American Heart Association | American Stroke Association
life is why™

Advocacy Department
1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036
P 202-785-7900 | F 202-785-7950 | www.heart.org

August 08, 2014

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189 / RIN 0910-AG38

Dear Commissioner Hamburg:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and more than 22.5 million volunteers and supporters, we appreciate the opportunity to provide comments on the proposed rule to deem tobacco products subject to the Federal Food, Drug, and Cosmetic Act.

AHA is extremely pleased that the Food and Drug Administration (FDA) has taken the first step to extend its regulatory authority over all tobacco products. Since the Family Smoking Prevention and Tobacco Control Act became law in 2009, the FDA has made great strides toward protecting the public from the dangers associated with cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Yet there is no federal oversight over cigars, e-cigarettes, or other tobacco products, nor are there any restrictions in place to protect against the risks posed by these products. It is time for that to change and we are glad that the FDA agrees.

Cigars, e-cigarettes, hookah and other unregulated tobacco products are rising in popularity. While cigarette smoking has decreased in both adults and children,[1,2] use of cigars, e-cigarettes, and hookah have all increased. Among high school students, for example, use of e-cigarettes nearly doubled from 1.5% in 2012 to 2.8% in 2013, hookah rose from 4.1% to 5.4% between 2011 and 2012, and cigar use increased dramatically during the same time period, particularly among black students, from 11.7% to 16.7%.[3] The lack of regulation has allowed the market for these products to grow unchecked.

We are encouraged that the FDA has decided to bring these products under the Agency's jurisdiction, and, overall, we support the proposed rule. We agree that the FDA should have regulatory authority over these products; these products should be subject to the same basic requirements as cigarettes, smokeless, and roll-your-own tobacco; and they should not be sold to individuals under 18 years of age. However, we are concerned that the rule does not go far enough, particularly in the areas of youth access, characterizing flavors, marketing, and childproof packaging. As we discuss in detail below, AHA urges the FDA to address these issues in the final rule or begin work on separate regulations that can be released for public comment in tandem with the final rule.

We also request that the Agency work quickly to finalize this rule and move forward with implementation. Ideally, the final rule will be released by the end of this calendar year, but no later than 12 months from the April 2014 publication of the proposed rule. The longer these products remain unregulated, the greater the number of individuals – including children – who will be exposed to these products and who may become addicted. As one tobacco retailer group put it, until the deeming rule is in place, retailers will have an "open window to capitalize on the enormous popularity" of unregulated products.[4] It is time for that window to close.

Deemed Tobacco Products

Premium Cigars

In the proposed rule, the FDA presents two options for extending the scope of its authority. AHA strongly prefers option 1, which would deem all products meeting the statutory definition of "tobacco products" except for tobacco product accessories. We urge the FDA to adopt option 1 in the final rule.

Option 2, which would exempt tobacco product accessories and premium cigars, is unacceptable. Premium cigars meet the statutory definition of "tobacco product" and should not be exempted from the deeming rule.

Premium cigars – like all cigars – pose risk. Cigar smoking exposes users to toxic chemicals; causes cancer of the oral cavity, larynx, esophagus, and lung; and increases risk for heart

---

[1] Agaku, IT, et al. Current Cigarette Smoking Among Adults – United States, 2005-2010. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report: 63(02); 29-34, January 17, 2014. Cigarette smoking decreased from 20.9% in 2005 to 18.1% in 2012.

[2] Kann, L, et al. Youth Risk Behavior Surveillance – United States, 2013. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report: 63(ss04); 1-168, June 13, 2014. Cigarette smoking decreased from 18.1% in 2011 to 15.7% in 2013.

[3] Tobacco Product Use among Middle and High School Students – United States, 2011 and 2012. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report: 62(45); 893-897, November 15, 2013.

[4] Odesser-Torpey M and Lofstock J. Who's Minding the E-Cigarette Industry? *Convenience Store Decisions*. June 2013; 26-32.

disease, chronic obstructive pulmonary disease, and aortic aneurysm.[5] And as the FDA itself acknowledges in the proposed rule, smokers of premium or large cigars may be exposed to higher levels of nicotine – as much as eight times higher than levels in cigarette smoke – because large cigars typically contain more tobacco, as much as a whole pack of cigarettes.[6] In addition, exposure to cigar smoke, which the National Cancer Institute found to be as, or more toxic and carcinogenic than cigarette smoke, places both smokers and nonsmokers at risk.[7]

If the Agency finds that premium cigars pose less of a public health risk due to the nature of the product and how it is used, the FDA is not required to regulate all cigars in the same manner. The Agency can, for example, create different requirements for little cigars than premium cigars. However, premium cigar smokers should, at a minimum, be provided with the same basic protections the FDA has proposed for other tobacco products such as product registration and ingredient listing. To do that, the FDA must assert its authority over <u>all</u> tobacco products, including premium cigars.

Failure to include premium cigars in the scope of this rule will send the wrong message. It may imply that premium cigars were not regulated because they are safe to use and pose no harm. This is particularly concerning given that cigar smoking is popular among youth and a higher percentage of young adults use premium cigars than older adults; more young adults smoke premium cigars (15.1%) than little cigars (11.9%).[8] It may also encourage manufacturers of other tobacco products to seek an exemption. And, perhaps of most concern, it would allow children under 18 years of age to purchase premium cigars because the federal minimum age requirement would not apply.

