June 7, 2012

Office of Information and Regulatory Affairs

Office of Management and Budget

ATTN: FDA DESK Officer

Re: OMB Control Number 0910—NEW "Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents" [Docket No. FDA-2011-N-0867]

To Whom It May Concern:

The undersigned organizations hereby submit their comments on the proposed collection of information by the Food and Drug Administration (FDA), "Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents."

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.

Section 904(d)(2) further requires the Secretary to conduct "periodic consumer research to ensure that the list published under paragraph (1) is not misleading." 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 the presence or absence of different constituents or different quantities of different constituents. In enacting the Tobacco Control Act, Congress was acutely aware that similar information had been misused to mislead consumers in the past and Section 904 was drafted to avoid such a result in the future.

Accordingly, FDA has submitted a proposed collection of information to the Office of Management and Budget for review and clearance for a proposed survey of consumers to gauge reactions to different

formats for presenting the information to consumers, as well as to different statements to help consumers understand what they may or may not conclude from the information. As noted in prior comments by the undersigned to the FDA regarding the implementation of Section 904, because the effects of publication of such information are potentially misleading, we believe it is very important for FDA to base any decisions regarding the method of publication on actual data regarding consumer understanding of such data.

We believe the critical point of the research should be to ensure that consumers do not use the information to make invalid comparisons between products based on the information presented, thereby increasing risk of initiation or discouraging cessation by encouraging tobacco users to switch rather than quit. We know from the experience with light and low tar cigarettes that smokers can be dissuaded from quitting if they mistakenly believe they can reduce their risk by switching to another product that appears less harmful but is not. Research has also shown that information on the amount of constituents can lead to false beliefs regarding health risks[1]. Therefore, FDA must be certain that the publication of the list of HPHCs is not only understood but does not lead to consumers making these mistaken comparisons and acting on them.

Due to the very large number of Harmful and Potentially Harmful Constituents (HPHCs), differences in how the content of such constituents are measured (e.g., by cigarette, by gram, and different scales within these), the multiple diseases such constituents cause, and other factors, there is potential for much confusion among consumers when they confront the lists for individual products. There is also the potential for misuse of the lists to make invalid comparisons as described above. The potential for misinterpretation include, but are not limited to, the following:

- Consumers may think that a product with fewer HPHCs is less harmful than one with more
- Consumers may think lower amounts of individual HPHCs mean a product is less harmful
- Consumers my think that if the HPCSs in one product are linked to fewer diseases that it is less harmful
- Consumers may think that the absence of information on a particular HPHC means the constituent is not present in the products and the product is therefore less harmful
- Consumers may 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.

These issues are further complicated by FDA's intention to initially require tobacco companies to report on just 20 of the constituents it has identified as harmful or potentially harmful. This limitation of the scope of the initially reported information to 20 constituents increases the likelihood that publication of such information would be misleading. Since the list would provide no information on nearly 80% of the

[1] Hammond, D, White CM, Improper disclosure: Tobacco packaging and emission labeling regulations, Public Health (2012), doi:10.1016/j.phhe.2012.03.012

harmful or potentially harmful constituents already identified by TPSAC, its potential to mislead consumers would increase.

The FDA recognizes many of these issues in the communication goals it lists in its announcement of the proposed submission of information. In addition to the goals it lists, however, we would add the following (some of which are addressed in the survey but nonetheless should be understood as explicit goals of the survey):

- Consumers understand that the constituents as measured by machines do not necessarily reflect what is delivered to the tobacco user
- Consumers understand that the number of diseases linked to a particular constituent is not necessarily a reflection of the relative harm of the constituent or constituent amount
- The overall take-away for consumers should be that these lists SHOULD NOT be used to compare the products for relative harm or for decisions on which if any products to use.
- Exposure to the lists should not increase risk of initiation or the risk of switching rather than quitting

As noted above, the survey submitted by FDA for review addresses many of these issues. The design's inclusion of a control group will presumably allow some conclusions as to whether consumers exposed to the lists are better able to answer questions about the meaning of the information than those not exposed to the lists. We are concerned, however, whether simply asking consumers to answer questions about the meaning of the numbers (e.g. whether fewer ingredients mean more/less harm) will effectively answer the question of whether consumers would use the data to make such comparisons anyway. These questions appear to do a better job measuring whether consumers understand the disclaimers than they do at ascertaining if consumers will make the comparisons despite being able to reflect what the disclaimers say.

