PUBLIC HEALTH LAW CENTER
Tobacco Control Legal Consortium

March 17, 2017

Acting Commissioner Stephen Ostroff, MD
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: The Prohibition of Distributing Free Samples of Tobacco Products, Draft Guidance

Docket No. FDA-2017-D-0113

Dear Dr. Ostroff:

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Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the FDA's draft guidance, "The Prohibition of Distributing Free Samples of Tobacco Products." 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]

Since its establishment, the Consortium has worked with state and local public health entities and their partners as they implement innovative tobacco control policies that are now mainstays throughout the country. With the Family Smoking Prevention and Tobacco Control Act of 2009, state and local tobacco control stakeholders recognized the massive potential to reverse the death and disease caused by the only consumer product that, when used as intended, kills up to half of its users worldwide.[2] In the U.S., that amounts to more than 480,000 deaths each

[1] The Tobacco Control Legal Consortium's activities are coordinated by the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Public Health Policy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Public Health and Tobacco Policy Center, 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.

[2] WORLD HEALTH ORG. TECHNICAL REP. SERIES, THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REG. 3 (World Health Org. Press 2007), http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf.

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year.[3] Since then, state and local tobacco control stakeholders have sought to understand the scope and impact of the FDA's tobacco product authority—both to lend a strong public health voice in the federal regulatory process and to inform their own tobacco control policy goals. The Tobacco Control Legal Consortium helps to facilitate that understanding and engage the public health community when opportunities arise to participate in the FDA's regulatory process.

In our role as facilitators, we received a number of questions about the FDA's deeming rule after its release in May 2016. One common set of questions was the impact of the deeming provisions on the sampling of e-cigarettes and the interaction with state and local sampling restrictions.

The FDA's draft guidance, as written, is helpful to reinforce that the prohibition on distributing free samples applies to *all tobacco products* now subject to FDA's tobacco product authority, including components or parts not made or derived from tobacco, such as atomizers, clearomisers, and e-liquids. Making this clear is beneficial not only to regulated industry as they determine how to comply with the regulations, but also to state and local public health partners as they determine what gaps exist that they might want to further address under their own authorities and how their own enforcement efforts can complement or build on the FDA's enforcement of its regulations. Federal, state, and local restrictions working in concert are most likely to produce the greatest public health benefit.

The sale of tobacco products to consumers at less than full price does not violate the free sample prohibition

In sections D and E of the draft guidance, the FDA makes clear that tobacco products must be *sold* to consumers and that *monetary payment is required* for tobacco product sales. Additionally, on lines 285-288 of subsection E.3. of the draft guidance, the FDA reminds manufacturers, distributors, and retailers that while contests and games of chance generally are not prohibited under the FDA's regulation, *a variety of state and federal laws restrict* how contests and games of chance promotions may be held. This clarity is again beneficial to regulated industry and to state and local tobacco control partners who have prioritized limiting the availability of tobacco products in their community.

Our comments are limited to two issues we believe would help meet the stated intentions of the guidance: "to help tobacco product manufacturers, distributors, and retailers understand the prohibition of distributing free samples of tobacco

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[3] U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL, ch. 12 p. 659 (2014), http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html.

products set forth in Title 21, Code of Federal Regulations (CFR), Part 1140 and to explain what you should do in order to comply with the regulations."

1. **A number of states and local jurisdictions prohibit or restrict not only the free distribution of tobacco products, but also their low-cost distribution.**

When only the free distribution of samples is prohibited, communities have witnessed manufacturers, distributors, and retailers create workarounds by selling products at low cost. Instead of handing out or permitting the tasting of a free tobacco product, some nominal cost is "charged" to skirt the intent of the restriction. Thus, to address this problem of ease of access, many communities prohibit the free or low-cost distribution of tobacco products.[4]

2. **Some states and local jurisdictions prohibit or restrict the redemption of coupons and discounts for tobacco products.**

In subsection E.1. of the draft guidance, the FDA makes clear that its free sample prohibition does not address price discounting through coupons or other means. However, relying on evidence that low-cost tobacco products facilitate initiation,[5] some communities have prohibited or restricted the redemption of coupons and other value-added price discounts.[6]

The FDA's free sample prohibition does not prohibit manufacturers, distributors, and retailers from selling tobacco products at a discount through coupons or other price discounting strategies. However, a statement similar to the one found on lines 285-288 reminding regulated industry that other state and local laws may restrict such tactics would further the goals of helping the industry understand how their obligations under the FDA's regulations might differ from those under state and local law. Such a statement would also bolster the efforts of state and local tobacco control partners who, like the FDA, seek to improve the public's health.

We appreciate the FDA's recognition of other state and local laws restricting contests and games of chance that might affect the distribution of tobacco products. We also encourage the FDA to consider adding a similar statement about state and local laws that prohibit or restrict (1) the low-cost distribution of tobacco products

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[4] *E.g.*, MINN. STAT. §§ 325F.76-.78 (2016); NEB. REV. STAT. §§ 69-1901 to -1904 (2016); RICHMOND, CA., CODE §§ 9.58.010-.040 (2061); WIS. STAT. § 134.66 (2016).

[5] *See, e.g.* Tobacco Control Legal Consortium, *Death on a Discount: Regulating Tobacco Product Pricing* (2015), http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-death-on-discount-2015.pdf.

[6] *E.g.*, NEW YORK, NY ADMIN. CODE § 17-176.1; PROVIDENCE, RI CODE OF ORDINANCES § 14-303.

and (2) the acceptance of coupons or other price discounting mechanisms for tobacco products.

Respectfully,

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