To protect the public health, the FDA must extend its authority over premium cigars and select option 1.

Accessories

AHA has no objection to the FDA's plan to exempt accessories from the definition of "tobacco product". However, we request that the Agency clarify in the final rule that vaporizers and pipes are not accessories; vaporizers and pipes should be listed as examples of covered "components" or "parts".

<u>Deeming Provisions</u>

According to the proposed rule, newly deemed tobacco products would automatically be subject to the following provisions:

1. Enforcement action against products determined to be adulterated and misbranded

[5] Cigar Smoking and Cancer Fact Sheet. National Cancer Institute, National Institutes of Health.
[6] 79 FR at 23151. April 25, 2014.
[7] Ibid, and Cigars: Health Effects and Trends. NCL Smoking and Tobacco Control Monograph 9. National Cancer Institute. 1998.
[8] 79 FR at 23,151.

2. Required submission of ingredient listing and reporting of harmful and potentially harmful constituents (HPHCs)
3. Required registration and product listing
4. Prohibition against use of modified risk descriptors (e.g., light, low, mild) and claims unless FDA issues an order permitting their use
5. Prohibition on the distribution of free samples
6. Premarket review requirements

AHA strongly supports these provisions. All tobacco product manufacturers should be required to register their products with the FDA, provide ingredient information, and obtain a marketing order for new tobacco products. In addition, no product should be allowed to use misleading modified risk descriptors or to provide free product samples, which may encourage tobacco use. The FDA must also have the ability to take enforcement action against a tobacco product manufacturer or retailer when necessary.

Modified Risk Claims

One area that warrants further discussion is the provision related to modified risk claims. According to the proposed rule, manufacturers that wish to make a modified risk claim must comply with Section 911 of the Tobacco Control Act. We support this requirement; tobacco products should not be allowed to make modified risk claims unless the manufacturer can provide evidence to support the claim.

We expect that a number of manufacturers will want to make modified risk claims. In the current unregulated environment, some e-cigarette manufacturers and retailers, for example, are already marketing their products using healthy, safety, and cessation messaging.[9] The Agency must rigorously evaluate these claims.

When reviewing these claims, the FDA should consider any "improvements" a tobacco product may offer, however, the FDA must evaluate a tobacco product based on its totality. In other words, the FDA's evaluation of a tobacco product cannot focus on the product's impact on one disease state or condition. The Agency's evaluation must consider all of the disease states affected by the product as well as the overall burden of disease, including the product's effect on cardiovascular disease and stroke. Similarly, modified risk claims that are based on a product's ability to help cigarette smokers switch to a non-combustible product or quit using nicotine altogether, must consider whether the claim will promote dual use or whether it will make it less likely that tobacco users will successfully quit. Any claims that imply that a tobacco product is a cessation aid should be referred to the FDA's Center for Drug Evaluation and Research and subject to evaluation as a nicotine replacement therapy product.

[9] Huang J, et al. A Cross-Sectional Examination of Marketing Electronic Cigarettes on Twitter. *Tob Control* 2014;23:iii26-iii30 doi:10.1136/tobaccocontrol-2014-051551.

Additional Provisions

Minimum Age of Purchase

AHA strongly supports the FDA's proposal to prohibit the sale of deemed tobacco products to individuals under the age of 18. Preventing tobacco use among children and adolescents is a key public health goal. We know that the majority of tobacco users (9 out of 10) initiate and establish tobacco use by age 18, and 99% start by age 26.[10] Thus, individuals who do not start using tobacco in their adolescence are unlikely to do so later.

Unfortunately survey data show that significant numbers of youth use cigars, e-cigarettes, and other novel tobacco products, and the popularity of these products continues to rise. This use is likely due, at least in part, to the fact that these products can be legally sold to minors in many states. The establishment of a federal minimum age of purchase, like the one that exists for cigarettes and smokeless tobacco, should help reduce youth consumption of these products when combined with an aggressive education and enforcement campaign.

We note, however, that the minimum age of purchase must apply to all tobacco products, including premium cigars. Although the cost of premium cigars may serve as a deterrent for some youth, the FDA should not assume that cost alone will stop children from obtaining and using these products.

In addition, we request that the FDA clarify that age verification is required for Internet sales. We believe that the proposed rule implies that age verification for Internet sales is required, but it is not clear. The Agency should make this requirement explicit in the final rule.

Likewise, because individuals under the age of 18 may find it easier to circumvent the age restriction using the Internet, the FDA should require Internet and mail-order retailers to check the ID and age of customers both at purchase and at delivery to stop underage sale of tobacco products. Internet and mail-order retailers already meet this requirement for cigarette and smokeless tobacco sales; the same requirement should apply to all tobacco products.

Vending Machine Sales

AHA is pleased that the FDA intends to ban vending machine sales unless the vending machine is located in a facility where individuals under the age of 18 are prohibited at all times. We agree this would eliminate an easy means of access to these products.

