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August 7, 2014

The Honorable Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products [FDA-2014-N-0189]

Dear Commissioner Hamburg:

The American College of Cardiology appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the notice of proposed rulemaking that would deem certain tobacco products to be subject to FDA regulation, also referred to as the "tobacco deeming" rule as published in the *Federal Register* dated April 25, 2014. The ACC is a 47,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

Tremendous strides have been made reducing mortality from cardiovascular disease in the last several decades. While there is still more to be done in this arena, it is crucial that we focus our attention on preventing the development of cardiovascular disease in the first instance, particularly cardiovascular disease caused by lifestyle choices. Since the publication of the first Surgeon General's report on Smoking and Health 50 years ago, an overwhelming amount of evidence has demonstrated the negative consequences of cigarette smoking and tobacco use on heart health. This elevation in risk is not limited to individuals who smoke cigarettes; it holds true for cigar smokers and others who use other tobacco products, as well as bystanders who are exposed to tobacco smoke. Attached please find a list of references on the outcomes or vascular effects of cigars and other products under consideration for regulation as part of this proposal. As such, the ACC strongly supports all efforts to restrict the availability, marketing and sale of tobacco products domestically and internationally.

KEY RECOMMENDATIONS

Despite the clear dangers posed by cigarette smoking and tobacco use, significant numbers of individuals continue to engage in the use of tobacco products, with new users each day. While the number of new smokers and tobacco users has declined, it is still too many. The College believes that it is incumbent upon the FDA to take all legally permissible steps necessary to restrict access to tobacco products and reduce the number of users. The FDA's current proposal regarding the regulation of tobacco products, including e-cigarettes, cigars and others, is groundbreaking in many ways, but it does not go quite far enough. Specifically, the College urges the Agency to:

- Move swiftly to issue all necessary regulations and guidance
- Regulate all tobacco products, including all cigars and those produced by small manufacturers
- Strictly regulate marketing of all tobacco products, including e-cigarettes, to youth
- Ban Internet sales of deemed products
- Prohibit characterizing flavors
- Require all five of the warnings from the Federal Trade Commission settlements be applied to cigars within a 12-month period
- Issue a product standard for liquid nicotine packaging to prevent liquid nicotine poisonings

Timing of regulations

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), which provided the FDA the authority to deem tobacco products, including e-cigarettes, as subject to regulation, was passed in 2009. It has taken more than four years to issue a proposed regulation. Each delay to the implementation of the deeming rule leads to the continued unrestricted of e-cigarettes and other tobacco related products to minors and potential harm to the public. And yet, the Agency does not anticipate the issuance of a final regulation until mid-2015, according to the recently released Department of Health and Human Services semiannual agenda, a full six years later. That is an additional six years that e-cigarette and tobacco manufacturers have had to expand their customer base, increasing the health risks of their customers and innocent bystanders. Providing them with an additional 24-month period of non-enforcement of pre-market review provisions only allows them more time to increase their customer bases, among minors in particular. **The ACC believes that it is long past time to take a stand and urges the Agency to move swiftly towards the adoption and enforcement of regulations that protect the public and the particularly vulnerable, specifically youth. The College opposes any delays in the implementation of such regulations, including, the substantial equivalence application period or any such proposal that would allow affected products to remain on the market unregulated or not regulated in a manner similar to cigarettes.**

Regulated products

Under the Tobacco Control Act, Congress explicitly recognized that tobacco products are, in fact, legal products available for adult use but still require regulation because virtually all new users of tobacco products are under 18 and the potential harms last far beyond the teenage years. Exempting "premium cigars" from regulation communicates the wrong message – that premium cigars are less harmful than other cigars. The evidence is clear – all cigars are harmful and potentially addictive to users, as well as pose health hazards to bystanders in the form of secondhand smoke. Tobacco use has been linked to a wide variety of hazardous health conditions that do not distinguish between those who can afford more expensive tobacco products and those who cannot. **As such, the ACC urges the FDA to exert its**

regulatory authority over all tobacco products, including cigars of all varieties. In the event that the FDA determines that "premium cigars" are less dangerous than others, the FDA should continue to assert its regulatory authority over them and establish regulations appropriate to the level of risk associated with premium cigars.

Cigar warning labels

The College supports the FDA's proposal to require health warnings on cigar packaging. However, the ACC is concerned that the FDA has not proposed to include all five of the warnings required for cigarette packaging by the Federal Trade Commission (FTC), excluding the warning pertaining to the potential reproductive harms associated with tobacco use. Given the available evidence supporting all five of the warnings, it would be inconsistent to exclude this warning from the list of requirements, and the College urges the FDA to amend this proposal to include all five FTC warnings for inclusion on cigar packaging as soon as possible.

