American College of Physicians
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August 8, 2014

Leslie Kux, Assistant Administrator for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 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 Assistant Commissioner Kux,

The American College of Physicians (ACP) appreciates the opportunity to submit comments in response to the proposed rule titled "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." The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 141,000 internal medicine physicians (internists), related subspecialists, and medical students committed to advancing the science and practice of medicine. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The proposed regulation would deem certain tobacco products, including cigars, electronic nicotine delivery devices (referred to as "e-cigarettes" in the proposed rule), waterpipe/hookah tobacco and others to be subject to the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act. Deemed products would be subject to enforcement action against adulterated and misbranded products, ingredient and harmful constituent reporting requirements, and prohibitions on use of modified risk descriptors, among other provisions. The proposed rule would also establish age restrictions on deemed tobacco products and require health warnings on packaging and marketing materials for cigars, cigarette tobacco, roll-you-own tobacco, and others.

The College strongly supports regulation of all tobacco products and has developed numerous policy statements calling for comprehensive tobacco control efforts to prevent smoking and tobacco product use among young people and adults. In 2009, the College released the policy paper *Tobacco Prevention and Control*. The paper included recommendations that state and federal governments work together to implement comprehensive tobacco use prevention and control efforts, that youth tobacco use education and prevention campaigns be initiated, that flavorings—including menthol—be banned in all tobacco products, and that electronic nicotine delivery systems (also known as electronic cigarettes) be regulated by the FDA.

In September 2013, ACP joined a number of stakeholders in sending a letter to President Obama calling for the Department of Health and Human Services to release a proposed rule to regulate all tobacco products. The FDA's proposed rule represents a promising first step toward eliminating tobacco product use in all forms. ACP makes the following recommendations to strengthen the proposed rule and urges the agency to extend its regulatory authority to all tobacco products, including all cigars, in a timely manner. The College is concerned that the effective implementation date of the rule's proposals will be up to 24 months following publication of the final rule. ACP urges the FDA to shorten the implementation period and expedite agency oversight of tobacco products.

Recommendations

ACP urges FDA to deem all cigars as subject to FDA's authorities in the FD&C Act as well as the additional provisions proposed under the proposed rule.

The College concurs with the Surgeon General that there is no safe tobacco product. ACP supports the regulation of all tobacco products, including all cigars. In its 2010 policy monograph *Tobacco Control and Prevention*, the College recommended that comprehensive tobacco control efforts should seek to reduce use of cigars and pipes in addition to cigarettes, particularly among young people and cigarette smokers.[1] Cigars have emerged as a popular alternative to cigarettes because they are subject to lower excise taxes and many users believe them to be safer. From 2000 to 2011, consumption of cigar and loose tobacco increased by 123 percent while cigarette use dropped by about 33 percent.[2] Further, while cigarette use rates among high school students are at their lowest in 22 years, reductions in cigar use among adolescents have stabilized, and 23 percent of male high school seniors reported that they currently use cigars.[3] An HHS report found that young people also believe cigars to be more accessible and less socially stigmatized than cigarettes.[4]

Cigars pose a number of health risks to users. Individuals who inhale cigar smoke are at an increased risk of heart and pulmonary disease.[5] Cigarette users who substitute cigars are more likely to inhale, exposing themselves to higher levels of nicotine, toxins, and carcinogens.[5] To encourage dual-use of cigarettes and cigars, some tobacco companies have marketed small cigars as alternatives to cigarettes by offering similar filter tips and packaging; a 2004 advertisement for Smoking Joe's small cigars described the product as "the perfect everyday smoke."[6] Despite misconceptions about relative safety of cigars, large cigars (referred to in the rule as "premium cigars") contain as much nicotine as a pack of cigarettes. ACP recommends that all cigars be deemed as subject to the FDA's regulatory authority, including those defined in the proposed rule as premium cigars.

ACP recommends that characterizing flavors be prohibited in all tobacco products, including cigars, e-cigarettes, and waterpipe/hookah tobacco.