The Agency should, however, take this one step further and also ban self-service displays in stores. We understand that individuals who select tobacco products from self-service displays are supposed to have their age verified at the point-of-sale, but this is not always the case. As it becomes more difficult for underage youth to obtain tobacco products, they

[10] Youth and Tobacco Use Fact Sheet. Centers for Disease Control and Prevention. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm

may resort to other methods, including shoplifting.[11] In this case, self-service displays make it easier for youth to obtain tobacco products and avoid a face-to-face transaction and the accompanying age verification. To prevent this problem, the FDA should ban self-service displays. Tobacco products would not necessarily have to be kept behind a store counter to comply with a ban, but they should not be accessible without the assistance of a store employee, such as in a locked display case. In addition, the FDA should direct retailers not to display tobacco products in the same area as candy, toys, or other products that appeal to children.

Health Warnings

According to the proposed rule, all covered tobacco products, as well as cigarette tobacco and roll-your-own tobacco would be required to bear the following health warning:

> WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

AHA supports this proposal. Nicotine is a highly addictive chemical; tobacco users come to rely on nicotine "to modulate mood and arousal, relieve withdrawal symptoms, or both."[12] We believe the proposed warning is appropriately worded to convey this risk. However, the FDA should allow itself the option to develop an alternative or additional warning(s) in the future as our knowledge of these products increase. For example, the Agency may determine that a stronger warning or a warning regarding specific health effects is warranted. The Agency may also decide to vary the warning by type of tobacco product. We recommend that the FDA plan to update this warning as more information becomes available about each type of newly deemed tobacco product.

We are pleased that the Agency has already proposed additional warnings for cigars. We agree that cigars should be required to bear the warnings that were developed as part of the 2000 settlement with the Federal Trade Commission (FTC), but cigars should be required to use <u>all five</u> statements approved as part of the FTC settlement, not just the four included in the proposed rule. The fifth warning regarding infertility, stillbirth, and low birth weight is intended to caution women of childbearing age against smoking cigars while pregnant, a laudable goal. We do not understand why this warning was not included in the rule when the seven largest cigar manufacturers have already been using it, and cigarettes (which bear a similar warning) and cigars contain many of the same chemicals. In addition, exposure to nicotine during fetal development has lasting adverse consequences for brain development.[13] This may indicate that an even stronger warning regarding the impact of smoking cigars while pregnant is warranted.

---

[11] Levy DT, et al. Strategies for Reducing Youth Access to Tobacco: A Framework for Understanding Empirical Findings on Youth Access Policies. *Drugs: Education, Prevention and Policy*, 9(3):285-303, 2002.

[12] Benowitz, N. Nicotine Addiction. N Eng J Med. June 17, 2010; 362(24):2295-2303.

[13] U.S Department of Health & Human Services. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Centers for Disease Control and Prevention, Office on Smoking and Health, 2014.

Finally, the cigar warnings should apply to all cigars, including premium cigars, and all cigar manufacturers, regardless of their size, should be required to rotate the warnings on a regular basis.

Premarket Review of New Products

As noted above, AHA strongly supports requiring "new tobacco products" to go through the premarket review process. We appreciate the FDA extending this core component of the Tobacco Control Act to newly deemed products. We are concerned, however, that the Agency intends to give tobacco manufacturers 24 months to submit a premarket tobacco application or a substantial equivalence application after the rule takes effect. This concerns us for two reasons. First, tobacco manufacturers will have an incentive to wait until the end of the 24-month period to submit their application. As long as manufacturers submit an application during that time period, the tobacco product can remain on the market until the FDA reviews the application and issues a decision. Based on the FDA's past performance, manufacturers are aware that the review process could take several years. Again, this provides an incentive for delay – the longer the manufacturer waits before submitting an application, the longer the tobacco product can remain on the market while it awaits FDA review. Second, if the FDA receives the bulk of the anticipated premarket tobacco applications and substantial equivalence applications at the close of the 24-month period, this will create a tremendous burden on the Agency. The FDA already has a backlog of more than 3,100 substantial equivalence applications awaiting review. We anticipate that this will only worsen, significantly increasing the time for the Agency to complete its review.

To avoid having new – and potentially dangerous – tobacco products remain on the market for years before the FDA completes a new product or substantial equivalence review, the Agency should tighten the premarket provisions of the proposed rule. We recommend the following:

- Establish a new review system designed to eliminate the current lengthy delays.
- Commit to promptly review all applications for completeness and notify the submitter if the application is incomplete. Applications that are not completed within a specified time frame (e.g., after an additional 30 days) should be rejected. This will remove the incentive for manufacturers to intentionally submit an incomplete application and draw out the review process.
- Prioritize applications for products that are currently on the market over products that have yet to be introduced.
- Shorten the deadline to submit a new product or substantial equivalence application from 24 to 12 months as proposed in the Agency's initial draft of the deeming rule, or, at a minimum, shorten the deadline for combustible products (i.e., cigars) to 12 months.

The Agency should also clarify that manufacturers must comply with all other regulatory requirements in order to take advantage of the 12-month (as AHA recommends) or 24-month timeframe for submitting a new product or substantial equivalence application. For example, manufacturers must submit ingredient listings and documents related to health,

toxicological, behavioral, or physiologic effects to the FDA within six months of the rule's effective date. Manufacturers that fail to meet these deadlines must face enforcement action, including possible removal of their product from the market regardless of the status of their new product or substantial equivalence application.

In addition, the FDA should require manufacturers to include samples of all advertising and promotional materials and relevant marketing research as part of any new product or substantial equivalence application.