Manufacturer size

The size of the manufacturer should have no bearing on the regulations to which its products are subject. According to all available evidence, tobacco products of all categories can cause significant harm, regardless of the size of their manufacturer. Given the potential implications, the cost of compliance for these small manufacturers is far outweighed by the public health benefits. **The College urges the FDA to apply the tobacco regulations to all manufacturers equally, regardless of size.**

Sales and marketing restrictions

Sale to minors

Manufacturers of tobacco products are well-aware that most new users of their products are under the age of 18. To take advantage of this and the lack of marketing restrictions to date, e-cigarette and other tobacco product manufacturers have targeted their marketing campaigns at this vulnerable demographic. These young new users of tobacco products become addicted before they fully understand the consequences. It is not until later in life, when they are diagnosed with a tobacco-related disease that has the potential to significantly shorten their lifespan that they truly understand those consequences – when it is far too late to change their course. **Given this, the College applauds the FDA's proposal to limit retail sales of tobacco products to individuals aged 18 or older and to require the performance of age verification procedures. The ACC also supports the Agency's proposal to prohibit the use of self-service displays.** In so doing, the FDA forces purchasers to interact with retail staff and ensures the opportunity for age verification for in-person sales.

Internet sales

However, the Agency's proposal does not extend quite far enough to really limit sales of tobacco products to minors. Internet sales are a significant portion of the market today and are far more vulnerable to illegal sales to minors than retail sales because it is much more complicated to verify age of purchasers online. **To ensure minors are unable to purchase deemed products online, the College supports a ban on Internet sales of deemed products.** Without such a ban, the prohibition against retail sales to minors will essentially be nullified and leave a significant loophole for minors seeking access to deemed products.

Marketing

Without regulations to prohibit them from doing so, manufacturers of e-cigarettes and other deemed products have adopted the marketing tactics of cigarette manufacturers, tactics that have since been prohibited by law, court decision or legal settlement. A recent Congressional hearing on the marketing tactics of e-cigarette manufacturers focused on the use of celebrities, cartoon characters and other such tactics clearly aimed at selling their products to minors. For instance, one member of Congress highlighted the use of a cartoon character similar to Joe Camel, one of the original brand mascots of Camel Cigarettes, while another focused on the use of Jenny McCarthy as a brand spokesman. The day after the hearing, McCarthy and the e-cigarette manufacturers announced a parting of ways, although both parties denied a connection to the publicity generated by the hearing. Given that these tactics are no longer permissible for use in the sale of cigarettes, the same should hold true of e-cigarettes and deemed products. **The College urges the FDA to limit the use of marketing tactics aimed at minors by manufacturers and sellers of tobacco products.**

Characterizing flavorings

One tactic the rule fails to address is the sale of characterizing flavorings for deemed products, despite clear and convincing evidence that these products are aimed specifically at minors. Research has clearly demonstrated that flavorings particularly appeal to youth, attracting them to tobacco use at a young age and greater risk of exposure to the health hazards associated with tobacco use. The Tobacco Control Act takes a strong stance in opposition to the sale of characterizing flavorings. These characterizing flavorings are generally candy and fruit varieties, designed to appeal to young people who are drawn to items that are sweet. **The College urges the FDA to ban the sale of characterizing flavorings for deemed products, as well as in currently regulated products.**

Event sponsorship

Companies also target youth through sponsorship activities. Family-oriented activities, such as music and sporting events, tend to be prime targets for sponsorship by tobacco products manufacturers because of the breadth and depth of the audience. Minors are particularly at risk for being targeted at these events because of their vulnerability and trust placed in celebrities and pop culture. Permitting sponsorship of such family-oriented events sends the wrong message to teens – that tobacco products are "cool" and potentially even healthy if connected to a sporting event, when they are anything but. **The ACC supports the extension of the current ban on sponsorship of music and sporting events by cigarette manufacturers to manufacturers of tobacco products and urges the FDA to include such a ban in the final rule.**

Nicotine poisoning concerns

Claims have been made that e-cigarettes are safer than cigarettes because the chemicals they release are closer to water than those released by cigarettes. However, there is little in the way of evidence to suggest that this is the case. In fact, similar to candy cigarettes and other similar products, e-cigarettes make smoking appealing and acceptable to minors and adults. Some have attempted to make the case that e-cigarettes can be used as a nicotine substitute and assist smokers attempting to quit, but evidence of this is ambiguous at best. While e-cigarettes may be less harmful than cigarettes in some respects because they do not require fire or produce the same type of smoke, they are just as addictive as cigarettes and other tobacco products. Pure liquid nicotine is considered to be a poison and should be treated as such. Poison control centers have seen a sharp increase in calls relating to accidental nicotine poisoning over the last three years, and more than half of those calls pertained to children under the age of five. At the very least, manufacturers must be forced to use childproof containers to store nicotine liquids. **The ACC urges the**

FDA to move swiftly to address concerns regarding the lack of childproof packaging of liquid nicotine containers through the issuance of a product standard for packaging.

Conclusion

The ACC supports the FDA's efforts to finally impose regulations upon e-cigarettes and other tobacco products but believes that the current proposal does not go far enough. Instead, we ally ourselves with the letters submitted by the Campaign for Tobacco-Free Kids, the state chapters of the ACC, the American Medical Association and thousands of others from medical professional societies, public health organizations, medical professionals, parents and others, urging the Agency to use the fullest extent of its authority to regulate tobacco products and to restrict their availability to minors. In fact, we believe that, as a public health agency, it is not only within the Agency's authority, but it is also the FDA's responsibility to do so.

Sincerely,

Patrick T. O'Gara, MD, FACC
President

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