



May 20, 2011

Via Electronic Mail

Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents (FDA Docket No. FDA-2010-D-0277).

Public Health Law & Policy (PHLP) and the Tobacco Control Legal Consortium are pleased to submit these comments on the FDA's "Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" ("Draft Guidance").

We urge you to amend the language in the Draft Guidance that states that cigars, little cigars and pipe tobacco are exempt from sampling restrictions under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The plain language of the Tobacco Control Act is clear that cigars, little cigars, pipe tobacco, and other "tobacco products" are included in the sampling restrictions. We believe the Draft Guidance's statement that they are exempt is contrary to the Tobacco Control Act and its intent, and would create a dangerous loophole in the strict sampling restrictions created by the Tobacco Control Act.

Public Health Law & Policy

PHLP is a nonprofit organization dedicated to creating healthy communities through policy and environmental change. PHLP works with community-based organizations, local public health and planning departments, schools, elected officials, and government attorneys, to help make healthy communities the norm, not the exception.

The Technical Assistance Legal Center, a project of PHLP, has worked with California tobacco control advocates for the past decade to create and strengthen policies to protect

the public—especially youth—from tobacco addiction and the effects of secondhand smoke. Through this work, we are familiar with the pernicious methods—such as tobacco sampling—that the tobacco industry employs to market its products and to initiate and maintain addictive behavior.

The Public Health Law Center

The Public Health Law Center at William Mitchell College of Law helps communities use the power of law to advance public health. The Tobacco Control Legal Consortium, a program of the Public Health Law Center, is a national network providing legal technical assistance on tobacco policy issues throughout the United States, including smoke-free regulation; tobacco product promotion, marketing, and sales restrictions; and taxation.

The Consortium serves as a consultant to the Centers for Disease Control and Prevention’s Office of Smoking and Health, and is the primary source of legal technical assistance to grantees under the new Communities Putting Prevention to Work Program with regard to their tobacco-related activities. The Consortium has prepared a wide range of materials and information, including materials about the Family Smoking Prevention and Tobacco Control Act and its implications for state and local tobacco control efforts.

1. The Exemption for Other Tobacco Products in the Draft Guidance is Contrary to the Plain Language of the Tobacco Control Act

a. Cigars, Little Cigars and Pipe Tobacco Meet the Definition of “Tobacco Product” That is Used in the Sampling Restriction

The plain language of the Tobacco Control Act clearly indicates that cigars, little cigars, pipe tobacco, and other “tobacco products” are included in the sampling prohibitions. Section 102 of the Tobacco Control Act created regulations that ban the distribution of “any free samples of cigarettes, smokeless tobacco, *or other tobacco products* (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act)” (emphasis added). This language is codified at 21 C.F.R. § 1140.16(d)(1).

“Tobacco products” are defined in the Food Drug and Cosmetic Act (as modified by section 101(a)(rr)(1) of the Tobacco Control Act) as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” Under this definition of “tobacco product,” cigars, little cigars, and pipe tobacco are clearly included: they are each products made from tobacco intended for human consumption. Therefore, the sampling of those products should be illegal under the Tobacco Control Act.

In spite of the Tobacco Control Act’s clear language, page 3 of the FDA’s Draft Guidance says that the Tobacco Control Act regulations—implicitly including the sampling regulations—“do not apply to cigars, little cigars or pipe tobacco.”

Additionally, the fact that the regulation promulgated under the Act bans the sampling of “other tobacco products” has been omitted from pages 2 and 23 of the Draft Guidance, where other restrictions of the Act are summarized. In these ways, the Draft Guidance is clearly incorrect about the regulation restricting free tobacco samples.

b. Principles of Statutory Construction Support the Conclusion that the Tobacco Control Act Bans the Sampling of Other Tobacco Products

It is noteworthy that the sampling provision is the only provision in the Tobacco Control Act that expressly includes “other tobacco products.” In statutory interpretation, there is a presumption that statutory wording in one law or part of a law that differs from the wording in another part of the law suggests a different statutory meaning. This is often referred to as the “presumption of meaningful variation.” As the U.S. Supreme Court has said, “where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Lopez v. Gonzalez*, 549 U.S. 47, 55 (2006) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).¹ Because section 102(a)(2)(G) of the Tobacco Control Act is the only provision that expressly applies to “other tobacco products,” the presumption of meaningful variation dictates that the FDA must conclude that this provision restricting sampling applies to cigars, little cigars, pipe tobacco, and other tobacco products—in addition to cigarettes and smokeless tobacco.