Continuum of Nicotine-Delivering Products

Throughout the proposed rule, the FDA addresses the continuum of nicotine-delivering products, noting that there are "distinctions in the hazards presented" by various tobacco products.[14] AHA agrees with this assessment – different types of tobacco products present different levels of risk.

Combustible products present the highest level of risk to the individual user and those exposed to secondhand smoke. Cigarettes cause heart disease, stroke, cancer, lung diseases, and diabetes. More than 16 million Americans suffer from a disease caused by smoking, and cigarette smoking is responsible for more than 480,000 deaths each year.[15] Because of the high level of risk inherent in cigarettes, cigarettes should be subjected to the highest level of regulation by the FDA.

Cigars also present significant risk. Cigars contain similar levels of nicotine, toxins, and carcinogens as cigarettes and are associated with certain types of cancer, gum disease, and tooth loss. In heavy smokers and those who inhale deeply, cigars also increase the risk for lung diseases and heart disease.[16] Although cigars may present a lower level of overall risk than cigarettes because of differences in patterns of use and inhalation, individuals are initiating cigar use at younger ages[17] and greater numbers of youth are now smoking cigars. Because of the risks associated with cigar use and their impact on youth initiation, cigars are also high on the continuum of risk.

Newer, non-combustible products may fall lower on the continuum of risk. We understand, for example, that proponents of e-cigarettes believe that they present less of a health risk than conventional cigarettes. Supporters also claim that e-cigarettes may help smokers reduce their cigarette use or completely abstain. We agree that e-cigarettes may have some potential if they can move smokers from combustible products and do not lead to increased

[14] 79 FR at 23147. April 25, 2014.
[15] U.S Department of Health & Human Services. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Centers for Disease Control and Prevention, Office on Smoking and Health, 2014.
[16] Smoking and Tobacco Use: Fact Sheet: Cigars. Centers for Disease Control and Prevention. http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/cigars/.
[17] Food and Drug Administration. Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act Proposed Rule: As submitted to OMB. Page 25.

initiation of tobacco use or promote nicotine addiction. However, it is important to remember that e-cigarettes have risk too; there is no risk-free tobacco product.

In general, e-cigarettes appear to contain lower amounts of harmful chemicals than combustible cigarettes or smokeless tobacco. Thus, e-cigarettes could be a less harmful alternative to traditional tobacco products. But studies have found that e-cigarettes users can still be exposed to toxins, metals (tin, iron, nickel, and chromium) from the heating coils,[18,19] ceramics, plastics, rubber, filament fibers, and foams, which may be aerosolized and inhaled.[20] Studies have also found contaminants such as non-pharmaceutical grade propylene glycol[21] and prescription weight loss and erectile dysfunction drugs in certain e-cigarette liquids.[22] There are also concerns about the potential toxicity of flavorings that are used in e-liquids. In addition, most e-cigarettes deliver nicotine, which as discussed above is a dangerous and highly addictive chemical. Currently, there are no studies that have examined the long-term health effects of e-cigarette use, and even though a few studies suggest that smokers may successfully use e-cigarettes as a cessation tool, this has not been rigorously established.

As noted above, AHA is also concerned that e-cigarettes could be a gateway to tobacco use for non- or former smokers, sustain dual use, or promote or maintain nicotine addiction. Acceptance of e-cigarettes also has the potential to re-normalize smoking behavior. We are especially concerned that e-cigarettes may lead to increased initiation among youth. As mentioned previously, e-cigarette usage doubled in one year among middle and high school students, and 9.3% of students who have used an e-cigarette reported never smoking conventional cigarettes,[23] making it appear that an e-cigarette may have been their first experience with a tobacco product. Youth may be attracted to e-cigarettes because they perceive them as safer than combustible cigarettes, more convenient to use, and more readily accessible; they are also available in flavors that appeal to children.[24]

These are just a few of the reasons why we believe that e-cigarettes must be regulated by the FDA, even though they may be lower on the continuum of risk than combustible products. The Agency must have the authority to establish product standards, quality controls for manufacturing, standards for contaminants, and product labeling requirements. As discussed elsewhere in this letter, the FDA should also use its authority to ban their sale to

---

[18] Brown, CJ and JM Cheng, Electronic cigarettes: product characterisation and design considerations. Tob Control, 2014. 23 Suppl 2: p. ii4-10.

[19] Williams, M, et al., Metal and silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid and aerosol. PLoS One, 2013. 8(3): p. e57987.

[20] Ibid.

[21] Palazzolo, DL, Electronic Cigarettes and Vaping: A New Challenge in Clinical Medicine and Public Health. A Literature Review. Front Public Health, 2013. 1: p. 56.

[22] Ibid.

[23] Dutra, LM and S.A. Glantz, Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents: A Cross-sectional Study. JAMA Pediatr, 2014.

[24] Choi, K, et al., Young adults' favorable perceptions of snus, dissolvable tobacco products, and electronic cigarettes: findings from a focus group study. Am J Public Health, 2012. 102(11): p. 2088-93.

minors, require warning statements and childproof packaging for all e-liquid containers, and implement flavoring and marketing restrictions to limit e-cigarettes appeal and access to kids. And, e-cigarette manufacturers or retailers who wish to make harm reduction or cessation claims should be required to provide data in support of those claims to the FDA.

