



May 17, 2017

Leslie Kux, Associate Commissioner for Policy  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Associate Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the [request for comments](#) titled, "Battery Safety Concerns in Electronic Nicotine Delivery Systems" as published by the U.S. Food and Drug Administration in the January 4, 2017 *Federal Register*.

The AAFP recognizes the increased use of [electronic cigarettes](#) (i.e., e-cigarettes) especially among youth. Electronic cigarettes are unregulated, battery-operated devices that contain 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 no empirical evidence supporting the efficacy of e-cigarettes as a smoking cessation device.

However, some physicians and public health groups consider the use of said devices as a viable 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 concurrent use of combustibles and e-cigarettes, and encourage nicotine consumption. E-cigarettes may also introduce children to nicotine and potential addiction.

We are concerned about the current lack of regulatory oversight by the FDA on the manufacture, distribution and safety of e-cigarettes. Within the AAFP's position paper titled, "[Tobacco: Preventing and Treating Nicotine Dependence and Tobacco Use](#)," we cite reports about using e-cigarettes to smoke marijuana and instances of e-cigarettes and their batteries exploding resulting in damage to persons and property. Therefore, 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, especially to children and youth, should cease immediately until e-cigarette safety, toxicity, and efficacy are established.

There have been many reports documenting that the lithium ion batteries in electronic cigarettes can cause serious burns and explosion injuries. These concerns about the hazards associated

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with e-cigarettes have resulted in the U.S. Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration last year banning portable electronic smoking devices in checked baggage. The FDA could reduce the risk for injury by requiring changes in the design of the devices.

We appreciate the opportunity to comment and make ourselves available for your questions. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or [rbennett@aafp.org](mailto:rbennett@aafp.org).

Sincerely,

A handwritten signature in cursive script that reads "Wanda D. Filer, MD".

Wanda D. Filer, MD, MBA, FAAFP  
Board Chair