



July 30, 2014

Mr. Mitch 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 Mr. Zeller:

We at C-Change thank you and the Food and Drug Administration Center for Tobacco Products for the opportunity to comment on Docket No. FDA-2014-N-0189. C-Change is a 501(c)(3) dedicated to eliminating cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of our members. We are comprised of approximately 150 of the Nation's cancer leaders from the private, public, and non-profit sectors. Working together, we are able to address system and societal level issues spanning the continuum of care that cannot be solved by one organization or even one sector alone.

We commend the FDA for taking this important step to deem e-cigarettes in addition to all types of cigars as tobacco products and support classification of flavoring cartridges as "component," and therefore also regulated as tobacco products as outlined in the Food, Drug, and Cosmetic Act. We also support the proposed inclusion of three additional provisions to covered tobacco products including: minimum age of purchase, health warnings, and prohibition of vending machine sales. We recognize that this step is of great importance to the public health of our nation, and encourage you to move quickly and finalize the rule without delay. We also ask that you consider the following important issues:

Cigars

We agree that the FDA should have the authority to regulate all tobacco products to protect public health, including those designated as "premium cigars," thus supporting "Option 1" as discussed in this proposed deeming rule. As FDA recognizes in the proposed deeming rule, "all cigars, regardless of size, produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produced in mainstream cigarette smoke." Given the carcinogenic effect of cigars, it is in the interest of public health and cancer prevention that all cigars are regulated by the FDA, and therefore are subject to minimum age requirements and health warnings. We also believe that it is a

dangerous precedent to exempt certain types of tobacco products from FDA regulation based on current use patterns, as use patterns change over time and the current use pattern does not change the fact that any use of the product is dangerous to health. This is especially true is the case of large premium cigars, as the FDA cites in the proposed deeming rule that “a large cigar may contain as much tobacco as a whole pack of cigarettes...” and “Nicotine levels in cigar smoke, can be up to eight times higher than levels in cigarette smoke.”

Flavored cigars and e-cigarettes

It is imperative for the public health of our Nation that FDA incorporates provisions in the final deeming rule that include regulation of flavored cigars and e-cigarettes, or issues a separate proposed rule quickly followed by a final rule banning flavors in tobacco products, especially candy flavors. Similar to the treatment of cigarettes in the Family Smoking Prevention and Tobacco Control Act, flavored e-cigarettes and cigars should be banned.

A Pediatrics study in JAMA noted that the “use of e-cigarettes does not discourage, and may encourage, conventional cigarette use among U.S. adolescents.ⁱ This is especially alarming for the public health given that e-cigarette use is on the rise. According to the CDC, e-cigarette use more than doubled between 2011 and 2012 among middle and high-school students. One in five of these kids had never tried a conventional cigarette, and kids prefer sweet flavored products. E-cigarettes are available in flavor such as “gummy bear,” “banana split,” “cotton candy,” “Kool-Aid,” “sweet tart,” “Hawaiian Punch,” “rocket pop,” “Fruit Loops,” “Skittles,” and “Cinnamon Toast” among others.^{ii,iii} These flavors, like their candy and cereal counterparts, have appeal to children and young adults. In order to discourage initiation of tobacco products through e-cigarettes by children and youth, these products should be banned.

Similarly, cigar consumption has increased amongst youth during the same time that cigarettes use has decreased, and this increase in cigar uptake is driven by availability of flavored products.^{iv} In 2013, 16.5% of high school boys smoked cigars, compared to 16.4 % who smoked cigarettes.^v This is especially important given that 80% of high school smokers are expected to continue smoking through adulthood.^{vi} The most popular cigar brands among youth come in flavors such as peach, strawberry, chocolate, grape, and blueberry, wild apple, pineapple, and watermelon, “purple haze,” “Banana split” and “Pinkberry” among other flavors.^{vii} We support that FDA should extend jurisdiction to cigars, and recommend strongly that in order to limit youth initiation of tobacco products, the FDA must extend its jurisdiction to include a ban on flavored cigars.

Childproof e-cigarette packages

The candy flavors and colors depicted on the packages of e-cigarettes combined with the lack of child-proof packaging poses another public health threat. According

to the CDC, “the number of calls to poison centers involving e-cigarette liquids containing nicotine rose from one per month in September 2010 to 215 per month in February 2014.” Half of these cases involved children age five years of age or younger.^{viii} As the FDA notes in the proposed deeming rule, in February, 2014, 41.7% of the combined calls to poison control centers for conventional cigarettes and e-cigarettes were for e-cigarette exposures. This is alarming given the toxic nature of the nicotine liquid, which “in tiny amounts, whether ingested or absorbed through the skin, can cause vomiting and seizures and even be lethal.”^{ix} Given this important threat, the FDA should act quickly to issue a proposed rule requiring child-proof packaging, and then take swift action to finalize the rule.