Under no circumstances should e-cigarettes or any other tobacco or nicotine product be exempted from the Agency's authority. The FDA may determine that it is appropriate to vary the regulatory requirements by product type based on the product's location on the continuum of risk, but all tobacco products should be subject to the deeming provisions, minimum purchase age, vending machine, and warning statement requirements contained in this proposed rule.

Compliance Period for Small Manufacturers

In the proposed rule, the FDA questions whether small tobacco product manufacturers should be given additional time to comply with the regulation. We oppose extending the compliance period for small manufacturers. While we understand that it may be more difficult for small manufacturers to comply with certain requirements, we do not believe this justifies weakening the rules for manufacturers of a certain size. The products made by small manufacturers are no less addictive or harmful than those produced by large manufacturers. Even a small manufacturer of tobacco products has the capability of causing harm to public health.

In addition, varying compliance dates by manufacturer size may be confusing to the public. If the FDA, for example, staggered the compliance date for warning statements by manufacturer's size, the public would not understand that the presence of a warning on one product and the lack of a warning on another was simply due to the size of the manufacturer. Individuals may incorrectly assume that the product without the warning was less harmful or risky.

We recommend that the FDA select one compliance date for all manufacturers regardless of the manufacturer's size.

Regulatory Gaps

As noted at the beginning of this letter, AHA is supportive of the proposed rule overall; however, we are disappointed that the Agency failed to address several important areas, including characterizing flavors, marketing, childproof packaging, and minimum pack size. The FDA must move quickly to address these regulatory gaps. We urge the Agency to address these issues in the final rule, when possible, or begin work on separate regulations that can be released for public comment in tandem with the final rule.

Characterizing Flavors

In the proposed rule, the FDA acknowledges that "many of the products proposed to be covered by this rule are offered in fruit and candy flavors"; that 20% of tobacco users report

using flavored products; that flavored product use is higher among youth/young adults; and that the prevalence of flavored products has increased since the 2009 ban on flavored cigarettes.[25] Yet, the Agency did not include any restrictions on characterizing flavorings in the proposed rule. We strongly urge the FDA to correct this omission as soon as possible.

As the Agency is aware, cigars, e-cigarettes, and other tobacco products are now available in a wide range of candy and fruit flavors, many of which are attractive to youth. Consider cigars which are available in flavors like chocolate, cherry, strawberry, grape, and lemonade, as well as with catchy names that appeal to children such as Da Bomb Blueberry, Pinkberry, and Banana Split.[26] E-cigarettes are also available in a variety of flavors. According to one recent survey, there are more than 460 brands of e-cigarettes online, offering more than 7,700 unique flavors.[27] The study authors found that more than 240 new flavors of e-cigarettes are introduced, on average, each month. E-cigarettes are available in flavors like graham cracker, Swedish Fish, and absinthe,[28] as well as flavors using the names of children's cereal (Cap'n Crunch, Froot Loops, Cocoa Puffs, Cinnamon Toast Crunch), candy and cookies (Tootsie Rolls, Thin Mints) or children's cartoon characters (Hello Kitty, Curious George). One can only assume that products like Cap'n Crunch Berries or Curious George e-juice are intended for a younger audience.

Another study found that candy-flavored tobacco products actually do taste like candy, because tobacco products contain the same flavor chemicals used in candy and children's drink mixes. According to the study's authors, there is "great overlap in the flavor chemicals used."[29] For example, benzaldehyde, benzyl alcohol, or both were found in "cherry" Jolly Rancher candies, Life Savers, Zotz Candy, Kool-Aid drink mix, and all cherry-flavored tobacco products.[30] The researchers also found overlap in grape and apple flavored candy and tobacco products and analogous patterns for peach and berry flavored products.

The appeal these flavored products have with youth is evident. Consider the recent rise in cigar use among adolescents. Every day, more than 2,700 youth try cigar smoking for the first time,[31] making cigars one of the most commonly used tobacco products among youth,

---

[25] 79 FR at 23146 – 23147. April 25, 2014.
[26] Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids. Campaign for Tobacco Free Kids. March 13, 2013.
[27] Zhu SH, et al. Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation. *Tob Control* 2014;23:iii3-iii9 doi:10.1136/tobaccocontrol-2014-051670. http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3.full
[28] Deborah Netburn. The E-Cigarette Boom: Study Finds 466 Online Brands, 7,700 Flavors. Los Angeles Times. June 17, 2014. http://www.latimes.com/science/sciencenow/la-sci-sn-research-food-companies-misleading-consumers-with-health-halo-buzzwords-20140617-story.html.
[29] Brown JE, et al. Candy Flavorings in Tobacco. N Engl J Med 2014; 370:2250-2252. June 5, 2014: DOI: 10.1056/NEJMc1403015.
[30] Ibid.
[31] SAMHSA, Results from the 2012 National Survey on Drug Use and Health: Detailed Tables, 2013

second only to cigarettes (15.7% vs. 12.6%).[32] Much of this increase in cigar use can be attributed to the availability of flavored cigars. The Maryland Youth Tobacco Survey, for instance, found that over 76% of cigar users in high school smoke flavored cigars, while less than 2% of adults do.[33] Another study found that 75% of the growth in cigar sales from 2008 to 2011 represents growth in the sale of flavored cigars.[34] Unfortunately flavored cigars have replaced flavored cigarettes as the gateway to tobacco use for many youth.

