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

**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**

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The American Association for Respiratory Care (AARC), together with numerous other advocacy organizations, has submitted joint comments to FDA on the subject “deeming” regulation filed by the Campaign for Tobacco Free Kids. In submitting separate comments, we want to highlight key points made in the joint entry that cannot be emphasized enough.

The AARC is a national professional organization representing 50,000 respiratory therapists who treat patients with chronic lung disease in all care settings. By virtue of their education and health care experience, respiratory therapists are professionals who have a clear understanding of the nature of cardiopulmonary disease and are in a position to act as advocates for healthy hearts and lungs. These highly trained professionals see every day the damaging effects to the health of their respiratory patients caused by use of tobacco products. Chronic obstructive pulmonary disease (COPD) is almost always caused by smoking, according to the National Heart, Blood and Lung Institute. Further, the Centers for Disease Prevention and Control reports COPD is the third leading cause of death.

The FDA currently regulates cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco under authority granted to it by the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA). The proposed rule would deem “all other tobacco products” to be subject to the same regulatory authority. This is a critical and long awaited step in protecting the public health against the risks posed by new and emerging tobacco products; however it does not go far enough to prevent manufacturers of tobacco products from designing and marketing their products in ways that undercut the full potential of the TCA to achieve its lifesaving objectives.

We strongly urge FDA to publish a final deeming regulation no later than one year of publication of the proposed rule, i.e., on or before April 25, 2015. Too many critical timelines such as those for warning labels are tied to when this rule is final. It has taken way too long to

get to this stage of the regulatory process, and any further delay and gaps left by the proposal will continue to have a negative impact on the health and safety of the public, especially young adults and children who are enticed by the tobacco industry's marketing techniques to use its products.

The AARC is an advocate for both tobacco cessation and tobacco prevention programs. As a responsibility to the public, we have taken a strong position against cigarette smoking and the use of tobacco in any form, including the inhalation of any toxic substance. Further, the AARC has developed a specific position statement on e-cigarettes as follows:

“In line with its mission as a patient advocate and in order to endure patient safety, the American Association for Respiratory Care (AARC) opposes the use of the electronic cigarette (e-cigarette). Even though the concept of using the e-cigarette for smoking cessation is attractive, they have not been fully studied and the use among middle school children is increasing year after year. There is no evidence as to the amount of nicotine or other potentially harmful chemicals being inhaled during use or if there are any benefits associated with using these products.”

### **FDA should regulate ALL TOBACCO PRODUCTS – There is no justification to exempt “premium cigars”**

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One of the first issues FDA proposes in its deeming rule is whether to regulate all cigars or carve out an exemption for “premium cigars.” To be exempt, FDA proposes such products must meet eight specific criteria.

In our view, there is no justification for exempting premium cigars or any other tobacco product. They should be deemed subject to the statute as all other products containing tobacco. Cigars are not just smoked by adults – kids smoke them too. 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 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. FDA should use its regulatory authority to its fullest extent.

### **FDA should set restrictions on sales and marketing**

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To prevent manufacturers from continuing to use many of the marketing strategies and techniques long used by cigarette companies to attract young people to their addictive products, FDA should impose on cigars, e-cigarettes and other deemed products the same

restrictions in the cigarette and smokeless regulations FDA published in 2010 as part of the mandate in the TCA. Of particular concern is flavoring in many of these products which attracts not only young adults but children as well. FDA should implement its proposed minimum age requirement of 18 and age verification for retailer sales of the deemed products.

1. It is imperative that FDA protect minors by extending the prohibition on self-service displays to cigars and e-cigarettes.

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, 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 can be placed next to candy in stores, making them attractive and accessible to minors.

2. FDA should prohibit internet sales of tobacco products, including e- cigarettes.

The internet makes buying all sorts of products easy. Minors should not be able to buy e-cigarettes and e-liquids online. At a minimum, the FDA should adopt the same age verification procedures for internet sellers of e-cigarettes and refill liquids that apply to internet sales of cigarettes.

3. FDA should restrict e-cigarette marketing appealing to minors.

E-cigarette companies 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. It's not surprising that the percentage of middle and high school students who reported ever using e-cigarettes doubled from 2011 to 2012.

Use of these non-cigarette tobacco products by youth is dangerous even if such use does not lead to or increase cigarette smoking. However, as FDA notes in its proposed rule, a non-cigarette tobacco product can be a starter product for new tobacco users before they migrate to cigarettes or other tobacco products or for existing users to become dual users.

4. FDA should implement its proposal to restrict vending machine sales and prohibit free samples.

We support FDA's proposal to extend the restrictions on vending machine sales of tobacco products that currently apply to cigarettes and smokeless tobacco products to all the deemed products. Vending machine sales present the potential for evasion of age verification

requirements and accordingly should not be permitted in any area to which persons under 18 have access. Likewise, we support FDA in prohibiting the distribution of free samples of tobacco products which increase the availability of such products to minors.

