Attachment F
Federal Register Comments

April 8, 2005

Attn: CDC Reports Clearance Officer
1600 Clifton Road
MS-D74
Atlanta, Georgia 30333

RE: Human Smoking Behavior Study [Federal Register, February 9, 2005, Volume 70, Number 26, Page 6878-6879]

To whom it may concern:

We are writing in order to provide comments on the proposal by the Centers for Disease Control and Prevention (CDC) and the National Center for Environmental Health (NCEH) to study human smoking behavior as published in the February 9, 2005 *Federal Register*.

Comments were requested on the following four areas:

1. Is the proposed collection of information necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility?
2. The accuracy of the agency's estimate of the burden of the proposed collection of information?
3. Ways to enhance the quality, utility, and clarity of the information to be collected?
4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology?

We are offering comments related to questions 1 and 3.

It is very important to preface our remarks with the following note of caution. It is unclear from the proposal whether or not it is the intention of this study to inform either the design of a new machine-smoking method that better mirrors human smoking patterns or whether the intention is to use smoking topography testing to better assess/evaluate cigarette design, to then examine the measurement of biomarkers (e.g., various blood, urine, saliva, expired air measurements) based on the topography and cigarette design data, and then relate those exposure measurements to risk reduction calculations based on exposure. If the intention is the

former – informing the design of a new machine smoking method – then we have very serious reservations about the implications and consequences of such an approach. Since no machine can be designed to match human smoking behaviors, which are unique to every smoker, such a pursuit seems ill advised and we would strongly recommend against such an approach. If, however, the intention resembles the latter approach, then we believe the study does have both scientific merit and it can inform the policy debate over human exposure and risk reduction as it relates to tobacco products.

Is the proposed collection of information necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility?

As noted above, the issue of whether or not the proposal by CDC and NCEH has "practical utility" is highly dependent on whether or not the intention and actual implementation of the proposed study is to "better reflect human smoking behavior" in terms of aiding in the design of a better [replacement] machine test than the current Federal Trade Commission (FTC) tar and nicotine yield testing protocol/system or if the intention is to assess more accurately human exposure to toxins in cigarette smoke. What gives us reason to be concerned is the statement in the proposal that says the following:

> "Although there is ample evidence of the inadequacies and biases inherent in machine-smoking protocols, they serve the purpose of ranking cigarettes smoked under standardized conditions. Comparison of cigarette smoke emissions using machine-smoking methods will persevere until something superior is developed. Therefore, ***machine-smoking must be adequately informed to yield results that better reflect human smoking behavior***." [Emphasis added]

If the intention or ultimate use of the data from this study is to develop or make recommendations for a "better" machine test then we want to raise serious questions about the practical utility of such a proposal and the spending of scarce taxpayer dollars on such a project. If there is one thing we have learned over the course of the past several decades it is that machine measured yields of tar and nicotine from the FTC testing method bare little if no relationship to both toxin exposure and any related reductions in risk. We learned this lesson for so-called "light" and "low tar" cigarettes, but it extends well beyond the light and low tar issue. Among the conclusions of the National Cancer Institute's Monograph 13 that examined light and low-tar cigarettes, were the following:

- "Measurement of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different brands of cigarettes."
- "Variations in the tar and nicotine delivery that result from the known compensatory alterations in smoking behaviors make the current U.S. cigarette tar and nicotine yields as measured by the FTC method not useful to the smoker either for understanding how much tar and nicotine he or she is likely to inhale from smoking a given cigarette or for comparing the tar and nicotine intake that is likely to result from smoking different brands of cigarettes."

- "Cigarettes with low machine-measured yields by the FTC method are designed to allow compensatory smoking behaviors that enable a smoker to derive a wide range of tar and nicotine yields from the same brand, offsetting much of the theoretical benefit of a reduced-yield cigarette." [1]

There is little evidence to suggest that any other machine test wouldn't fall prey to the same problems of the current FTC test – that it could be manipulated by the tobacco companies to generate yields that bear little or no relationship to the actual exposure of individual users and/or actual risk and, as a result, would be perceived by consumers as being a safer product without reducing their risk from use. Even in the CDC-NCEH proposal they state that, "the current method of measuring constituents that smoke is via the Federal Trade Commission's machine smoking method, which does not accurately reflect human smoking patterns."

However, if the goal is not to develop a new machine test, but rather to develop a process to begin to assess actual toxin exposure in humans by first using such exposure assessments to study related cigarette design issues which in turn lead to efforts to assess actual human exposure through the development of biomarkers which then leads to assessments of risk reduction, then this proposal is worthy of proceeding forward. Such information would be very useful given the proliferation of similar smoking topography and human exposure research by the tobacco industry. Having an objective counter weight to industry proclamations of reduced exposure and risk would be very helpful. But we also do not want to minimize the difficulties and challenges that lie with this approach.

Ways to enhance the quality, utility, and clarity of the information to be collected?