We believe the same trends are developing with flavored e-cigarettes. As noted earlier, e-cigarette use among middle and high school students nearly doubled in one year, and the number of e-cigarette flavors has increased exponentially in recent years. Even the tobacco industry has acknowledged that flavored e-cigarettes may appeal to youth. According to Lorillard, the parent company for blu e-cigarettes, "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry."[35]

Given the appeal fruit and candy flavors have with youth and the increasing prevalence of flavored cigar and e-cigarette use, we recommend that the FDA ban the use of characterizing flavors other than tobacco or menthol. AHA's recommendation is based on the clear evidence that flavored cigars, just like flavored cigarettes, are attractive to youth and have led to increased initiation and use among adolescents. Thus, cigars should not be allowed to use characterizing flavors. While the evidence base for e-cigarettes is still emerging and the link is not as clear, it is reasonable to believe that flavored e-cigarettes will have a similar impact on youth initiation and use. It is therefore reasonable to assume that flavored e-cigarettes are likely to follow a parallel track as flavored cigarettes and cigars and appeal to youth. We believe this justifies a flavor ban for both cigars and e-cigarettes.

We expect that cigar and e-cigarette manufacturers will disagree with our position and advocate for the continued use of characterizing flavors. We urge the FDA to reject their arguments and establish a ban. Characterizing flavors should only be allowed if manufacturers can prove that flavored tobacco products do not appeal to youth, that the flavors are safe, and that they have been tested for toxicity and teratogenicity. Until then, the Agency must be proactive and establish a flavor ban to protect public health.

On a related note, the FDA should take immediate action against flavored cigarettes that are masquerading as "little cigars" or "cigarillos" simply to circumvent the existing flavoring ban. Flavored "little cigars" are very popular with youth; a nationwide survey found that more than one in three (35.9%) of middle and high school students who smoke cigars use flavored

[32] Kann, L, et al. Youth Risk Behavior Surveillance – United States, 2013. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report: 63(ss04); 1-168, June 13, 2014.
[33] Cigar Use Among Youth. Maryland Department of Health and Mental Hygiene. November 17, 2011.
[34] Delnevo C, et al. Preference for Flavored Cigar Brands Among Youth, Young Adults and Adults in the -
[35] What You Need to Know About E-Cigarettes – Infographic. Real Parents Real Answers. Sponsored by Lorillard's Youth Smoking Prevention Program, 2014. www.realparentsrealsanswers.com

little cigars.[36] The Agency already has authority under the Tobacco Control Act to remove these products from the market; you do not need to wait until the deeming regulation is finalized to do so.

Advertising and Marketing

AHA is very concerned that the proposed rule does not address the advertising and marketing of newly deemed products. Alluring ads in major media have likely fueled the rising use of e-cigarettes, cigars, and other tobacco products by children and adolescents. To prevent youth from being targeted by tobacco manufacturers and retailers, the FDA must extend existing advertising and marketing restrictions to all tobacco products.

The lack of advertising restrictions is readily apparent to anyone who watches television or reads a magazine. Tobacco products – particularly e-cigarettes – are being heavily advertised in the mass media, on social media, and through sponsorship of events. Spending on advertising of e-cigarettes alone has skyrocketed in the past few years. In 2010, e-cigarette manufacturers spent $5.6 million on advertising; but in 2013, the number jumped to $82.1 million.[37] And the advertising appears to be effective; U.S. sales of e-cigarettes are expected to surpass $10 billion by 2017 if current trends continue.[38]

Unfortunately studies have shown that e-cigarette advertisements are not only targeting adult smokers, they also reach significant numbers of youth. One study found that awareness of e-cigarette advertisements among youth and young adults is very high, "ranging from 89% for those ages 13-17 to 94% for young adults ages 18-21."[39] Another study found youth exposure to e-cigarette advertisements on television increased 256% from 2011 to 2013 – reaching over 24 million youth – while young adult exposure increased 321% during the same time period.[40] Like the study's authors, we are extremely concerned that the increase in e-cigarette advertising and awareness will lead to increased initiation and use among youth and young adults.[41]

We are also concerned that manufacturers are using some of the same advertising techniques we saw the tobacco industry use to market cigarettes. Many advertisements include cartoon characters, celebrity spokespeople, and sexual themes, or depict users as extremely masculine, glamorous, or rebellious. Manufacturers are also sponsoring events such as music festivals, sporting activities, comedy tours, and even fashion weeks.[42] And, at

---

[36] Emerging Tobacco Products Gaining Popularity Among Youth. Centers for Disease Control and Prevention Press Release. November 14, 2013.

[37] Vaporized: E-Cigarettes, Advertising, and Youth. Legacy. March 2014.

[38] Herzog, B, et al. Equity Research: E-Cigs Revolutionizing the Tobacco Industry. New York: Wells Fargo Securities. 2013.

[39] Ibid.

[40] Duke JC, et al. Exposure to Electronic Cigarettes Television Advertisements Among Youth and Young Adults. *Pediatrics*. Volume 134, Number 1, July 2014. Doi:10.1542/peds.2014-0269.

[41] Ibid.

