AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

June 2, 2014

Leslie Kux, Assistant Commissioner 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 FDA

Dear Assistant Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, I write in response to the "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" proposed rule as published in the April 25, 2014, *Federal Register*.

In this regulation, the FDA takes an initial step to "deem" its authority to regulate currently unregulated nicotine delivery devices, including electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvables. The regulation also proposes to prohibit the sale of "covered tobacco products" to individuals under the age of 18 and to require the display of health warnings on cigarette tobacco, roll-your-own tobacco, and on covered tobacco product packages and in advertisements.

Especially since the AAFP joined with other national organizations in a letter sent September 19, 2013 to the President urging the FDA to move forward promptly and assert jurisdiction over all tobacco products, the AAFP wholeheartedly supports the FDA's assertion of authority over all nicotine delivery devices regardless of flavor and we agree that tobacco products should not be sold to anyone under the age of 18.

Given that nicotine is an addictive drug, AAFP policy specifies that the FDA must have full jurisdiction over all tobacco products and nicotine delivery devices and be permitted to use the same procedures to regulate tobacco. Further, FDA decisions should be subject to the same standard of review that generally applies under the Food, Drug and Cosmetic Act. The tobacco industry should respond to the same regulatory forces that govern other similar industries and should not be able to choose the amount of regulation they accept. Further, the FDA should have authority to regulate the manufacture, sale, labeling, distribution and marketing of tobacco products and nicotine delivery devices. It is our policy on e-cigarettes that we recognize increased use among youth and those attempting to quit smoking tobacco. Electronic cigarettes are unregulated, battery-operated devices that contain

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nicotine-filled cartridges. The resulting vapor is inhaled as a mist that contains flavorings and various levels of nicotine and other toxic substances. Although e-cigarettes may be less toxic than smoking combustible tobacco cigarettes, there is inadequate empirical evidence supporting the efficacy of e-cigarettes as a smoking cessation device. However, some physicians and public health groups consider the use of these devices as a harm-reduction strategy. Anecdotal accounts of people using e-cigarettes as a cessation device have led some to believe that these products have the potential to help them quit – especially the long-term, highly addicted smoker. Others are concerned that e-cigarettes may contribute to nicotine dependence, promote dual use of both products, and encourage nicotine consumption. E-cigarettes may also introduce children to nicotine and potential addiction.

The AAFP calls for rigorous research in the form of randomized controlled trials of e-cigarettes to assess their safety, quality, and efficacy as a potential cessation device. The AAFP also recommends that the marketing and advertising of e-cigarettes to children and youth cease immediately. We encourage the FDA to consider regulations that tighten distribution of these products when purchased through Internet vendors, to ensure that minors do not circumvent face-to-face sales restrictions. Social media and the Internet are becoming the advertising platforms of choice for these novel products, and the AAFP encourages the FDA to regulate these advertising venues. The AAFP is particularly concerned that many of these products, including little cigars and e-cigarettes, feature flavors that are attractive to youth and we encourage the FDA to ban the use of such flavors.

The AAFP remains fully committed to assist in the development of educational campaigns related to the dangers of tobacco use in all forms. The AAFP's Tar Wars campaign is a tobacco-free education program for fourth- and fifth-grade students. The goal of the program is to educate and motivate students to be tobacco free, mobilize health care professionals to become proactive in their community's health education, and encourage community involvement in support. Our separate Ask and Act tobacco cessation program encourages family physicians to ask all patients about tobacco use, then to act to help them quit.

Finally, the AAFP urges the FDA to promulgate promptly a final rule and begin in earnest to regulate the manufacture, distribution and safety of e-cigarettes and other nicotine delivery devices.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Jeffrey J. Cain, MD, FAAFP
Board Chair

CC: Mitch Zeller, J.D., Director, Center for Tobacco Products