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August 4, 2014

Mitchell Zeller, JD

Director, Center for Tobacco Products  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Docket No. FDA-2014-N-0189, Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.

Dear Director Zeller,

On behalf of the Prevent Cancer Foundation, the only national nonprofit in the United States dedicated solely to cancer prevention and early detection, we appreciate this opportunity to submit comments regarding the proposed rule FDA-2014-N-0189. This rule is critical in the protection of the health of the American public as outlined by the 2009 *Family Smoking Prevention and Tobacco Control Act*. It is important that this rule be finalized within a twelve month period and implemented efficiently within the 24 month compliance period, without exception or delay.

We commend the U.S. Food and Drug Administration (FDA) for taking this important step to regulate e-cigarettes, cigars, little cigars, hookahs, pipe tobacco and other tobacco products. We are pleased that the proposed rule would give the FDA basic oversight authority over these products and require manufacturers to register with the FDA; disclose product ingredients to the agency; and prohibit tobacco companies from making health claims without FDA review. Additionally, it is critical that tobacco products be strictly available only to adults over the age of 18.

The products outlined in the proposed rule should be subject to deeming as outlined in the Federal Food, Drug and Cosmetic Act (FD&C Act). The FDA must move forward with this rule in order to be equipped with the necessary tools to regulate such tobacco products and reduce the threat to public health. The FD&C Act defines the term "tobacco product", in part, as any product "made or derived from tobacco" that is not a "drug," "device" or combination

product and has thus far only been applied to regulate cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco.

### *E-Cigarettes*

E-cigarettes have proliferated in recent years. With over 250 brands on the market and an industry valued at \$2.5 billion, it is vital that these products, including their components, be regulated by the FDA. Not only do they contain nicotine at drastically varying levels (between 1.8 and 10 percent<sup>i</sup>) but studies have shown that e-cigarette samples contain carcinogens and toxic chemicals. The chemicals and their quantities/concentrations utilized in e-cigarettes cartridges must be documented and consistent.

As noted in the proposed rule, adolescence is the peak time for tobacco product use initiation and experimentation. The Centers for Disease Control and Prevention (CDC) found that the use of e-cigarettes between 2010 and 2011 more than doubled for middle and high school students<sup>ii</sup>. According to the Surgeon General, adolescents are particularly vulnerable to the adverse effects of nicotine and adolescent exposure may have lasting adverse consequences for brain development. According to a study in the Journal of the American Academy of Pediatrics (2008), nicotine metabolism plays a significant role in addiction among adolescents. The study, which used “light adolescent smokers” as subjects, found that the faster an individual is able to metabolize nicotine, the quicker that person develops an addiction. Because a quick metabolism leads to a “rapid decline in blood and brain nicotine concentrations after smoking a cigarette,” those with fast metabolisms experience severe withdrawal symptoms and are thus led to smoke more often, developing a greater addiction<sup>iii</sup>.

Additionally, a study which appeared in the medical journal JAMA Pediatrics, notes that the “use of e-cigarettes does not discourage, and may encourage, conventional cigarette use among U.S. adolescents<sup>iv</sup>.” Characterizing flavors such as fruit and candy (gummy bear, sweet tart, cola, chocolate, etc.) are dangerously appealing to minors and studies have shown that younger smokers are more likely to use flavored products. Currently, there is a statutory prohibition against characterizing flavors only in traditional cigarettes. There should be a complementary prohibition of characterizing flavors in e-cigarettes.

Further, e-cigarettes are widely available online and in outlets such as mall kiosks and vending machines. This widespread availability exposes children to e-cigarettes on a regular basis and puts them at risk of utilizing the products at a young age. As nicotine is especially addictive to adolescents, the Prevent Cancer Foundation supports regulation that will decrease the appeal and availability of e-cigarettes to those who are under the age of 18. Vending machines should be completely banned unless they are located in a facility in which individuals under the age of 18 are not permitted.

