



City and County of San Francisco
Edwin M. Lee
Mayor

San Francisco Department of Public Health

Barbara A. Garcia, MPA
Director of Health

August 5, 2014

The Honorable Margaret Hamburg, Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act
Docket No. FDA-2014-N-0189, RIN 0970-AG38

Dear Commissioner Hamburg,

On behalf of the San Francisco Department of Public Health I am writing to provide comments on the proposed rule "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act." The City and County of San Francisco has long recognized the need to tackle tobacco addiction head-on, leading the country in some of the earliest and strongest regulations of the use, sale, and marketing of tobacco products in our community. Even with our investment in our proven community-engagement policy development model and ongoing innovative educational and quitting programs, we continue to see the substantial impact of the tobacco industry negatively affecting the health of San Franciscans.

San Francisco Department of Public Health applauds the Food and Drug Administration (FDA) for proposing this rule to identify additional products to be deemed as tobacco and subject to the requirements of the Family Smoking Prevention and Tobacco Control Act. Many cities and counties across the country such as San Francisco have passed our own legislation regulating these products in order to protect their communities. Federal regulation is absolutely needed to unite efforts already begun at the local level, provide a uniform set of standards and take action where local jurisdictions are prohibited from doing so. We can only take the regulation so far at the local level, and there are considerable gaps in our system that only FDA action is empowered to resolve.

In response to the proposed rule, San Francisco Department of Public Health offers the following comments and recommendations.

1. Cigar regulation option

San Francisco Department of Public Health recommends use of Option 1 regarding cigar deeming, to include all types of cigars. Our agency does not recommend Option 2, which excludes premium cigars from the proposed rule, defeating the intention of regulating various cigar products equally under the law. This is important, as producers have skirted the intention of various laws by claiming their youth-marketed products are technically cigars. We need a consistent application of the law around cigars. Both premium and non-premium cigars contain cancer causing chemicals that increase the smoker and non-smoker risk for lung disease, chronic bronchitis, and oral cavity, larynx, esophagus, pancreas, bladder, and lung cancers.^{1,2} Both types of cigars

negatively affect the public's health. The differences between these cigar types speak to the ingredients and price, but not to their effects on health. Thus, if the FDA's intent for this proposed rule is to take action to address the public health risk associated with the use of tobacco products, premium cigars should not receive an exemption. Exempting premium cigars may set back the FDA's work to reduce tobacco use and disease risk in the United States.

Cigar use is popular among youth. The Centers for Disease Control and Prevention (CDC) reported that cigarette and cigar use in high school students was nearly identical in 2012. This similarity is also seen in middle schools students who smoked cigarettes and cigars.³ When youth are faced with premium cigars and cigarettes of the same price, premium cigars may be the product of choice because premium cigars are not subject to accessibility restrictions as promulgated for cigarettes. For example, cigars can be sold in self-service displays and sold individually.

2. Flavored products

San Francisco Department of Public Health urges the FDA to apply the same flavor restrictions promulgated by the Tobacco Control Act on cigarettes to newly-deemed tobacco products. As flavors such as cherry, vanilla, and apple contribute to the increasing popularity of e-cigarettes, hookah, and cigars among youth, regulation is critical for the same reasons the FDA restricted flavor options for cigarettes. The FDA's *Parental Advisory on Flavored Tobacco Products* states that flavored tobacco products:⁴

- Appeal to kids.
- Disguise the bad taste of tobacco, easing adoption by youth.
- Are just as addictive as regular tobacco products.
- Have the same harmful health effects as regular tobacco products.

Local and state health departments have already taken the initiative to regulate the sale of non-regulated flavored tobacco products in their jurisdictions. Maine banned the sale and distribution of flavored cigarettes and cigars in the state in 2009.⁵ In 2011, New York City banned the sale of flavored tobacco products.⁶ Providence (RI) banned sale of flavored tobacco products and redemption of tobacco industry coupons and discounts in 2013.⁷ In 2014, Chicago banned the sale of all flavored tobacco products, including e-cigarettes (regulated as tobacco products), within a 500-foot radius of any elementary, middle, or secondary school.⁸ Our community continues to examine options for addressing how the harsh flavors of cigarettes can be masked by candy and sweet flavorings. Prior generations became addicted to cigarettes in large numbers despite the harsh taste and difficulty initiating the smoking habit. With cherry and cotton candy and vanilla starter products now, the current generation of youth face fewer barriers to initiation of nicotine addiction and are more targeted by the industry than ever before.

