Tobacco Control Legal Consortium

Law. Health. Justice.

March 4, 2016

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Request for Information on Psychosocial Predictors of Update of Tobacco and Other Similar Consumer Products

Docket No. FDA-2016-N-0073

Dear Commissioner Califf:

The Tobacco Control Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the psychosocial predictors of initiation into tobacco use. The Tobacco Control Legal Consortium is a national network of nonprofit legal centers providing technical assistance to public officials, health professionals and advocates concerning legal issues related to tobacco and public health.[1]

We applaud the FDA for gathering this important information and we encourage the agency to evaluate the information it receives in light of the Family Smoking Prevention and Tobacco Control Act's public health standard, a population-level standard of which initiation is only one component. Because this broad standard is central to the FDA's authority to regulate tobacco products, and because the public health standard is different from the standards used by other FDA centers, it is important for the agency to expand this dialogue with the public health community to better establish how this standard ought to operate in practice.

The public health standard, a population-based assessment of likelihoods, was developed as a counter to the individual-level safety and efficacy standards that the FDA has worked with historically. Tobacco products are unique among the products in the FDA's regulatory authority and there is a vast community of scientists, lawyers, advocates, and other public health

[1] The affiliated legal centers include ChangeLab Solutions in Oakland, California; the Legal Resource Center for Tobacco Regulation, Litigation & Advocacy at the University of Maryland School of Law in Baltimore, Maryland; the Tobacco Control Resource Center, a project of the Public Health Advocacy Institute at Northeastern University School of Law in Boston, Massachusetts; the Smoke-Free Environments Law Project at the Center for Social Gerontology in Ann Arbor, Michigan; the Public Health Law Center at the Mitchell Hamline School of Law in Saint Paul, Minnesota; the Tobacco Control Policy and Legal Resource Center at New Jersey GASP in Summit, New Jersey; and the Public Health and Tobacco Policy Center at Northeastern University School of Law in Boston, Massachusetts, which provides technical assistance to communities in New York.

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professionals who have extensive experience that can benefit the agency as it attempts to understand how scientific evidence relates to this new legal framework in the adoption of regulations that will best protect public health. The current request for information will provide the agency with important information, but in our view the request is too narrow. The FDA is requesting information regarding the psychosocial predictors of uptake of tobacco which the agency considers to include "constructs that can be measured at the level of the individual . . ." While this information about individual impact may prove useful to the FDA, the agency must be guided by the public health standard in its evaluation of scientific evidence.

I. A population-level standard is the only appropriate manner in which to approach tobacco product regulation.

The Food, Drug and Cosmetic Act establishes standards for the regulation of food, drugs, devices and other products over which the FDA has regulatory authority. The regulation of food and drugs focuses on ensuring that consumers receive the benefits of the products without being exposed to unnecessary risks. For food, the FDA must ensure that food is safe, wholesome, sanitary, and properly labeled.[1] For drugs, the FDA must ensure that drugs are safe and effective.[2] Tobacco is different from food and drugs in that it is an inherently deadly product and thus clearly not safe. Cigarette smoking kills more than 480,000 Americans each year,[3] and is the single largest cause of preventable death and disease in the U.S.[4] Nor is tobacco effective (other than at killing more than half of its users).[5] Because tobacco is neither safe nor effective, and because it has no health benefits, only risks and harms, federal food and drug standards simply do not work for the regulation of tobacco products.

Thus, Congress had to develop a new standard for FDA regulation of tobacco products: the public health standard.[6] Rather than focusing on the safety of the individual, when Congress established the public health standard it focused on the effect of tobacco products on the entire population. Under this standard, the FDA must consider three factors when regulating tobacco: 1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products; 2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and 3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.[7]

This comprehensive public health standard can be a very powerful tool for the FDA, allowing the agency to not just mitigate the ongoing damage caused by tobacco use, but also to prevent future harm. Because the standard speaks to likelihoods and not certainties, and because it operates at the population level rather than the individual level, the FDA has wide latitude to take sweeping actions to protect the public from the harms caused by tobacco use.