5. FDA should require notification regarding advertising

Current rules require manufacturers, distributors, or retailers intending to disseminate advertising for cigarettes or smokeless tobacco in a medium other than newspapers, magazines or periodicals, billboards, posters or placards, non-point-of-sale promotional material (including direct mail); point-of-sale promotional material; and audio and video formats delivered at the point of sale to notify FDA prior to the use of such medium. The purpose is primarily to provide notice on the extent to which such advertising or labeling may be seen by minors. Notification also applies to television advertising and advertising on the internet and social networks. FDA should also apply this requirement to advertising of the newly deemed products.

It is imperative that FDA act quickly to limit sales and marketing of cigars and e-cigarettes to minors.

**Flavored tobacco products pose a risk to public health; FDA should ban flavors in cigars and e-cigarettes**

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In addition to the data provided in joint comments on the appeal of flavors to young people, an article by Brady Dennis in the June 17, 2014, *Politics and The Nation* section of The Washington Post reports a recent study published in the journal “Tobacco Control” and co-authored by Shu-Hong Zhu, a professor in the Department of Family and Preventive Medicine at the University of California at San Diego. Zhu and other researchers found a “‘staggering’ proliferation of e-cigarette brands and flavors on the Internet in the past two years alone, with roughly 10 new brands and 240 new flavors arriving on the market every month.” The article goes on to say that a search of English-language web sites “identified 466 e-cigarette brands and 7,764 flavors...”

FDA’s proposed deeming rule fails to adequately address the use of characterizing flavors in deemed products. Therefore, FDA should take action immediately to develop rules to prohibit characterizing flavors (other than tobacco) in the deemed products, including cigars and e-cigarettes, as well as in currently regulated tobacco products.

Fruit and candy flavors are banned in cigarettes, and they should be banned in cigars and e-cigarettes. The increase in cigar use has been driven by an increase in the use of small, flavored cigars, with flavors like grape, watermelon and chocolate. E-cigarettes also are available in numerous flavors, including sweet tart, cotton candy, gummy bear and bubble gum. As studies

and tobacco industry internal documents reveal, sweet flavors are especially appealing to minors.

FDA should commence proceedings to issue a final rule governing flavors either as part of, or to be issued coincident with, the final deeming rule.

### **FDA should require child-proof packaging for e-cigarette liquid nicotine**

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Nicotine is a powerful neurotoxin, and even small amounts when ingested or absorbed through the skin can cause vomiting and seizures. The fact that these flavored liquids smell and taste sweet makes them even more appealing to children. Calls to poison control centers about liquid nicotine poisoning have risen dramatically. The FDA must act swiftly to require child-proof packaging of nicotine e-liquids and related products. We urge FDA to issue a proposed rule mandating child-resistant containers for liquid nicotine products no later than September 2014 to that a final rule can be issued coincident with the final deeming rule no later than April 25, 2015.

### **Proposed health warnings proposed by FDA should be adopted in the final rule**

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Although the TCA requires addiction warnings for cigarettes and smokeless tobacco, the absence of such warnings on products like cigars and electronic cigarettes may suggest to young people that such products pose little or no risk of addiction. The AARC is supportive of FDA's proposed mandate for nicotine-containing tobacco which states, "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." FDA also proposes several warning labels for cigars, one of which is "WARNING: Cigar Smoking Can Cause Lung Cancer and Heart Disease."

These proposed health warnings would promote public health and should be adopted in the final rule. The final rule also should provide for regular FDA review of the effectiveness of the warnings and revision of their content as necessary to ensure their freshness and informative power. Strong, prominent health warnings on tobacco products are an effective tool to inform consumers about the risks of disease and addiction. The AARC was supportive of FDA's earlier attempt to expand the size and graphic display of cigarette warning labels and encourages the agency to continue to push for the strongest content possible.

### **Conclusion**

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Passage of the TCA, designed to reduce tobacco-related disease and death, gave FDA the authority to regulate all tobacco products and FDA should exercise its authority to the fullest extent under the law. Every day that passes without FDA action exposes more young people to

the risk of nicotine addiction and tobacco-related disease. That is why the AARC, and other advocacy organizations who joined in comments filed by the Campaign for Tobacco Free Kids call for FDA to finalize the deeming rule no later than one year of publishing its proposed rule or April 25, 2015.

The final rule should be comprehensive in scope and sufficiently strong enough to protect the public, and particularly children, from known or potential risks of the newly-deemed products. FDA should reject the regulatory option that would exempt “premium cigars” from the deeming rule. Any gaps in FDA’s regulatory authority will be an invitation to tobacco industry manipulation to ensure that addictive and dangerous products escape regulation which can threaten to addict young people and inflict inevitable disease and death.

The AARC appreciates the opportunity to comment on this important proposal.

A handwritten signature in black ink, appearing to read "George Gaebler", with a long horizontal flourish extending to the right.

George Gaebler, MEd, RRT, FAARC  
President