



February 13, 2012

Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0867

The undersigned organizations hereby submit their comments on the notice of proposed agency information collection in the above-designated docket.

Section 904(a) of the Family Smoking Prevention and Tobacco Control Act (“FSPTCA”) requires all tobacco product manufacturers to submit, by brand, sub-brand, and quantity, a list of all constituents, including smoke constituents, identified by FDA as harmful or potentially harmful to health. Section 904(e) requires FDA to establish and periodically revise, as appropriate, in a format that is understandable and not misleading, a list of harmful and potentially harmful constituents, including smoke constituents in each tobacco product by brand and by quantity in each brand and sub-brand. On August 11, 2011, in Docket No. FDA-2011-N-0271, FDA published a proposed list of harmful and potentially harmful constituents based on a list compiled and endorsed by the Tobacco Products Scientific Advisory Committee. Significantly, the explanatory materials accompanying the notice stated that the list was incomplete because FDA “has only focused on []five disease outcomes” rather than all potential harms and because the criterion for listing dependent upon a substance “being both studied and listed by another entity.” 76 F.R. at 50228. As FDA noted, there could well be other constituents that would warrant listing had they been studied more extensively. The undersigned groups submitted comments on that list on November 11, 2011, a copy of which is attached hereto at Tab A.¹

Section 904(d) requires the Secretary to “publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under Subsection (e).” Section 904(d)(2) directs the Secretary to conduct periodic consumer research to ensure that the list published is “not misleading to lay persons.” In enacting these requirements, the Congress was attempting to reconcile two important objectives: (1) to ensure that detailed information concerning constituents in tobacco products was systematically gathered and made available to the public; and (2) that the information so gathered was made available in a way that facilitated understanding by lay persons of substances in tobacco products and in smoke that are hazardous but did not lead to misperceptions about the relative risk of different brands and products or misperceptions about the health impact of presence or absence of different constituents or different quantities of different constituents.

¹ Those comments called into question, *inter alia*, discrepancies between the list endorsed by the TPSAC and the list published by FDA.

In this notice, FDA seeks public comment on a proposed collection of information designed to determine how FDA can publish the List of Harmful and Potential Harmful Tobacco Constituents (“Harmful Constituents List”) in a format that is understandable and not misleading to a lay person. In developing such a comment, it is useful to review both the reasons for developing such a list and making it publicly available and the reasons why there are legitimate concerns that publication of such a list, in the absence of appropriate safeguards, could mislead lay readers and lead to a result that would not be beneficial to the protection of the public health.

Reasons for developing and publishing a list of harmful and potentially harmful constituents.

Prior to the enactment of the FSPTCA, tobacco companies were not required to report to a federal agency the constituents² in their products and were not required to disclose these constituents to the public. There was a legitimate concern that neither agencies charged with protecting the public health nor consumers could possibly know what they were being exposed to when they smoked or otherwise consumed a tobacco product. Disclosure of this information to FDA serves several purposes. First, it serves a regulatory purpose by helping to establish a baseline for product regulation. Once such information has been provided to FDA, it should be clear that any increase in any harmful constituent would render the product a “new product” within the meaning of the statute and require the manufacturer to obtain pre-market approval before any such product could be marketed. This standard will therefore require a degree of consistency and standardization that is highly desirable. Second, submission of the information will facilitate research on tobacco products. Prior to the legislation, only the companies themselves knew precisely what the constituents in their products were. Researchers could “reverse engineer” the product, but submission of test results by the companies will greatly facilitate useful research. Furthermore, neither government nor researchers were able to evaluate the impact of specific changes, including seemingly benign changes in substances like sugar, that could impact other ingredients and constituents. Third, consumers are entitled to information that is not misleading about the contents of tobacco products to help them more accurately evaluate the health or potential health impact of using those substances. The need for such information seems particularly compelling when the substances at issue are toxic, carcinogenic or addictive and have profound effects on the consumer.

The form and content of disclosure should take into account how consumers will perceive and interpret the information disclosed.

