



November 22, 2016

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

Re: Procedures for Evaluating Appearance Issues and Granting Authorizations
for Participation in FDA Advisory Committees, Draft Guidance

Docket No. FDA-2016-D-1399

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Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the FDA's draft guidance, "Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees." The Tobacco Control Legal Consortium, a program of the Public Health Law Center, 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

As experts in tobacco control policy and engaged stakeholders of the FDA's regulation of tobacco products, our comment specifically addresses the potential impact of this guidance on the FDA's Tobacco Products Scientific Advisory Committee (TPSAC), which plays the crucial function of advising the FDA's Center for Tobacco Products on tobacco product regulation.

Of particular concern in this draft guidance is the FDA's interpretation of the circumstances that fall into section 502's "catch-all" language on appearance issues. Specifically, on page 13, FDA identifies their own "catch-all" category of "Other Relationships or Interests, Whether Current or Past, that May Raise Questions about

¹ The Tobacco Control Legal Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

the Member's Impartiality." Within this category, the FDA suggests that "[p]ast involvement in a lawsuit related to the product(s) or issues before the committee or otherwise involving the sponsor," could potentially disqualify an individual for service on an advisory committee. While this disqualifier may be logical for other FDA regulated products and industries, it is detrimental to the recruitment of talented experts who can inform FDA's regulation of tobacco products. In addition, applying this disqualifier in the tobacco context would not uphold the intent of Congress when it enacted the Family Smoking and Prevention and Tobacco Control Act of 2009 that established the FDA's TPSAC.

Tobacco is unlike all other products within the FDA's regulatory authority. It is the only regulated product that when used as intended kills up to half of its users worldwide. In the U.S., that amounts to more than 480,000 deaths each year—something Congress recognized when it developed a new statutory framework with which to regulate tobacco. The public health standard of regulation that Congress established in the Act focuses on population health rather than individual risk and is distinct from the safety and efficacy standards that the FDA applies to all other product regulation. Again, the introduction of the public health standard was a recognition by Congress that the FDA's regulation of tobacco products ought to be different than its regulation of other products. This is also true in the context of recruiting experts to serve on TPSAC.

The Tobacco Control Act explicitly identifies specific conflicts provisions that apply to the TPSAC and states an overarching public health-oriented tobacco cessation policy priority. Congress's findings in the Act recognize tobacco products as "addictive" and "inherently dangerous," conclude that the "actions of the tobacco industry" have caused a "public health crisis" in the United States, and hold that one of the law's primary purposes is "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." To that end, the TPSAC was structured by Congress to reflect and advance the policy priorities established in the Tobacco Control Act. The Act's conflicts provisions applicable to the TPSAC were intended to be consistent with those aims, focusing on limiting tobacco industry involvement in the TPSAC. In other words, Congress clearly intended that the TPSAC's voting members would include the top non-industry experts on tobacco control and smoking cessation.

Historically, tobacco control has been a grassroots movement. While the first Surgeon General's report on smoking and health came from a federal official and ushered in a new era in tobacco control, very little happened at the federal level between 1964 and 2009 in terms of regulation. Tobacco control advocates worked tirelessly at the state and local levels to change laws and social norms through legislative advocacy as well as lawsuits brought by individuals, groups, and state governments. One byproduct of the many lawsuits against the tobacco industry, was

a demand for talented and qualified scientists to serve as expert witnesses. As a result, many leading tobacco control researchers have testified in various legal proceedings in which tobacco companies are parties and tobacco products are at issue.

In 2011, this type of involvement in legal proceedings served as the basis for a tobacco industry lawsuit claiming that several members of TPSAC who worked on the committee's report on menthol in cigarettes had conflicts of interests that should disqualify them from serving on TPSAC entirely and asking the court enjoin the FDA from relying on the report.² While the tobacco industry plaintiffs convinced a lower court to issue an injunction, upon appeal to the Court of Appeals for the District of Columbia Circuit, the district court judgment was vacated for lack of jurisdiction and its injunction prohibiting the use of the menthol report and ordering reconstitution of the committee was dissolved. Though the merits of the industry challenge were not decided, we believe that the FDA's initial determination that the challenged experts were not conflicted from participation on the TPSAC would best uphold Congress' intent with regard to FDA tobacco product regulation. There is no need for the FDA to limit the field of tobacco control experts who can serve on TPSAC to only those who have not been involved in a lawsuit. Quite the contrary, adopting such a policy would eliminate some of the most respected and well-qualified experts in tobacco control science and policy, the very type of expert whose experience and perspective would be most valuable to inform the agency's tobacco product regulation.

We urge the FDA to consider the uniqueness of tobacco product regulation in issuing its final guidance on appearance issues for advisory committee members. We reiterate that this comment is only intended to address the application of the FDA's guidance to TPSAC. Eliminating experts who have had "past involvement in a lawsuit related to the product(s) or issues before the committee or otherwise involving the sponsor" would be detrimental to the recruitment of qualified tobacco control experts.

Respectfully,



Joelle M. Lester
Lead Senior Staff Attorney



Desmond Jenson
Staff Attorney

² See, R.J. Reynolds Tobacco Co., v. U.S. Food and Drug Admin., 810 F.3d 827 (D.C. Cir. 2016).