ACP strongly supports Section 907 of the Tobacco Control Act that prohibits the inclusion of flavorings in cigarettes, particularly as a means to deter youth from using tobacco. College policy states that "given flavored tobacco's strong appeal to youth, all types of flavored tobaccos should be prohibited." ACP also supports prohibition of menthol flavoring in all tobacco products, although we acknowledge that this proposed rule does not discuss such action. Young people are more attracted to flavored tobacco products than older individuals. Fifty-two percent of smokers between the ages of 13 and 18 who had heard of flavored cigarettes stated an interest in trying them, and 60 percent stated that they would taste better than non-flavored cigarettes.[7] For decades, tobacco companies have used flavored tobacco as a means to attract young and inexperienced smokers. Internal tobacco company research from the 1980s and 1990s found that young people preferred flavored tobacco and believed such products provide enhance social acceptance and "smoking enjoyment."[8]

Youth attraction to flavored tobacco persists despite the ban on flavored cigarettes and evidence shows that flavored products can lead to a lifetime of tobacco addiction. A 2013 study published in the American Journal of Preventive Medicine found that "young adults were more likely to use flavored tobacco products" and concluded that "those most likely to use flavored products are also the most at risk of developing established tobacco-use patterns that persist through their lifetime."[9] Further, young smokers may believe that flavored tobacco products are less harmful; a survey of hookah users aged 18 to 30 found that 35 percent believed that the fruit flavoring in hookah tobacco "detoxif[ied] tobacco's harmful chemicals."[10] Because tobacco users most often initiate use during adolescence[11] and are more likely to be attracted to flavored products, the FDA should use its authority to ban characterizing flavors in all tobacco products.

Electronic nicotine delivery systems—commonly known as e-cigarettes—should be deemed subject to the Tobacco Control Act.

Electronic nicotine delivery systems (ENDS), popularly known as e-cigarettes, are devices designed to imitate conventional cigarettes that deliver nicotine via inhalation. In contrast to cigarettes, which involve combustion of tobacco, electronic cigarettes heat the nicotine solution in order to produce a vapor that is inhaled by the consumer. The College strongly supports the regulation of electronic cigarettes, stating that, "ACP believes that since e-cigarettes deliver nicotine and may contain a host of dangerous carcinogens and chemicals, they should be aggressively reviewed and regulated by the FDA."[1] There has been a substantial increase in e-cigarette use in recent years: a survey of more than 10,000 U.S. adults estimated the use of ENDS quadrupled from 2009 to 2010.[12] E-cigarette use among young people is also growing. Data from the Centers for Disease Control and Prevention estimated that e-cigarette use has more than doubled among U.S. middle and high school students from 2011 to 2012.[13]

Although e-cigarettes are touted by supporters for their potential as a smoking cessation aid, at this time empirical data on their efficacy to help smokers quit is limited and inconclusive.[14,15] It is apparent that e-cigarettes may expose users to a number of toxins and dangerous chemicals. FDA chemical analysis suggests that e-cigarettes contain a number of carcinogens and that one product tested by the agency contained ethylene glycol, a toxic chemical.[16,17] E-cigarette use may have negative side effects, including mouth irritation and dizziness.[18] Other potential health hazards include the effect of battery vapor inhalation and battery liquid leakage. [19]

Lack of e-cigarette market oversight has led to inconsistencies in product quality. For example, the nicotine content of e-cigarettes varies widely. A study that analyzed nicotine levels in vapor generated from sixteen popular electronic cigarette brands found that nicotine levels varied between 0.5 to 15.4mg after twenty series of fifteen puffs.[20] E-cigarette product labeling is variable and may mislead consumers. One study found nicotine content labels to be highly inaccurate, determining that products claiming to be nicotine-free actually did contain nicotine.[21]