The tobacco industry has and will continue to attempt to persuade the FDA to focus on individual level harm. Doing so allows the industry to cast doubt on the impact of different ingredients and constituents and their connection to disease. For decades the industry attempted to cast doubt on the connection between tobacco use and disease by focusing on those individuals who used tobacco and never contracted diseases like lung cancer. However, analyzing rates of disease among tobacco users and non-users at the population level paints a very different picture. The population-level data regarding the harms of tobacco is so damning that tobacco industry has consistently attempted to shift the focus to the individual.

Despite tobacco industry claims to the contrary, the agency does not need to establish that a cigarette with a particular constituent is more harmful than a cigarette without that constituent in order for the FDA to require that the constituent be removed from all tobacco products (although such a finding would support the constituent's removal). Instead, the agency can find that the constituent is likely to increase initiation or likely to decrease cessation. If it so chooses, the FDA may rely solely on epidemiological evidence related to likely initiation and cessation to support broad regulatory actions.

Shifting the level of analysis to the population level should have the effect of reducing the amount of new research that the FDA must conduct in order to take many important actions that are likely to significantly benefit public health. The FDA may rely on the decades of epidemiological evidence related to the effect of individual constituents like menthol and nicotine, the effect of advertising and marketing, and the effect of various sales restrictions. The agency does not need to know how a particular action will affect an individual tobacco user or non-user, it only needs to understand the *likely* effect on the health of the entire population.

II. The current request for information is important but far too narrow.

We are pleased that the FDA is requesting information about one prong of the public health standard and what one particular facet of that prong might mean for future regulation. We encourage the FDA to review this information in the broader context of all three prongs of the standard and to evaluate how the prongs operate together. In addition, the FDA needs to begin discussing not just the type of evidence but the amount of evidence that the agency must gather to support a particular regulatory action.

The agency should begin a public dialogue, perhaps a series of meetings and a public docket, to gather information and perspectives on the public health standard and the existing evidence to support future FDA action. Scientists and public health officials who have been working in tobacco control for decades have valuable information that will inform agency policy. It is these scientists and public health officials outside of the agency who will be providing most of the data that the agency will ultimately rely on when taking future actions. A public health community that understands the type of evidence and the amount of evidence necessary for regulation benefits the FDA. This type of understanding only comes from a robust and open discussion.

While the public health standard is a scientific standard, it sits inside of a legal framework. The FDA could benefit from discussing legal issues with the public health community as well. There are seasoned lawyers within the public health community who can provide support to the FDA to best protect its regulations against legal challenges by helping the FDA frame its evidence base. A discussion of the public health standard with lawyers allows FDA scientists to hear the public health community's legal perspective, which may be different from that of the FDA's own lawyers. An informed discussion between FDA lawyers, FDA scientists, public health scientists, and public health lawyers would be beneficial to all parties and lead to better, more effective federal tobacco control regulation.

We reiterate that the unique elements of the newly developed public health standard –as distinct from the agency's well-established safety and efficacy standards – coupled with the vast and robust experience within the public health community could provide the FDA with a large

untapped resource that can help the agency better understand how to analyze scientific evidence within this legal framework. Harnessing scientific and legal expertise from the public health community in this way will result in tobacco product regulations that will best protect public health.

Respectfully,

Maggie Mahoney
Executive Director
Tobacco Control Legal Consortium

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[1] 21 U.S.C. § 393(b)(2)(A).

[2] 21 U.S.C. § 393(b)(2)(B).

[3] U.S. DEP'T OF HEALTH & HUMAN SERVS. THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS A REPORT OF THE SURGEON GENERAL 107 (2014).

[4] Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000-2004,* 57 MORBIDITY & MORTALITY WKLY. REP. 1226, 1226-28 (2008), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf.

[5] WORLD HEALTH ORG. TECHNICAL REPORT SERIES, THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REGULATION 3 (World Health Org. Press 2007), *available at* http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf.

[6] H.R. REP. NO. 111-58, pt. 1, at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.

[7] 21 U.S.C. § 387g(a)(3)(B)(i).