FDA has recently issued a proposed guidance with regard to modified risk tobacco products under Section 911 of the Tobacco Control Act. One important purpose of that guidance is to ensure that claims made by tobacco product manufacturers regarding the health effects of tobacco products not mislead consumers and to ensure that any such claims actually benefit the public health of the population as a whole. In order to ensure that this will be the case, the guidance requires, inter alia, a range of studies, including consumer perception studies, designed to determine how a given claim will affect consumer behavior. In many ways, the information at issue here has a similar potential to mislead consumers. The requirements FDA adopts for modified risk claims under Section 911 are thus instructive for the inquiries that should underlie disclosure of information under Section 904. At the same time, information provided under Section 904 is potentially important for researchers. FDA should seek both to make it possible for researchers to have access to this data while at the same time providing for disclosure in a manner that minimizes the likelihood that consumers would be misled.

Given the critical goal of understanding how the consumers will use the information and what conclusions they will reach from it, FDA should consider presenting the consumers with two (or more)

lists in the same format for different products with varying numbers of ingredients, amounts of ingredients, diseases causes, etc. and asking a series of questions about the two products, such as:

- Is one more or less harmful than the other?
- Does one cause more cancer (or one of other diseases)?
- Does one have more harmful ingredients?
- Would you choose one over the other based on the information?

We believe assessing whether consumers will make the comparisons, whether or not they can repeat the information in the disclaimers, is critical. Having respondents answer questions about two products seems to be the best way to do this. This process will help determine whether certain formats, if any, are better or worse at keeping consumers from making invalid comparisons.

FDA also states in its announcement of submission that the research will include cognitive testing of the statements it is using to try to educate consumers about the proper use of the lists. Such testing is critical because even the disclaimers could be misinterpreted by some respondents. For example, we need to make sure that the statements that attempt to educate about the limits of the data such as "Research is ongoing to find out which chemicals in tobacco and tobacco smoke cause harm" or "The amount of chemical that gets into the body may be higher or lower depending on how a person uses the tobacco product" are not interpreted by some to suggest that the health harms are not clear or that one can mitigate these harms by the way they use the product. These are just a couple of examples that illustrate some of the ways a smoker or would-be smoker could possibly use these statements to rationalize tobacco use.

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 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.

In this same vein, it may be useful for FDA to include in its testing the information in its simplest and most straightforward format. The key to the ingredient disclosure list for public health is not so much that consumers understand every element of it, which will be difficult for most lay people, but that it not mislead them into making judgments that cannot validly be made from the information in the lists and make decisions based on those judgments. The information also needs to be available for researchers and other interested parties beyond consumers. For these reasons, FDA should consider testing a list in its simplest form (the list of HPHCs with quantities by brand) and determine if consumers are misled by or misuse it.

The final survey should also include demographic items and sufficient sample sizes to allow the examination of key subgroups with disproportionately high smoking rates or other vulnerabilities to

ensure that information is not misleading to them. These include those with lower education and income levels, members of the LGBT populations, and groups of smokers who may be more concerned about health risks and thus perhaps more likely to want to try a "less harmful" product that may not be. Obviously, the promise of confidentiality on these potentially sensitive data items is critical.

As FDA moves forward in determining how to make the information available to consumers, we believe it will be important to conduct usability research to better understand how consumers would navigate and use the information if made available on a website. Research firms that specialize in this kind of work to determine how consumers use the site and what they take away from it could be enlisted for this work.

We commend the FDA for moving forward with consumer research on this critical issue, hope this input is helpful to OMB in ensuring that the research accomplishes the objectives, and are willing to provide any additional information that would be helpful.

Sincerely,

Campaign for Tobacco Free Kids
American Heart Association
American Lung Association
Legacy