2. The Exemption of Other Tobacco Products in the Draft Guidance is Contrary to the Intent of the Tobacco Control Act

We believe the FDA’s exemption of these tobacco products in the Draft Guidance not only goes against the plain language of the Tobacco Control Act, but it is contrary to the intent of the Act. The provision of the Tobacco Control Act that restricts sampling permits free samples of one type of tobacco—smokeless tobacco—in limited circumstances. The Act allows for the sampling of smokeless tobacco, only when done in a qualified adult-only facility (QAF) that meets specific requirements, and even then, there are limits on the amount of tobacco that can be given out and the places where QAFs may be located. 21 C.F.R. § 1140.16(d)(2).

It is illogical that the regulation would prescribe such extreme limitations on the sampling of one type of tobacco but allow other types of tobacco popular among youth—such as little cigars—to be given away unfettered, with no requirement that the sampling take place in a tent where minors cannot see the sampling or that the age of the recipient be verified through an ID check. The regulation’s clear intent is to ban sampling of nearly all tobacco products and to place close limitations on the sampling that is allowed. The

¹ Though the presumption may be inapplicable when there is a reasonable explanation for variation (e.g., different provisions are enacted at different times), that is not the case here with the sampling restriction, the text of which was included in the Tobacco Control Act. See *Lawrence v. Florida*, 549 U.S. 327, 334 (2007).

FDA's Draft Guidance frustrates that intent by exempting whole categories of tobacco products.

3. The Tobacco Industry is Exploiting the Draft Guidance Document

The disparity between the language of the Tobacco Control Act and the Draft Guidance has given the tobacco industry a new way to challenge tobacco control efforts. One recent example occurred in Long Beach, California, where the local Health Department was recently confronted with a tobacco industry representative who wanted to give out free samples of little cigars at the Long Beach Grand Prix. A representative of Swisher International requested permission to operate a booth at the Grand Prix, a yearly event that draws many families, in order to give out free samples of little cigars. The Long Beach Health Department initially refused the request based on its belief that the sampling of cigarettes, smokeless tobacco, and other tobacco products was restricted under the Tobacco Control Act. The Swisher representative showed the Health Department a copy of the Draft Guidance, and pointed out that it specifically states that little cigars are not covered. Although the Health Department believed that the Draft Guidance contravened the Tobacco Control Act's prohibition on cigar sampling, the Health Department felt it had no choice but to allow the Swisher booth to offer free little cigar samples at a family event where children would be present. It is exactly this type of sampling that the Tobacco Control Act was trying to ban when it specifically included "other tobacco products" in the regulation restricting sampling.

4. The Exemption of Cigars, Little Cigars, and Pipe Tobacco in the Draft Guidance Would Create a Dangerous Loophole in the Strict Sampling Restrictions That the Tobacco Control Act Created

There is overwhelming evidence that tobacco companies distribute free samples for the purpose of luring young adult tobacco users. After the 1998 Master Settlement Agreement (MSA) between major tobacco companies and most states, tobacco companies were prohibited from explicitly targeting minors.² The tobacco industry responded by focusing efforts on 18 to 24 year olds—the youngest group of legal smokers.³ Studies have shown that this focus was part of a marketing strategy designed to initiate young tobacco users through the distribution of free samples to college students and the sponsorship of events at college bars, music events, and fraternities.⁴

² Settling States and Participating Manufacturers, *Master Settlement Agreement* (2008). Available at: www.naag.org/backpages/naag/tobacco/msa/msa-pdf/MSA%20with%20Sig%20Pages%20and%20Exhibits.pdf/file_view.

