



August 8, 2014

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Docket No. FDA-2014-N-0189)

Dear Commissioner Hamburg:

The Society for Public Health Education (SOPHE) is a 501 (c)(3) professional organization founded in 1950 to provide global leadership to the profession of health education and health promotion. SOPHE contributes to the health of all people and the elimination of health disparities through advances in health education theory and research; excellence in professional preparation and practice; and advocacy for public policies conducive to health. SOPHE is the only independent professional organization devoted exclusively to health education and health promotion. Members include behavioral scientists, faculty, practitioners, and students engaged in disease prevention and health promotion in both the public and private sectors. Collectively, SOPHE's 4,000 national and chapter members work in universities, medical/health care settings, businesses, voluntary health agencies, international organizations, and all branches of federal/state/local government.

SOPHE has a vested interest in changing systems to support smoke-free policies and smoking cessation and welcomes the opportunity to comment on Deeming Tobacco Products proposed rule. FDA takes some important steps in this proposed rule to regulate e-cigarettes, cigars, dissolvable nicotine products and hookah. But there are critical gaps in the proposal that must be addressed in the final rule.

Comments on Proposed Rule

First, **FDA should not exempt any cigars from regulation.** Cigars are not just smoked by adults – kids smoke them too. Declines in cigar smoking among young people appear to have stalled since 2005 and in 2011, more than 1.2 billion cigar units (i.e., single cigars, or packs of two or more) were sold in U.S. convenience stores.¹ Tobacco companies now use candy flavors

¹ Cigar Smoking Among U.S. Students. Corey, Catherine G. et al. American Journal of Preventive Medicine, Volume 47, Issue 2, S28 - S35. Available at: <http://www.sciencedirect.com/science/article/pii/S0749379714001950>.

in their cigars such as cherry, grape, peach and chocolate. These candy-flavored products come in the same sizes, shapes and colors as other youth-oriented products like candy and lip balm. High school boys now smoke cigars at the same rate as cigarettes (16.5 percent for cigars and 16.4 percent for cigarettes), and more male high school seniors smoke cigars than smoke cigarettes, according to the latest National Youth Tobacco Survey. The survey also found that prevalence of cigar use was greater among non-Hispanic blacks and Hispanics than non-Hispanic whites.

FDA should regulate all cigars and not try to exempt so-called premium cigars. According to the FDA's proposed rule, "all cigars are harmful and potentially addictive" and "a large cigar may contain as much tobacco as a whole pack of cigarettes." Exempting any category of tobacco product creates a dangerous loophole that the tobacco industry can exploit to create and market products that appeal to kids.

Second, while FDA sets a national age of 18 for purchase of tobacco, there are additional steps FDA must take to protect kids. **Prohibiting self-service displays would help keep tobacco products out of the hands of kids by requiring customers to ask a sales clerk for assistance.** These rules currently apply to cigarettes and smokeless tobacco, which is why they are typically located behind the counter, and they should apply to cigars and e-cigarettes. Without a prohibition on self-service displays, these products are often placed next to candy in stores. The new colorful packaging makes them look like candy making them even more attractive and accessible to kids.

Third, **FDA should restrict e-cigarette marketing and flavors that appeal to kids.** The percentage of middle and high school students who reported ever using e-cigarettes doubled from 2011 to 2012, according to the CDC.² The growing use of e-cigarettes among youth is of particular concern to the public health community considering there is no research on the long-term health impacts. E-cigarettes contain nicotine, and while the aerosol from e-cigarettes is different than secondhand smoke, it remains a clean air issue. The aerosol contains metals (tin, chromium and nickel) and at least ten chemicals identified on California's Proposition list of carcinogens and reproductive toxins.³ Additionally, poison center calls related to e-cigarettes has surged in the past four years. More than half of these calls involved children ages five and younger.⁴ As with cigarettes, warning labels should be attached indicating possible risks.

There is widespread support to restrict the sale of e-cigarettes to adults only given the high degree of unknown factors or sufficient research surrounding the effects of first and second hand vapor emissions. Despite claims from leading e-cigarette companies that they only market to adults, they are using the same tactics that have long been used to market regular cigarettes to kids – including celebrities and cartoon characters to pitch products, sponsorships of race cars and music festivals, and ads that portray e-cigarettes as glamorous and rebellious. E-cigarettes

² Centers for Disease Control and Prevention. Tobacco product use among middle and high school students – United States, 2011 and 2012. *MMWR Morb Mortal Wkly Rep.* Nov 15 2013;62(45):893-897.

³ Americans For Nonsmokers' Rights, Electronic (e-) Cigarettes and Secondhand Aerosol. Available at: http://www.ctri.wisc.edu/HC.Providers/ecigs_aerosol.pdf.

⁴ Center for Disease Control and Prevention, Morbidity and Weekly Report (MMWR) *Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014*, available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm>.

are also being sold in a wide-variety of kid-friendly flavors, including sweet tart, cotton candy and gummy bear.

Finally, **FDA must move quickly to finish this rule by April of next year.** Too many critical timelines such as those for warning labels are tied to when this rule is final. We cannot afford to wait years for changes in the marketplace and to have FDA regulate cigars, e-cigarettes, and other tobacco products.

The Role of Health Education to Influence Tobacco Cessation

The proposed rule acknowledges that many consumers, especially young adults, have mistaken perceptions about the adverse health effects of cigarettes, smokeless tobacco, cigars, and hookah tobacco. The rule also acknowledges, “studies have observed at least some correlation between the enforcement of youth access restrictions and reduced tobacco product use among youth when enforcement is coupled with educational campaigns.” SOPHE applauds the FDA for its plans to continue to conduct various types of public education regarding tobacco products. **SOPHE encourages the FDA to employ Health Education Specialists when developing and implementing health education campaigns.**

Health Education Specialists work to encourage healthy lifestyles and wellness through educating individuals and communities about behaviors that can prevent diseases, injuries, and other health problems. Although many professionals may possess the requisite skills to conduct education campaigns, Health Education Specialists are equipped to provide the necessary education to more vulnerable populations. A core competency of Health Education Specialists is communicating with and understanding the needs of the underserved, vulnerable and/or limited English-speaking populations, including those who are disabled and suffer from one or more chronic diseases. Health education specialists also supervise community health workers, i.e. trusted members of the community served, who can facilitate access to priority populations, and improve the cultural competence of the education or service delivery. Given the wide range of populations with which they work and the diverse settings in which they are employed, health education specialists have significant capacity to conduct education about the harms of tobacco products. Their skills in health communications, cultural competency, community engagement, community needs assessment, health coaching, and inter-disciplinary collaboration make them natural leaders in FDA’s quest for healthier America.

Thank you for consideration of our comments. Tobacco use is the number one cause of preventable death in the United States and SOPHE looks forward to working with the FDA on education programs that convey the necessary health education to allow people to make the necessary changes in behavior will reduce tobacco use among youth and adults. Please contact Jerrica Mathis at (jmathis@sophe.org) or 202-408-9804 with any additional questions.

Sincerely,



Elaine Auld, MPH, MCHES
Chief Executive Officer