The goals of this study, as articulated in the proposal, are:

- to characterize the range of human smoking behavior for a variety of cigarette categories and machine-smoked yields:
- to estimate the levels of biomarkers of exposure with the various cigarette styles; and,
- to assess known indicators of smoking behavior (ventilation pore-blocking behavior, puff volume, puff duration, puff velocity and inter-puff interval) to determine typical patterns of smoking behavior.

In isolation, these goals are good. However, these goals become less clear when contrasted with other statements in the proposal about creating a "better" machine test. The best way to enhance the "quality" and "clarity" of this proposal is for CDC and NCEH to articulate a clear statement about its goals for this proposal and whether, in fact, it does view this study as part of a larger process to change/replace the FTC testing method with a new and "better" machine test.

If you have any questions about our comments, or if you wish to discuss our comments in greater detail, please do not hesitate to contact Matt Myers at (202) 296-5469.

Sincerely,

[1] National Cancer Institute. *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine.* Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October 2001.

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Response to Federal Register Comments

Response to joint comments from the Campaign for Tobacco-Free Kids and the American Heart Association regarding Human Smoking Behavior Study [Federal Register, February 9, 2005, Volume 70, Number 26, Page 6878-6879]

The Centers for Disease Control and Prevention (CDC) appreciates the written comments provided by the Campaign for Tobacco-Free Kids and the American Heart Association regarding the Human Smoking Behavior Study. Tobacco use is the leading preventable cause of death in the United States. Both the Centers for Disease Control's (CDC) Office on Smoking and Health (OSH) and CDC's Environmental Health Laboratory are working together to advance public health efforts to prevent death and disease caused by tobacco use and exposure to secondhand smoke.

It is widely accepted that all people do not smoke cigarettes the same way. Analysis of chemicals in cigarette smoke delivered to a smoker (i.e., the "delivered dose") is hampered by limited information on how smokers alter their smoking behavior because of physical (e.g., cigarette length) or chemical (e.g., flavorants) cigarette characteristics.

Pursuant to 15 U.S.C. §1341 of the Federal Cigarette Labeling and Advertising Act (FCLAA), CDC has delegated authority to conduct and support research on the effects of cigarette smoking on human health. This authority also allows CDC to collect and analyze information, studies, and other data relating to the effect of cigarette smoking on human health. Thus, to compare how cigarettes deliver toxic chemicals to smokers and to investigate the link between tobacco use and disease, CDC is conducting a study of human smoking behavior (also known as smoking topography) among current smokers of the major styles and varieties of cigarettes consumed in the United States. The project has a major and minor objective. The major objective of the project is to better understand how human and cigarette variables influence the delivered dose of harmful chemicals in smoke in order to better understand risk factors that result in adverse health effects from smoking. Solanesol levels in cigarette butts and biological samples will be collected for investigation of filter vent blocking behavior and biochemical markers of exposure. Information on solanesol levels in cigarette butt filters, biochemical measurements, vent blocking behavior, and smoking behavior will be used to

measure dose based on number of cigarettes smoked, amount of each cigarette smoked, and puff characteristics.

Laboratory scientists rely on automated smoking machines to generate cigarette smoke for chemical and toxicological testing. All current smoking machine methodologies are “one size fits all” approaches to generating cigarette smoke. Thus, the second objective of the study is to define average or “composite” smoking patterns from the quantitative and observational data. The composite conditions can be used to establish human behavior-based smoking machine methods for major categories of cigarettes to be used in laboratory studies that require cigarette smoke for chemical or toxicological testing.

Addendum:

Following extensive discussion and careful consideration of the issues raised in public comments and by the Office of Management and Budget, it was decided to refocus the goals and methodology of the study. The refocused study is designed to address the question of how cigarette yield category influences levels of biomarkers of exposure and cardiovascular effects. Specifically, the refocused study will evaluate how body burdens of selected carcinogens, other smoke-derived toxic chemicals, and measures of cardiovascular reactivity vary in proportion to machine-smoked yields of tar, nicotine, and carbon monoxide across a wide range of commercially available cigarettes (ultralight, light, and full-flavored cigarettes).

We feel that the new focus of the study addresses the major concern regarding development of a new smoking machine method as a minor objective. We are further convinced of the value of the refocused study goals and design by the statements submitted above: “to assess actual toxin exposure in humans by first using such exposure assessments to study related cigarette design issues which in turn lead to efforts to assess actual human exposure through the development of biomarkers which then leads to assessments of risk reduction, then this proposal is worthy of proceeding forward.” And, “[using] smoking topography testing to better assess/evaluate cigarette design, to then examine the measurement of biomarkers (e.g., various blood, urine, saliva, expired air measurements) based on the topography and cigarette design data, and then relate those exposure measurements to risk reduction calculations based on exposure. … [has] both scientific merit and it can inform the policy debate over human exposure and risk reduction as it relates to tobacco products.”