Finally, uncontrolled quantities of nicotine along with the lack of child-proof packaging on e-cigarettes and components are a serious threat to safety, particularly for children. As such, the

FDA should expediently issue a proposed rule requiring child-proof packaging for these products.

### ***Cigars***

All types of cigars are harmful and potentially addictive and should therefore be subject to deeming. The amount of nicotine found in the majority of full size cigars is the same or greater than in cigarettes. For instance, while a cigarette typically has approximately 8 mg of nicotine, there are several brands of full size cigars that have about 100 to 200 mg of nicotine, and some full size cigars have over 400 mg of nicotine. According to the National Cancer Institute (NCI), “some premium cigars contain the tobacco equivalent of an entire pack of cigarettes<sup>v</sup>.”

Additionally, cigars pose a substantial threat to those who inhale. People who inhale cigar smoke are “seven times more likely to die from tongue, mouth, and/or throat (oral) cancer, 39 times more likely to die from cancer of the larynx, face about 3 times the risk of death from cancer of the pancreas, and face about 4 times the risk of death from bladder cancer<sup>vi</sup>.” As such, the Prevent Cancer Foundation supports option 1 as outlined in the proposed regulation which would extend FDA’s authority to all products meeting the definition of “tobacco product” except the accessories of such products. The FDA would not restrict the categories of cigars that fall under the umbrella of deeming. This includes but is not limited to small cigars, cigarillos, large cigars, and premium cigars. There should be no subset of cigars for purposes of FDA regulation.

Finally, as noted above in the instance of e-cigarettes, characterizing flavors are dangerously appealing to underage consumers and should therefore be banned in all types of cigars as well.

### ***Sales and Marketing***

Marketing of all tobacco (and deemed) products should be regulated by the FDA. According to a study by the CDC, marketing has a profound influence on the purchase of tobacco products. In 2012, the three most heavily advertised cigarette brands were the most purchased, accounting for nearly 60 percent of sales in the tobacco market<sup>vii</sup>. Additionally, adolescents are most vulnerable to marketing, as “more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.” The Family Smoking Prevention and Tobacco Control Act of 2009 extended FDA regulations to make it “unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission” and declared that advertising could be “text only<sup>viii</sup>.” The Prevent Cancer Foundation supports extending these regulations to cover the marketing of all tobacco (and deemed) products including all types of cigars and e-cigarettes as well. It is also a dangerous practice to allow manufacturers of newly deemed products to use cartoon characters, celebrities, etc. to advertise their products. The advertising restrictions on cigarettes and smokeless tobacco products should also apply to newly deemed products.

Additionally, sales of tobacco-containing products must be strictly limited to adults over the age of 18 through age verification measures. This is particularly important through online outlets;

however, it is recommended that internet sales of tobacco (and deemed) products be banned completely.

The FDA should also prohibit self-service displays of tobacco products, particularly in establishments which cater to children and families, such as retail stores. Colorful displays which feature nicotine products, particularly those with characterizing flavors and within eye-level of children, are unacceptable.

Further, there should be an FDA regulation regarding minimum pack size. Many non-cigarette tobacco products are sold in single “doses” and data show that cigars and cigarillos are most popular among minors. As a result, there have been increased marketing efforts put behind such products<sup>ix</sup>.

Finally tobacco companies’ sponsorship of athletic and musical events that could be widely attended by minors should be banned, including (on free giveaway items) sampling at festivals, events, shows, and concerts, etc.

#### ***Public Education and Warnings***

The FDA should educate the public immediately regarding all nicotine-containing tobacco products through the use of mandated health warnings for e-cigarettes and Federal Trade Commission warnings (in addition to the nicotine warnings) for all cigars. There is already a considerable amount of confusion and misinformation regarding e-cigarettes in particular, including that they are a safe alternative to traditional tobacco cigarettes. Consumers deserve scientifically-sound information and evidence to support their choice whether or not to utilize tobacco products. In addition to the dearth of evidence regarding e-cigarettes helping smokers of traditional cigarettes quit, we are concerned that e-cigarettes may entice individuals, particularly young users, to eventually consume additional tobacco products.

