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RE: Docket No. FDA-2013-N-0001-0055

Mr. Bravo:

The undersigned organizations submit the following comments to the above-referenced docket for consideration by the joint meeting of the Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee to be held on August 15, 2013. The purpose of the meeting is to discuss the results of the FDA consumer research, "Experimental Study on the Public Display of Lists of Harmful and Potential Harmful Tobacco Constituents" (Experimental Study).

The results of the Experimental Study have not yet been made public and we have not had the opportunity to review them. 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.

The Experimental Study was designed to test various formats for communicating the information on harmful and potentially harmful constituents (HPHC) to consumers. While we cannot fully comment until the study materials are made available, we have provided comments to the Food and Drug Administration (February 13, 2012) and the Office of Management and Budget (June 7, 2012) outlining some key issues regarding the publication of the information on HPHCs and the Experimental Study and believe it is worth reiterating some of the key points. We have also attached the previously submitted comments.

- As the FSPTCA dictates, it is critical that the information on HPHCs be provided to consumers only when it can be concluded that the information does not mislead consumers. Even if they understand listings and even quantitative measures (which in itself will be difficult), the critical point of the research should be to ensure that consumers do not misinterpret the public health significance of the information and do not use the information to make invalid health related comparisons between products based on the information presented, thereby increasing the risk of initiation or discouraging cessation by encouraging tobacco users to switch rather than quit or prompting consumers to switch from one product to another based on a false belief that one product is safer.
- Finding a way to communicate the data in a way that is not misleading is made difficult by a number of factors, including the following.

    - Consumers may falsely believe that it has been proven that a product with fewer HPHCs is less harmful than one with more.
    - Consumers may falsely believe that it has been proven that lower amounts of individual HPHCs mean a product is less harmful.
    - Consumers may falsely think that if the HPHCs in one product are linked to fewer diseases that it is less harmful.
    - Consumers may falsely think that the absence of information on a particular HPHC means the constituent is not present in the product and the product is therefore less harmful.
    - Consumers may falsely think the quantities of constituents are comparable even if they are measured on different scales or that the same amount of one constituent is as harmful as that amount of another.
    - Consumers may not understand that the amount of the constituents listed may not represent the amount consumed by the user.

- The fact that the FDA will initially require reporting on only a subset of HPHCs will have to be addressed in testing consumer reactions.

- The research must address not only how consumers understand the information but how they intend to act on it. Through its research, FDA must establish that consumers will not make unwarranted decisions based on the information about HPHCs before it makes that information public.

- Research must be conducted with key demographic subgroups to make sure that the most vulnerable in terms of tobacco use behavior (e.g., low income, low education, youth) are not misled by the information into making decisions that will harm health.

- The venue and format for making the data public will also have important implications. FDA should conduct usability testing of any proposed final format to understand how consumers interact with the information, consider it, and possibly use it to make decisions.

- Steps must be taken to ensure that tobacco companies do not use the information to get around the modified risk provisions (Section 911) in the FSPTCA.

Because of the number of issues regarding the information on HPHCs, it is likely not possible for consumers to make valid comparisons across products. The research must establish that they are not making invalid ones. With the amount of information on each product, the many communication goals, and the important objective of ensuring that consumers do not make decisions based on the publication of these lists that would increase tobacco use (by encouraging initiation or discouraging cessation), it is critical that this research (the Experimental Study) not be seen as providing the definitive answer on how to make this information public but rather as the first in a series of studies to determine how this information will be consumed. While we believe it is important that consumers, researchers, and others have access to information on the harmful constituents in all tobacco products, this has to be balanced with ensuring that the publication of this information improves public health – the standard used throughout the FSPTCA.

Sincerely,

American Association for Cancer Research
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
American Public Health Association
Campaign for Tobacco-Free Kids
Tobacco Control Legal Consortium