[42] Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth. A report written by the staff of Senator Durbin, Representative Waxman, Senators

least one manufacturer has used an animated cartoon game on Facebook to promote its e-cigarettes.[43] As with the use of candy and fruit flavors, many of these advertising techniques appear to target, or at least reach, a lot of youth.

That is why we recommend that the FDA extend the current advertising restrictions for cigarettes and smokeless tobacco to all tobacco products, including the newly deemed products. These restrictions include:

- A ban on the sale or distribution of promotional items, such as hats and tee shirts, with tobacco brands or logos.
- A ban on brand name sponsorship on any athletic, musical, or other social or cultural event, or any team or entry in those events.
- A requirement that manufacturers notify the FDA 30 days prior to the dissemination of advertising or labeling for a tobacco product in a medium other than one of the following (in newspapers, magazines, periodicals or publications, billboards, posters, placards, non-point-of-sale promotional material, point-of-sale promotional material, or audio or video formats delivered at point-of-sale) and discuss the extent to which the advertising may be seen by persons younger than 18 years of age.

We also repeat our request that the FDA require manufacturers to include advertising and promotional materials as part of any new product or substantial equivalence application. The Agency should carefully consider the way a product is advertised and marketed when evaluating these applications.

The FDA must also conduct routine surveillance and review of the tobacco industry's marketing, promotional, and advertising activities, and must take enforcement action when advertisements are misleading or target children and adolescents.

Childproof Packaging

One area the FDA needs to address immediately is childproof packaging for containers of e-cigarette liquid (also known as e-liquid or e-juice).

In the proposed rule, the FDA expresses concern about the potential for acute nicotine toxicity upon exposure to e-cigarettes. The Agency even acknowledges the new and very troubling data that shows an increase in calls to poison centers for accidental exposure to e-liquid. Calls jumped from an average of one a month in September 2010 to 215 per month in February 2014, and more than half (51.1%) of the calls for e-cigarettes involved children under the age of five.[44] Many e-liquid manufacturers also acknowledge the risk associated with exposure, warning consumers not to let the liquid come into contact with their skin or

---

Harkin, Rockefeller, Blumenthal, Markey, Brown, Reed, Boxer, Merkley, and Representative Pallone. April 14, 2014.

[43] Ibid.

[44] Chatham-Stephens K, et al. Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010-February 2014. MMWR, Centers for Disease Control and Prevention. 63(13);292-293. April 4, 2014.

eyes, inhale it, or swallow it. Yet there is no requirement that this toxic liquid be packaged and sold in childproof containers, nor is there a limit on the amount of nicotine an e-liquid can contain. This means that children can be exposed to nicotine at significantly higher concentrations than other tobacco products. A typical combustible cigarette, for example, contains 10 to 15mg of nicotine and delivers a systemic dose of approximately 1mg of nicotine, yet e-cigarette base solutions with as much as 100mg/ml of nicotine for "do-it-yourself" e-liquid formulation are available for purchase on the Internet.

We can only expect that poisonings associated with e-liquids will continue to rise. The lack of childproof packaging and the enticing fruit and candy flavors will remain a dangerous – and potentially deadly – combination until the FDA acts. To protect the most vulnerable members of our society, the Agency should require childproof packaging of all e-liquids and related products, and require a warning statement advising consumers to keep the products away from children.

Minimum Pack Size

The Tobacco Control Act prohibits retailers from selling cigarettes in quantities less than 20. This restriction was put in place because single cigarettes provided minors with an option to buy cigarettes cheaply.[45]

The FDA should consider creating minimum pack sizes for other tobacco products, such as inexpensive cigars. As discussed earlier, cigars are one of the most commonly used tobacco products among youth, second only to cigarettes. Cigars appeal to children because they are frequently sold individually and many can be purchased for a very low price. Establishing a minimum pack size for these products may help prevent the sale of inexpensive single cigars or other products that are appealing to price-sensitive youth.

Regulatory Impact Analysis

AHA is extremely concerned about the Regulatory Impact Analysis (RIA) that was published in conjunction with the proposed rule. The RIA repeats an error that was first made by the Agency in the rule on Required Warnings for Cigarette Packages and Advertisements. In the RIA, the FDA discounts or offsets by 70% the benefits that individuals would realize if they stopped using tobacco products to account for lost "welfare" or "consumer surplus" or what is loosely defined as the pleasures associated with tobacco use. We strongly object to the application of the "consumer surplus" concept to tobacco use and we cannot overstate our disappointment that the FDA has used this flawed methodology again.

As several distinguished scholars and economists communicated in a recent paper to the FDA, it is inappropriate to consider lost consumer surplus or lost pleasure when evaluating

[45] Compliance and Enforcement Report: June 2, 2009 through September 30, 3013. Center for Tobacco Products, Food and Drug Administration.

a tobacco regulation.[46] The concept of lost consumer surplus should only by considered when individuals are able to make fully rational and fully informed decisions. However, as the FDA acknowledges in the proposed rule, the overwhelming majority of tobacco users begin while they are still underage. Adolescents are not fully aware of the health consequences of tobacco use, have little concept of their own mortality, and heavily discount the threat of addiction, making their decisions neither fully-informed nor rational. It is this premise – that youth may not be able to make fully rational decisions – that led the Agency to propose the minimum purchase age restrictions.