It is normally the case that any increased disclosure of information to consumers will enhance the quality of decision-making. However, Congress recognized that factual disclosures that the public misinterprets can do more harm than good and, therefore, required FDA to disclose information about harmful and potentially harmful constituents in tobacco products in a way that is not “misleading.” Congress recognized that there are legitimate reasons to be concerned that disclosure of these lists to the public, without adequate safeguards, could mislead consumers and be detrimental to the public. This is the case both because of the limitations of the lists themselves and because of the possibility that the information

² Unless otherwise noted, the term “constituents” as used in this comment refers to constituents in the product and smoke constituents as well.

about these constituents—accurate in itself—could very well be misunderstood either if they were not put in context or if consumers misinterpreted the significance of the information in making individual decisions about the use of tobacco products. Such misperceptions could influence consumer behavior in ways that are detrimental to the public health. If current scientific knowledge is not sufficient in all cases to describe accurately the health consequences attributable to the presence of specific constituents or specific combinations or quantities of specific constituents, but consumers interpret the disclosures as implying that products with fewer harmful constituents or products with lower levels of certain constituents are safer, then the disclosure or disclosure format would be inconsistent with the goals of the statute and intent of Section 904. The potential for misunderstanding is substantial. In attempting to develop a format for disclosure that would minimize the risks of misunderstanding, it is helpful to list the major potential sources of misunderstanding.

First, the lists themselves are incomplete. They include only some of many disease outcomes. Moreover, the list includes only substances that have been found by other agencies to be carcinogenic, toxic, or addictive. Many other substances that have not been the subject of comparable study may fit one or more of the categories. FDA must study the impact of such a partial disclosure, including the adequacy of a disclaimer that states that there may well be other harmful constituents that cause cancer or other diseases that do not appear on the list. If such a disclaimer is not sufficient to undo the misinterpretation that results, FDA must develop a disclosure plan that does not suffer from this problem.

Second, the quantitative test data currently available do not accurately measure the actual exposure of consumers. Although the FDA's proposed rule for testing requires submission of data from the FTC testing method and the Canadian government testing method, it is conceded that neither method—and no existing machine testing method—accurately measures constituents as smokers experience them in practice. Again, FDA must evaluate the efficacy of such a disclaimer to prevent consumers' misperceptions; if such a disclaimer is inadequate to do so, FDA should develop an alternative disclosure plan that does not mislead consumers about the health impact of these numbers.

Third, there is a high likelihood consumers will conclude that lower numbers or fewer constituents means a product is less risky even though the scientific evidence is not sufficient to reach such a conclusion. In most instances, current scientific information does not exist to evaluate or quantify the impact of individual harmful constituents or, indeed, of such constituents in combination or of different levels of different constituents. Tobacco products are also unique in the number of harmful constituents each product contains. The multiplicity of harmful constituents makes it more difficult to draw conclusions about the relative risk posed by various tobacco products and makes it more likely that consumers will misinterpret the significance of fluctuations in the level of one or more such constituents. Even if Product B had only half as much of Constituent X as Product A, this difference might be immaterial to the health consequences of using one rather than another. With thousands of brands and subbrands and hundreds of harmful constituents, even the most sophisticated consumer would not be able to draw reliable conclusions about the relative safety of competing brands on the basis of this information.

In developing its system for numerical disclosures of harmful and potentially harmful constituents, FDA must also carefully take into account the mandate of Section 911 of the FSPTCA. Section 911 recognizes that an assertion by a manufacturer that a product exposes consumers to a lower

level of a constituent constitutes a “Modified Risk Claim” that triggers the protections of Section 911. FDA must be careful not to allow its own disclosures to cause the same harm.

The danger of such misunderstandings has been underscored by the regulatory experience in the listing of tar and nicotine content in cigarettes. The attached statement submitted in this docket by Professor Joel Cohen, an acclaimed consumer behavior researcher with more than thirty years of experience in evaluating government and industry communication of health-related information, describes this experience in more detail and draws important conclusions from it that are highly relevant in considering what must be done to avoid unintended harm to the public health. Drawing on historical experience regarding “light” and “low tar,” Professor Cohen describes the potential that disclosure of the information at issue here could have unintended consequences for the public health and suggests approaches for minimizing this potential.

In the current context, where there is legitimate concern that public disclosure of this information could have negative public health consequences, the use of surveys to test the actual results of information disclosure is particularly important. No plan of disclosure should be implemented unless and until FDA has conducted surveys that demonstrate how consumers perceive and digest information, that consumers find understandable and not misleading, and that produce results where the benefits of disclosure outweigh the costs.