3. Regulation of the new noncombustible products

San Francisco Department of Public Health urges FDA to regulate the newly-deemed tobacco products, including e-cigarettes, dissolvables, hookah, and cigars, in the same manner as existing tobacco products. Federal regulation offers an opportunity to more fully assess the public health risks of these products, which have grown in popularity since the passage of the Tobacco Control Act. There are currently no federal consumer protections in place to ensure that e-cigarettes are properly labeled and tested. FDA and other independent scientists have found numerous potentially dangerous chemicals and carcinogens as well as varying levels of nicotine that are inconsistent with the amount indicated on the labels of e-cigarette solutions. For example, a recent study of e-cigarette refill fluids found that the majority (65%) of nicotine fluids tested deviated by more than ten percent from the nicotine concentrations on the label.⁹ Furthermore, because e-cigarettes are unregulated, there is a lack of credible information on the full range of chemicals being produced by the large number of different e-cigarettes currently on the market. The same flavoring, marketing, and self-service access rules should apply to newly-deemed products because they also pose risk to the public and can spur initiation or joint use of multiple tobacco products.

CDC reported that e-cigarette use more than doubled among U.S. middle and high school students between 2011-2012. There is evidence that e-cigarettes help youth to initiate smoking habits – only 20% of middle school e-cigarette users reported never having smoked conventional cigarettes.¹⁰ Youth are also impressionable and can succumb to marketing ploys such as the numerous fruity and candy flavored e-cigarettes and to youth-oriented company advertising.

It is these startling facts about youth use of e-cigarettes and alternative products that caused San Francisco to join Los Angeles, Chicago, Philadelphia, and New York early this year in regulating e-cigarettes locally. We recognized that these products pose a threat to the public health and are clearly serving as starter products for young people in our community. Without regulation of advertising, content of the product, claims made by the industry, and flavors available, the proliferation of this product will likely continue exponentially. Surveys of local youth and adults show that the industry has created a great deal of confusion about these products and the general public repeats back the unsubstantiated claims made by e-cigarette marketers- eerily similar to claims made by the tobacco industry a generation earlier.

San Francisco Department of Public Health calls on the FDA to restrict the flavor offerings as in cigarettes for the same reasons that the agency restricted cigarette flavor offerings. Current e-cigarette advertisements target youth with marketing strategies such as celebrity endorsements, and messaging that promote freedom, rebelliousness, and glamour with e-cigarette use. The FDA should also restrict new product advertising in the same way that cigarette and smokeless tobacco advertising is restricted.

4. New product warnings

Product warning labels are incredibly useful tools in FDA's effort to protect public health. However, the proposed warning labels for newly covered tobacco products can be strengthened to be more effective.

Since the first warning labels appeared on cigarette packages in 1965, warning labels have been an important source of information for tobacco users.¹¹ While there is evidence that warning labels can become stale,¹² and the need for large graphic warning labels is clear,^{13,14,15} the newly covered products will be marketed with minimal warning. This may contribute to confusion about the health effects of the newly covered products. The proposed textual warnings for cigars are fairly strong, but the single warning for the remaining products is weak and does not convey the potential extent of health risk associated with use of the products. The FDA should require large graphic warnings for all tobacco products, similar to those required for combustible cigarettes. There is significant evidence of the specific health harms of the new products and those caused by nicotine that support stronger, more specific warnings in the "2014 U.S. Surgeon General's Report: The Health Consequences of Smoking—50 Years of Progress." The City of San Francisco cannot introduce a mandate for packaging with striking graphic images that tells consumers the truth about the health impacts of tobacco (similar to those required in nearly every country in the world), but we very much support the move by FDA to require those warnings.

5. Additional opportunities

The proposed rule presents an opportunity to require child-resistant packaging for e-cigarette liquids to prevent child poisonings. Currently, e-cigarette liquid refill containers are not required to be sold in child-resistant packaging and that may encourage children to ingest the product's poisonous content.¹⁶ Some e-cigarette refill product packaging features cartoons, colorful labeling, or illustrates edible ingredients representing particular flavors, such as cherry, chocolate, or bubble gum. The contents themselves can have the aroma of the edible ingredient pictured on the label.¹⁷ Any of these factors can prompt a child to investigate and the contents can be extremely dangerous, if not lethal.

CDC analyzed calls to U.S. Poison Centers from 2010 to 2014 related to e-cigarette exposures. The results showed that e-cigarettes accounted for an increasing proportion of the calls, 0.3% in September 2010 to 41.7% in February 2014.¹⁸ Half of the calls made regarding exposure were for incidents involving children ages 0-5.¹⁸ The prevalence of poisonings and the potential danger to children promoted the American Association of Poison Control Centers and its member centers to issue a statement warning e-cigarette users to keep the devices and

liquids away from children.¹⁹ One teaspoon (5 ml) of a 1.8% nicotine solution can be lethal for a person weighing 200 pounds.¹⁶ Most nicotine solutions range between 1.8% and 2.4%, and the refill bottles contain 10-30 ml of solution.²⁰ Due to the dramatic increase in calls to poison control centers, some states have taken precautions through new regulations. Minnesota and Vermont created statutes that require child protective packaging on all liquid nicotine refill bottles, and some retailers have voluntarily begun selling their refills with child-resistant caps.²⁰ While those who oppose such requirements note there have been no confirmed poisoning deaths in the United States due to the ingestion of liquid nicotine, the FDA must not wait for tragic consequences before acting.