Further, appropriate and specific health warnings must be included on all tobacco products including a requirement to carry an addiction warning appropriate to the type of product. Such warnings should include language that the product contains nicotine, which is a highly addictive substance derived from tobacco.

#### ***Premarket Review of New Products***

Although the *Family Smoking Prevention and Tobacco Control Act* prohibits the introduction of new tobacco products unless the FDA determines, prior to their marketing, that their introduction would be “appropriate for the protection of the public health,” there is an alternate pathway for products that are “substantially equivalent” to already existing products<sup>x</sup>. The FDA is proposing to suspend enforcement of the premarket review provisions until two years after issuance of the final deeming rule. Therefore, existing deemed products will be permitted to stay on the market and manufacturers will be able to introduce newly deemed products until two years following the final rule. New product applications or substantial equivalence applications also have the

potential to follow the same path as their previous counterparts, existing on the market until the FDA denies the application.

As such, the provisions of the proposed deeming rule on new products and substantial equivalence should be stricter. All applications must be processed without delay (within six months) in order to prevent the potential harm from unregulated tobacco products. Tobacco-containing products cannot remain on the market without approval for extended periods of time.

Again, we appreciate the opportunity to comment. The issues outlined in the proposed rule must be addressed in order to protect the public safety and reduce the risk of cancer in the United States. Please contact us for further information or if we can serve as a resource. I can be reached at Carolyn.Aldige@preventcancer.org or 703.519.2114.

Sincerely,

*Carolyn Aldigé*

Carolyn Aldigé  
President and Founder

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<sup>i</sup> Richtel, M. (2014). Selling a poison by the barrel: Liquid nicotine for e-cigarettes. *New York Times*. Retrieved from <http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html>

<sup>ii</sup> Centers for Disease Control and Prevention. (2013). *E-cigarette use more than doubles among U.S. middle and high school students from 2011-2012*. Retrieved from <http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>.

<sup>iii</sup> Rubenstein, M.L., Benowitz, M.L., Auerback, G.M., & Moscicki, A.B. (2008). Rate of nicotine metabolism and withdrawal symptoms in adolescent light smokers. *Pediatrics*, 122(3), pp. 643-647.

<sup>iv</sup> Dutra, L.M., & Glantz, G.A. (2014). Electronic cigarettes and conventional cigarette use among US adolescents: A cross-sectional study. *JAMA Pediatrics*, 168(7).

<sup>v</sup> National Cancer Institute. (n.d.). *Cigar smoking and cancer*. Retrieved from <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars>.

<sup>vi</sup> American Cancer Society. (n.d.). *Cigar Smoking*. Retrieved from <http://www.cancer.org/acs/groups/cid/documents/webcontent/002965-pdf.pdf>

<sup>vii</sup> Centers for Disease Control and Prevention. (n.d.). *Tobacco brand preferences*. Retrieved from [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/brand\\_preference/index.htm?utm\\_source=feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+cdc%2FGElA+%28CDC+-+Smoking+and+Tobacco+Use+-+Main+Feed%29](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+cdc%2FGElA+%28CDC+-+Smoking+and+Tobacco+Use+-+Main+Feed%29).

<sup>viii</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123, Stat. 1776-1858, (2009).

<sup>ix</sup> Centers for Disease Control and Prevention. (2010). *State Cigarette Minimum Price Laws—United States, 2009*. Retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5913a2.htm>

<sup>x</sup>Regulate All Tobacco. (2014). *Brief summary of the proposed deeming rule asserting FDA's jurisdiction over other tobacco products, such as cigars, pipe tobacco, and e-cigarettes*. Retrieved from <http://regulatealltobacco.org/content/wp-content/uploads/2014/07/Summary-of-deeming-rule-for-microsite.pdf>