Accordingly, in developing a research protocol to design a survey to determine how information can be conveyed to consumers in a way that would minimize the prospect that such information would lead consumers to draw misleading conclusions from the data, the protocol should be designed to identify consumer perceptions from the disclosures, examine alternate formats and methods of disclosure and examine whether clarifying statements that accompany the published lists are adequate to prevent consumers from being misled. If clarifying statements can accomplish this goal, the FDA should test different statements and different forms of disclaimers to determine which are most effective. Furthermore, FDA should not conclude that inclusion of such statements is adequate to prevent consumer misperceptions unless and until survey results demonstrate that such statements actually accomplish this goal.

Moreover, the manner in which the information would be disseminated is extremely important. While it might be appropriate to publish the lists on the FDA website where they could be accessed by interested members of the public, it might be highly misleading to publish the same information on the pack. Moreover, publication of a part of the list while leaving certain constituents off the list could well be misleading. Thus, any study should seek to determine the effect of disclosure in various modes of dissemination.

Finally, the study should take into account the consequences of disclosing such a list on the ability of manufacturers to use the information contained on the list. Section 911 of the Act significantly constrains this ability. In the absence of an order issued by the under Section 911(g), a manufacturer may not represent, in its labeling or advertising, that

- (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed products;

- (2) the product contains a reduced level of a substance or presents a reduced exposure to a substance; or
- (3) the product or its smoke does not contain or is free of a substance.³

In addition, the Act prohibits a manufacturer from taking any other action directed to consumers through the media or otherwise “that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.”

In order to ensure that publication of the list does not result in misleading characterization of the information contained in it by tobacco product manufacturers, FDA should make it clear to tobacco product manufacturers that any characterization of or reference to any such list is subject to the limitations contained in section 911. Moreover, FDA should make it clear that any quotations from the list used by manufacturers in labeling or in advertising must also fully comply with Section 911.

Format of Publication

FDA should give careful consideration to the manner in which the list should be made available to the public. If it is made available on the agency’s website, it should be presented with sufficient explanatory materials to minimize the possibility that the results would be misleading to lay persons. Moreover, the format of presentation should be considered so that the results are grouped in a manner designed to avoid misleading presentation.

If FDA uses any portion of the list or any characterization of it in any media campaign, it must ensure that any such publication or characterization should include sufficient explanatory material to ensure that such publication is not misleading.

Design of the Survey Sample to Meet These Criteria

It is appropriate for FDA to conduct surveys to minimize the possibility that publication of the list could mislead the public. In devising the surveys, FDA should bear in mind that there are many different segments of the public and that presentations that might not be misleading to one group would be misleading to others. FDA’s goal should be to identify presentations that avoid misleading any segment of the public. In order to accomplish this goal, FDA will need to conduct surveys in multiple demographic groups. Given this requirement, FDA should consider whether the intended sample size is sufficient and whether it will be sufficiently representative of the many different segments of the public to yield the information necessary to provide appropriate protection to all segments of the public.

The survey should be specifically designed to determine what the effect of disclosure would be on actual consumer behavior. Insofar as possible, the survey should seek to determine what consumers would likely have done in the absence of the information and what they are likely to do once the information has been provided. FDA should proceed with disclosure only if survey results demonstrate that disclosure would more likely than not result in changes in consumer behavior that, on balance, have a positive impact on the public health.

³ FSPTCA, Sec. 911(b)(2)(A)(i)

The survey should seek to provide persuasive answers at least the following essential questions:

Do consumers understand the information that is being provided?

What conclusions regarding the relative health risks of various products will consumers take from looking at the data?

Will consumers understand that even products that have lower levels of some harmful substances still contain many substances that cause death and disease and that products that contain lower levels of such substances may be just as dangerous?

Can the information be conveyed to consumers in a way that that the dominant message is that every tobacco product exposes users to many potentially fatal substances? If so, how should format and context of disclosure be formulated to achieve this result?

How likely are consumers to focus on the differences in content of hazardous constituents between combustible and smokeless tobacco products as opposed to differences in content of hazardous constituents as between different brands?

In evaluating the survey results and considering what disclosure can best contribute to the protection of the public health, the FDA should keep in mind the Congressional directive to ensure that disclosure will not be misleading. If a more extensive disclosure cannot be accomplished without misleading the lay public, FDA should consider limiting publication to a listing on its website. In any event, FDA should make it clear to manufacturers that Section 911 applies to any characterization of the listing.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Legacy
Campaign for Tobacco-Free Kids