San Francisco Department of Public Health is pleased to support the deeming of additional products as tobacco as proposed in the rule and urges FDA to do the following: include premium cigars in cigar regulations; apply the same requirements of the Family Smoking Prevention and Tobacco Control Act for combustible cigarettes to all of the newly deemed products regarding flavors, marketing, and self-service access; strengthen the content and requirements for the warning labels on newly deemed products; and create a requirement for child-resistant packaging for e-cigarette liquids. Thank you for your attention to these recommendations.

Sincerely,



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¹ National Cancer Institute. (2010). Fact sheet: Cigar smoking and cancer. Retrieved Jul. 16, 2014, from <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars>.

² American Cancer Society. (2014). Cigar smoking: Tobacco and cancer. Retrieved Jul. 16, 2014, from <http://www.cancer.org/cancer/cancercauses/tobaccocancer/cigarsmoking/cigar-smoking-cancer-and-health>.

³ Centers for Disease Control and Prevention. Youth and tobacco use webpage. Retrieved Jul. 22, 2014, from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm.

⁴ U.S. Food and Drug Administration. (2013). FDA parental advisory on flavored tobacco products - what you need to know. Retrieved Jul. 22, 2014, from <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183196.htm>.

⁵ State of Maine. (2007, September 25). News: Governor celebrates ban on flavored cigarettes. Retrieved Jul. 16, 2014, from <http://www.maine.gov/tools/whatsnew/index.php?topic=Portal+News&id=42524&v=article-2006>.

⁶ New York City Department of Health and Mental Hygiene. Smoking legislation webpage. Retrieved Jul. 22, 2014, from <http://www.nyc.gov/html/doh/html/environmental/smoke-law.shtml>.

⁷ City of Providence, Rhode Island. (2013). Providence tobacco laws go into effect January 3. Retrieved Jul. 16, 2014, from <http://www.providenceri.com/healthy-communities/providence-tobacco-laws-go-into-effect-january-3>.

⁸ City of Chicago. Tobacco regulations webpage. Retrieved Jul. 16, 2014, from http://www.cityofchicago.org/city/en/depts/bacp/supp_info/tobaccoregulations.html.

⁹ Davis, B., Dang, M., Kim, J., Talbot, P. (2014, May 26). Nicotine concentrations in electronic cigarette refill and do-it-yourself fluids. *Nicotine & Tobacco Research* (published online). doi: 10.1093/ntr/ntu080.

¹⁰ Centers for Disease Control and Prevention. (2013, September 6). Notes from the field: Electronic cigarette use among middle and high school students – United States, 2011-2012. *MMWR*, 62(35), 729-730. Retrieved on Jul. 7, 2014, from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>.

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- ¹¹ U.S. Department of Health and Human Services. (2000). *Reducing tobacco use: A report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- ¹² Institute of Medicine (U.S.). Committee on Reducing Tobacco Use: Strategies, Barriers, and Consequences. (2007). *Ending the tobacco problem: A blueprint for the nation*. R. J. Bonnie, K. Stratton, R. B. Wallace (Eds.) Washington, DC: National Academies Press.
- ¹³ Azagba, S., & Sharaf M.F. (2013). The effect of graphic cigarette warning labels on smoking behavior: Evidence from the Canadian experience. *Nicotine & Tobacco Research*, *15*(3), 708-17. doi: 10.1093/ntr/nts194.
- ¹⁴ Cantrell, J., Vallone, D. F., Thrasher, J. F., Nagler, R. H., Feirman, S. P., Muenz, L. R., et al. (2013). Impact of tobacco-related health warning labels across socioeconomic, race and ethnic groups: Results from a randomized web-based experiment. *PLoS One*, *8*(1), e52206. doi: 10.1371/journal.pone.0052206.
- ¹⁵ Strasser, A. A., Tang, K. Z., Romer, D., Jepson, C., & Cappella, J. N. (2012). Graphic warning labels in cigarette advertisements: Recall and viewing patterns. *American Journal of Preventive Medicine*, *43*(1), 41-7. doi: 10.106/j.ameprev.2012.02.026.
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- ¹⁹ American Association of Poison Control Centers. (2014, March 25). News Release: AAPCC and Poison Centers issue warning about electronic cigarette devices and liquid nicotine. Retrieved Jul. 7, 2014, from https://aapcc.s3.amazonaws.com/pdfs/releases/E-cigarette_Release.pdf.
- ²⁰ Richtel, R. (2014, March 23). Selling a poison by the barrel: Liquid nicotine for e-cigarettes. *The New York Times*. Retrieved Jul. 4, 2014, from <http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?module=Search&mabReward=relbias%3Aw>.