Sale, Marketing, and Advertising

We support applying the national minimum age of 18 for purchase of newly deemed tobacco products and other restrictions including free distribution, sale in vending machines, and internet sales. Internet tobacco vendors sell to minors due to inadequate age verification.^x Therefore, with regard to internet sales, it is imperative that FDA create enforceable age verification requirements (as in the Prevent All Cigarette Trafficking Act of 2010) or ban the sale of these products on the internet all together in order to successfully limit youth purchase of deemed products.

In addition to items in the proposed deeming rule, all sales and marketing restrictions currently applicable to cigarettes should apply to all newly deemed products, including cigars and e-cigarettes, especially with regard to targeted marketing toward kids. The FDA should quickly issue a new proposed rule to extend marketing restrictions on cigarettes to all deemed products as follows:

- Limit display of products at retail locations to black and white text only, at minimum. A 2013 pilot study in Central Harlem, New York, found 26% of retailers licensed to sell tobacco had colorful e-cigarette advertisements “located less than 3 feet above the ground (at the eye-level of children) and feature products in flavors, which in this study were characterized as menthol, strawberry, blueberry, wine or similar.”^{xi}
- Ban brand sponsorship at athletic and musical events that may be widely attended by youth, and free giveaways of merchandise bearing the name of the tobacco product. According to research from the Stanford School of Medicine, GreenSmoke and Blucigs have sponsored NASCAR drivers or teams and Mystic e-cigs and Swisher Cigarettes intend to serve as sponsors of a KSVH racing car for the 2014-15 IndyCar series.^{xii} Further, “Blu e-cigs has sponsored a number of music festivals including the popular Governors Ball Music Festival, SXSW, Bonnaroo Music Festival, Hard Summer, and the Sasquatch Music Festival. Veppo had a lounge at the 2013 Billboard Music awards.” In addition, “a 2014 congressional investigation found that the companies had promoted their products at such youth oriented events as music concerts, sporting events, and comedy shows, often providing free samples, and running advertisements on television and radio programs with

substantial youth audiences, including the broadcast of the National Football League championship, the Super Bowl.”^{xiii}

- Eliminate use of cartoon characters and celebrities, especially those with appeal to youth, and any advertisement with significant teen or youth readership or viewership. Similar to previous cigarette advertisement, e-cigarette use of cartoon and celebrity images as part of their campaigns to glamorize e-cigarette use. Examples include use of major celebrities for Blue cigarettes and NJOY, and the cartoon character “Bob” for Blue e cigarettes, and the Sports Illustrated magazine article featuring bikini clad women bearing Blu e-cigarette logos—all of which clearly target youth and should be banned in order to thwart further youth initiation.^{xiv}
- It is well documented that lower price through individual sale of cigarettes promotes youth consumption. Therefore, banning individual sale of cigars and other products is a necessary step in limiting youth consumption of tobacco products.

Again, we thank you for taking this step toward improving the public health, and for this opportunity to comment.

Sincerely,



Tom Kean
Chief Executive Officer

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

ⁱⁱ Nine E-Juice Flavors That Sound Just Like Kids’ Favorite Treats: Industry Leader Lorillard Even Admits “Fun Flavors” Attract Kids. Campaign for Tobacco-Free Kids. Retrieved from http://www.tobaccofreekids.org/tobacco_unfiltered/post/2014_06_11_ecigarettes.

ⁱⁱⁱ Retrieved from: <http://www.vapedojo.com/products/cinnamon-toast-chata-premium-vape-juice>

^{iv} Tynan, M.A., McAfee, Tim., Promoff, G., Pechacek, T. (2014). Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6130a1.htm>.

^v CDC. (2013). Youth Risk Behavior Surveillance. *MMWR*, 63(4).

^{vi} U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: 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, 2012.

^{vii} Campaign for Tobacco Free Kids (2013). Not Your Grandfather’s Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation. Retrieved from http://www.tobaccofreekids.org/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf.

^{viii} CDC. (April 4, 2014). Calls to Poison Center for Exposure to Electronic Cigarettes. *MMWR*, 63(13).

^{ix} Richtel, M. (March 23, 2014). Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes. New York Times.

^x Jensen JA, Hickman NJ, 3rd, Landrine H, Klonoff EA. (2004). Availability of tobacco to youth via the Internet. *JAMA*, 291:1837

^{xi} Ganz, O., Cantrell, J., Moon-Howard, J., Aidala, A., Kirchner, T.R., VAllone, D. (2014). Electronic cigarette advertising at the point-of-sale: a gap in tobacco control research. *Tobacco Control*. doi: 10.1136.

^{xii} Stanford School of Medicine. Retrieved from:

http://tobacco.stanford.edu/tobacco_main/images.php?token2=fm_st346.php&token1=fm_img15201.php&theme_file=fm_mt025.php&theme_name=Electronic%20Cigarettes&subtheme_name=Sponsorships.

^{xiii} McCarthy, M. (2014). *BMJ*. E-cigarette companies target youth, US congressional study finds. 348:g2871. doi.org/10.1136/bmj.g2871.

^{xiv} 7 Ways E-Cigarette Companies Are Copying Big Tobacco's Playbook. Campaign for Tobacco-Free Kids. Retrieved from http://www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_02_ecigarettes.