³ U.S. v. Philip Morris USA Inc., 449 F. Supp. 2d 1, 561, 861 (D.D.C. 2006); Campaign for Tobacco-Free Kids. *Tobacco Company Marketing to College Students Since the Multistate Settlement Agreement was Signed* (2001).

⁴ Campaign for Tobacco-Free Kids. *Tobacco Company Marketing to College Students Since the Multistate Settlement Agreement was Signed* (2001); Sepe E, Ling P and Glantz S. "Smooth Moves: Bar and Nightclub Tobacco Promotions that Target Young Adults." *American Journal of Public Health*, 92(3): 414-419 (2002).

Tobacco industry documents confirm that the distribution of free tobacco samples is critical to recruiting new users and demonstrate that bar promotions are highly effective at increasing sales due in part to resulting brand switching, smoking uptake, or relapse by former smokers.⁵ For example, a US Smokeless Tobacco Company document stated:

“The most important aspect of our marketing strategy is getting new users to try our products. The most effective means of familiarizing new users with our products is through continuous controlled sampling at special events, as well as through daily sampling in and around retail accounts. This type of marketing philosophy, based upon sampling, will undoubtedly insure [sic] U.S. Tobacco’s continued dominance of the smokeless industry.”⁶

Tobacco companies are clearly targeting young adults, if not minors, with free samples and this marketing strategy has created more demand for their products. This information is even more concerning in light of the fact that tobacco manufacturers have implemented aggressive campaigns to expand sales of cigars and little cigars in response to increasing regulation.

Between 1997 and 2007, the sale of little cigars—which are very similar to cigarettes in shape, size, and packaging, and are also offered in candy flavors attractive to youth—has increased by 240%.⁷ A study which reviewed tobacco industry documents found that little cigars were intended to replace cigarettes because cigarette advertising became increasingly restricted, and taxes on cigarettes, but not cigars, continued to increase.⁸ The study went on to state that “RJ Reynolds engaged in a calculated effort to blur the line between cigarettes and little cigars with Winchester, a little cigar designed for cigarette smokers that was as close to cigarettes as legally possible.”⁹ The marketing of these products is clearly a calculated effort to lure young users.

The fact that little cigars can be distributed for free at public events, including events where children are present, is a dangerous loophole in the sampling provisions created by the Tobacco Control Act. This loophole will lead to negative public health consequences for communities throughout the country.

Conclusion

⁵ Katz S and Lavack A. “Tobacco Related Bar Promotions: Insights from Tobacco Industry Documents.” *Tobacco Control*, 11: i92-i101 (2002).

⁶ U.S. Tobacco Intra-Company Correspondence from R.M. Glasscox, Vice President-Sales to all field personnel, October 11, 1984. USST 1984 Sampling fundamentals guide tid:muv11b00. Legacy Tobacco Documents Library at UCSF, <http://www.library.ucsf.edu/tobacco>. In: Ling P, Center for Tobacco Control Research and Education, Division of General Internal Medicine, University of California San Francisco. “Why Sampling is Important to Tobacco Companies” (Powerpoint presentation). Project SMART Money TA call, July 1, 2009.

⁷ American Legacy Foundation. “Cigars, Cigarillos & Little Cigars Fact Sheet.” (June 2009).

⁸ Delnevo CD, Hrywna M. “A Whole ‘Nother Smoke’ or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars.” *Am J Public Health*, 97: 1368–1375 (2007).

⁹ *Id.*

We hope that the FDA will soon exercise its broad authority to regulate the sale, advertising and marketing of cigars, little cigars, and pipe tobacco, as it is entitled to do under the Tobacco Control Act. In the meantime, it is imperative that the FDA implement the law and the regulations as they now stand and enforce the limitations on the sampling of all tobacco products including the prohibition on free samples of cigars, little cigars, and pipe tobacco.

Thank you for the opportunity to comment. If you have any questions, please feel free to contact us through the information provided below.

Sincerely,



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