommend that cigarette testing with the current FTC method be retained. This would provide archival continuity for comparison to cigarettes manufactured in previous years. Furthermore we urge that other information that can be easily obtained during the FTC testing procedure, including the number of puffs taken per cigarette and the percentage air ventilation of the filter vents, be reported. This information would permit comparisons of cigarettes for other characteristics that could affect the level of exposure to various tobacco-derived toxins.

#### Specific Comments

1. While the high intensity smoking parameters proposed by FTC would be somewhat more realistic than the standard testing parameters, the proposed tests do not adequately inform the smoker about the maximal levels of exposure.
2. Most purportedly lower-yield cigarettes achieve low yields in part by placing ventilation holes in the filter. Smokers may occlude these ventilation holes with their fingers or lips, resulting in much higher exposure to tobacco smoke toxins(Ref. #1). These holes are not blocked in the current or the proposed FTC method. Cigarettes with filter ventilation holes should be labeled as such, and yields should be measured in the high intensity smoking paradigm with and without filter vent hole-blocking. For cigarettes with filter vent holes, three yields should be published--standard yield, high intensity yield without hole-blocking, and high intensity with hole blocking.

3. Consumers should be as informed that blocking the ventilation holes with filters or lips will substantially increase smoke yields. The ventilation holes should be made visible to the smoker so he or she could avoid hole-blocking if desired.
4. The standard machine test smokes cigarettes to 3 mm of the filter overwrap. However, many cigarettes contain substantial amounts of tobacco below the level of the overwrap, and this tobacco can be smoked. Smoking cigarettes closer to the filter may be more likely in use in people with limited financial resources, and may become as cigarettes become more expensive due to taxation and price increases by the tobacco companies. It is important to recognize that each cigarette puff, as one gets closer to the mouth-end of the cigarette, delivers greater amounts of tar and other toxins (Ref. 2). Therefore, smoking even one or two puffs at or below the overwrap could have a large impact on yields. For this reason we recommend that the test paradigm smoke cigarettes to or very near to the filter itself.
5. We do not believe a mathematical model can adequately predict yields with intensive smoking. There are many ways to engineer cigarettes to test low-yield under standard test conditions, no one mathematical model can account for all of the engineering devices. Even if a mathematical model could be validated with currently marketed cigarettes, the use of such a model would invite cigarette manufacturers to engineer new types of cigarettes so as to make cigarette yields seem lower by the mathematical than they really are.
6. We recommend that carbon monoxide ratings be added to the standard warnings. Carbon monoxide is an important human toxin. This would also encourage cigarette companies to devise and/or employ technologies to produce CO delivery. Some smoking devices, such as Eclipse, might have low tar but high carbon monoxide(CO) ratings. The consumer should be made aware of this by specific labeling.
7. The most appropriate place for information on yields, vent blocking, and ways to avoid obtaining high-yield smoking cigarettes in general - is on the cigarette packet. At a minimum such information should be readily available to the consumer at every point-of-sale. One way to do this would be to have a package insert, somewhat similar to that found for many drugs, that would be contained in every package or carton and would be available wherever cigarettes are sold.
8. Machine testing, even with the modified test paradigm, provides information on ranges of yields for particular cigarettes, but does not provide information on how that particular cigarette is actually smoked in the population. A mechanism of regular (e.g. annual) surveillance should be developed, such as human exposure to various tobacco toxins in representative groups of smokers are measured and related to machine-determined yields of these cigarettes. This monitoring would be via measuring various bio-markers of tobacco smoke exposure. This would be the best way to assess the degree of compensatory smoking of low-yield cigarettes. It is worth noting that most

foods and all drugs must be accurately labeled, and that drugs must be tested for actual bioavailability. It makes no sense that what are arguably among the most dangerous legally available produces, (i.e. cigarettes) remain exempt from evaluation of the actual bio-availability of their constituent chemicals.

9. Human exposure to nicotine and carbon monoxide from cigarettes can be estimated by measuring blood or saliva levels of cotinine, the approximate metabolite of nicotine, and by measuring blood carboxyhemoglobin or the level of carbon monoxide in expired air, respectively (Ref. 3).
10. At present there is no definitive measure of human exposure to tobacco-smoked tar. Urinary mutagenicity has been used as a biomarker (Ref. 4), but may not be a valid means to quantitate the wide range of potential exposures in people. Similarly, measurements of levels of adducts of four amino bifennal or polycyclic aromatic hydrocarbons to albumin or DNA in blood reflect tar exposure (Ref. 5 & 6), but none appear to be adequate for human dosimetry. An important research priority is to develop a better way to measure human tar exposure to assess compensatory cigarette smoking.
11. The use of terms such as Light, Ultra-light, Low-tar, and Mild constitute unfounded health claims for cigarettes carrying these designators. Both industry documents and research studies from the 1960's to the present have indicated that a significant percentage of smokers assume that lighter cigarettes are lower in tar and nicotine delivery and both lower disease risks to the smoker. Such claims should not be allowed until persuasive proof is available that (a) the tar, nicotine and CO exposures to smokers when they smoke low-yield cigarettes are substantially lower (substantially means that measurable differences are not necessarily adequate evidence) and (b) there is evidence of substantially reduced risk of disease. Since smokers are aware of these designators for their cigarettes (but few smokers are aware of their FTC tar and nicotine yields), is most urgent that consumers be protected from such misleading descriptors.

SRNT appreciates the opportunity to comment on the proposal and is willing and eager to help in any way to assist FTC with its deliberations on the FTC cigarette test method.

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