E-cigarette marketing has increased dramatically in the last few years, with upstart manufacturers and long-established tobacco companies like Lorillard devoting millions of dollars to promoting the nicotine delivery products. In 2013, the largest e-cigarette companies spent $60 million on marketing, and e-cigarette company NJOY has said that it plans to spend $30 million on U.S.-based marketing in 2014.[22,23] Young people are getting the e-cigarette message: youth exposure to e-cigarette television advertisements increased 256% from 2011 to 2013 and young adult exposure increased 321% over the same period.[24] E-cigarette use may reduce the stigma attached to smoking, making it seem like a socially acceptable practice, particularly among impressionable young people. A survey of young male (aged 15 to 17) e-cigarette smokers found the devices to be popular because they are "accessible, healthier than tobacco cigarettes, and more aesthetically pleasing."[25] Like other tobacco products, e-cigarettes are available in a variety of flavors that may appeal to children, such as vanilla, chocolate, and bubble gum. ACP reiterates that flavorings should be banned from all tobacco products, including e-cigarettes. Children can be

adversely affected by nicotine exposure; poison control centers have reported an increasing number of calls seeking assistance for young children and infants who have been exposed to e-cigarettes and their components.[26]

The College urges the FDA to expedite implementation of regulatory authority over e-cigarettes. Given the health consequences that such products may pose, it is important that the agency begin to collect data and conduct research on manufacturing standards, nicotine content, chemical composition, and the product's efficacy as a cessation device. Further, the agency must take action to prevent youth marketing and sales, such as by restricting youth-oriented advertising and marketing and providing strong oversight of online sales to ensure age restrictions are being enforced. The agency must also scrutinize e-cigarette advertising and promotion to ensure that manufacturers do not make unsubstantiated claims about smoking cessation benefits.

Strengthen the warning statements for tobacco products.

In January 2011, ACP submitted comments regarding the proposed rule titled "Required Warnings for Cigarette Packages and Advertisements."[27] The College recommended that the FDA:

- Require that smoking cessation resource and referral information be included on all new graphic health warning labels,
- Increase the overall size of the warning labels to 50% of package space, and
- Strengthen the textual warning statement language to be more conclusive and consider adding supporting explanatory language.

Strong warning statements should be included on all tobacco products and advertisements, including premium cigars. Multiple warning statements for cigars should be established to ensure that the message remains impactful and does not become stale and overexposed. Similarly, the FDA should consider developing multiple warning statements regarding the addictiveness of nicotine.

Establish strong restrictions on all tobacco product sales, advertising and marketing directed at and appealing to children and young people.

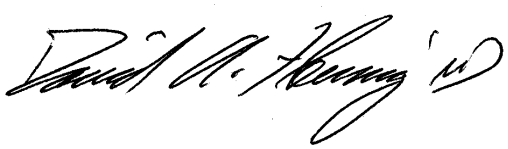
ACP policy supports a ban on the marketing and promotion of tobacco. The proposed rule would restrict tobacco product sales to individuals aged 18 or older, establish age verification requirements, and a prohibition on the distribution of free samples. These policies are a step in the right direction, but ACP recommends that the FDA strengthen marketing and sales restrictions by aligning them with those established for cigarettes and smokeless tobacco. Doing so will ensure regulatory consistency and prevent sending mixed messages to consumers that exempt tobacco products are less harmful than cigarettes and smokeless products. ACP recommends that the final rule include blanket prohibitions on self-service retail displays; use of tobacco brand names on non-tobacco products; and restrictions on marketing, sponsorship, and promotion of newly-deemed products at sporting, athletic, and music events for all tobacco products including newly-deemed products.

Conclusion

ACP applauds the Food and Drug Administration for taking a first step toward expanding the Tobacco Control Act provisions to all tobacco products. The College urges that the agency expedite publication of a final rule, so that all tobacco products are regulated and kept away from young people.

Please contact Ryan Crowley at rcrowley@acponline.org if you have any questions regarding this letter.

Sincerely,



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