By including consumer surplus, the FDA is also ignoring that tobacco is addictive and once an individual becomes addicted, the decision to continue buying tobacco products is no longer rational. Addiction is not a pleasurable experience. Instead, addiction can lead to frustration and anger as individuals find it very difficult to quit using tobacco. Surveys have found that 70% of adult smokers want to stop smoking and 42.7% made a quit attempt in the past year;[47] most wish they had never started. It is therefore inconceivable to consider addiction to tobacco a "pleasure".

In addition, it is unclear how the Agency determined that the "appropriate" discount for the consumer surplus is 70%. In the rule on graphic warnings, the FDA used a 50% discount, but the proposed deeming rule offers no explanation of why the offset was increased by 20%. We strongly believe that there should be no discount for lost pleasure – 0% – but note that the Agency's decision to increase the amount of the discount in this rule is also troubling.

As noted above, AHA is not alone in our concerns; many experts and public health groups object to the use of this economic concept when evaluating behaviors related to tobacco. Even the economist whose work was cited by the FDA in the RIA as a source for their 70% discount believes it is wrong to apply the consumer surplus concept to tobacco, calling it "a misapplication of [his] work."[48]

The FDA must remove the concept of lost welfare or consumer surplus from the RIA. The flaws in the analysis mischaracterize the benefits and the costs associated with the regulation. If the Agency continues to use these flawed criteria, it will lead to the repeated failure of FDA regulation of tobacco and the American people will fail to realize the public health benefits that Congress intended when it passed the Tobacco Control Act.

---

[46] Chaloupka FJ, et al. An Evaluation of FDA's Analysis of the Costs and Benefits of the Graphic Warning Labels. July 2014. http://tobacconomics.org/research/evaluation-fda-graphic-warning-label-regulation-benefit-cost-analysis/.

[47] U.S Department of Health & Human Services. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Centers for Disease Control and Prevention, Office on Smoking and Health, 2014.

[48] Begley S. FDA Calculates Costs of Lost Enjoyment if E-Cigarette Rules Prevent Smoking. Reuters. June 2, 2014.

Regulatory Review Process

Finally, AHA would be remiss if we did not take this opportunity to express our disappointment upon learning that the proposed rule and the RIA were significantly altered by the Administration during the regulatory review process. We understand that the regulation development process is an arduous and time-consuming endeavor, and that many factors must be considered when developing an important public policy. However, it appears that the Administration lost focus on what the Tobacco Control Act was enacted to do – to protect the public health. That goal should have been the Administration's sole priority when reviewing the draft rule and RIA. Instead, it appears that other elements such as the tobacco industry's financial welfare may have been taken into consideration.

The proposed rule and RIA that were originally submitted by the FDA for review were noticeably stronger and geared more heavily toward protecting the public health. Unfortunately the versions approved by the Administration weakened the rule – proposing the possible exemption for premium cigars, softening language about the dangers of cigars and safety concerns with e-cigarettes, and eliminating language addressing the number of lives and the amount of money that would be saved by regulating cigars and requiring cigar warnings. We can only assume that these changes were made in response to the tobacco industry's numerous appeals to the Administration; these changes appear to have no public health justification.

Moving forward, we hope the FDA will have the autonomy to create a strong, final rule focused on reducing the death and disease toll from tobacco. We urge the Agency to reject any calls to weaken the rule and make concessions to the tobacco industry. AHA is prepared to stand behind you and support you in these efforts.

Conclusion

In closing, the American Heart Association reiterates its overall support for the proposed rule. The FDA must have regulatory authority over all tobacco and nicotine products and we are pleased that the Agency has finally started the process to bring cigars, e-cigarettes, and other tobacco products under its jurisdiction. We agree that all tobacco products should be subject to the basic deeming provisions, as well as the minimum age, vending machine, and warning statement requirements.

We do, however, urge the FDA to strengthen the rule in the following ways:

- Include premium cigars as a "deemed" tobacco product
- Clarify that age verification is required for Internet sales
- Require Internet and mail-order retailers to check the ID and age of customers at both purchase and delivery
- Ban self-service displays
- Direct retailers not to display tobacco products in the same area as candy or toys
- Require use of the cigar warning regarding infertility, stillbirth, and low birth weight
- Shorten the deadline for submission of a premarket review application to 12 months

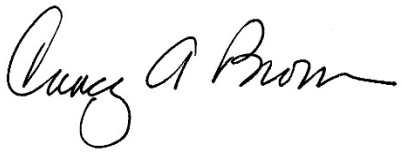
- Ban the use of characterizing flavors
- Ban the sale or distribution of branded promotional items
- Prohibit brand name sponsorship of events
- Require submission of advertising and labeling samples to the FDA
- Require warning labels and childproof packaging on e-liquid containers
- Establish a minimum pack size for inexpensive cigars

AHA also encourages the Agency to work as expeditiously as possible to release the final rule. Several years have passed since the FDA first announced it would assert its authority over these products. During that time, the market for cigars and e-cigarettes exploded and the number of youth using these products increased significantly. We fear that any additional delay will have real, and continuing, public health consequences. Therefore, we urge you to release the final rule by the end of this calendar year, but no later than 12 months from the publication of the proposed rule.

Thank you for consideration of our comments. We look forward to continuing to work with you to combat the significant public health threat posed by tobacco.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Senior Regulatory Affairs Advisor, at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,



Nancy Brown
Chief Executive Officer