



American College of
Preventive Medicine

August 8, 2014

Margaret Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg,

On behalf of the American College of Preventive Medicine (ACPM) we would like to thank you for the opportunity to comment on the Food and Drug Administration's (FDA) "deeming rule" to expand its regulatory authority to various "deemed" tobacco products, including electronic cigarettes. ACPM is the national medical professional society for over 2,500 physicians who dedicate their careers to disease prevention and health promotion at the individual and population levels. Because tobacco use is the single most preventable cause of death and disease in the US, ACPM commends the FDA's efforts to protect the public's health from the harms of tobacco products.

In the past, tobacco companies have misled the general public regarding the health impact of their products resulting in premature morbidity and mortality. Thus, we urge that FDA not exempt premium cigars from its regulatory authority; 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. Furthermore, cigars may contain greater quantities of nicotine than cigarettes and high school boys now report they smoke cigars at the same rate as cigarettes.

ACPM supports FDA's proposal to establish a national minimum age (18) for the purchase of the newly-deemed tobacco products sold by retailers, as well as requiring age verification. Additionally, to protect youth from purchasing these products, because of the difficulty in enforcing age verification on internet purchases, stronger restrictions should be placed on internet sales,. Also, restrictions on deemed products should be similar to those that apply to cigarettes and smokeless tobacco products, including;

- prohibition of self-service displays,
- imposing a minimum pack size to prevent sale of inexpensive cigars to price-sensitive kids,
- prohibition of the distribution of non-tobacco merchandise carrying a tobacco product logo., and

- prohibition of brand sponsorship of athletic or musical events that may have significant youth attendance.

The FDA's proposal does not include advertising restrictions, and given studies showing that the majority of teenagers have been exposed to TV and print ads, along with the increasing use of e-cigarettes among youth, ACPM encourages FDA to enforce the same or similar advertising reporting restrictions currently applied to cigarettes and smokeless products to all deemed products.

ACPM fully supports FDA's proposal to require additional health warnings on cigars and further urges the FDA to include the Federal Trade Commission (FTC) warning addressing increased risk of "infertility, stillbirth and low birth weight," especially with the Youth Risk Behavior Survey showing that cigar smoking prevalence among high school students is declining at a far slower rate than cigarette smoking prevalence. Health warning requirements for deemed products also should be mandated for a 12-month compliance period from the date of the final rule in order to comply with the minimum compliance period included in the Tobacco Control Act (TCA).

The lack of an FDA proposal for restrictions on the sale of flavored cigars or e-cigarettes poses concern for usage of these products among youth. Studies have shown that every day a large number of kids try cigar smoking for the first time. Studies also note growing use of e-cigarettes among youth. Electronic cigarettes are available in numerous flavors, including vanilla, chocolate, peach schnapps, bubblegum and cola, and there is little doubt that these sweet, fruity flavors are especially appealing to kids. ACPM urges the FDA to impose restrictions on the use of flavors that appeal to kids in newly-deemed products.

Despite the recent report from Centers for Disease Control and Prevention (CDC) that poison control centers received over 215 phone calls related to e-cigarette exposures in February 2014 alone, FDA's proposed rule would do nothing to address the widespread availability of the candy-flavored, nicotine-laced liquid used in e-cigarette containers with no child-resistant features. Given the urgency of this threat to children, FDA should issue a proposed rule to require child-resistant packaging of e-liquids.

ACPM urges that the FDA apply modified risk claims with rigor, particularly in light of the health claims often made by manufacturers of electronic cigarettes, so that the public will be protected against false and misleading claims of "reduced risk" made by the tobacco industry. The FDA should thoroughly substantiate the claim and grant an application that the claim can be made, thereby providing a pathway to market for evidence-based modified risk claims.

It is imperative that FDA issue a final deeming rule within one year of publishing its proposed rule (i.e., no later than April 25, 2015) to close the gaps left by the proposed deeming rule, including the failure to address the problems caused by current advertising and sponsorship of deemed products and the use of flavors in these products that make them appealing to youth. For every day that passes without FDA action, there will be more young people exposed to the risk of nicotine addiction and tobacco-related disease.

ACPM applauds the FDA for its commitment to public health. Thus, we strongly support FDA oversight of tobacco products and establishment of a scientifically-based, regulatory framework for all tobacco products. This tobacco deeming regulation represents a landmark achievement for FDA and all public health stakeholders. Today, FDA is uniquely positioned to prevent the costly and deadly addiction to tobacco products, an addiction that has no social, economic, or cultural boundaries. We look forward to working with you to protect the public from the harms of tobacco products and offer our assistance in your efforts. Should you have any questions, please contact Paul Bonta, Associate Executive Director, Policy, Advocacy and External Affairs, at pbonta@acpm.org or 202-466-2044, extension 110.

Sincerely,

A handwritten signature in black ink that reads "Halley S. Faust, MD". The signature is written in a cursive, slightly slanted style.

Halley S. Faust, MD, MPH, FACPM
President