

February 1, 2019

The Honorable Scott Gottlieb, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; Docket No. FDA-2018-N-3952

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to *Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies*. The AMA appreciates the U.S. Food and Drug Administration's (FDA) efforts to address the epidemic of youth tobacco use. Tobacco products in any form are harmful and addictive and can cause disease and death. Tobacco use is the leading cause of preventable deaths in the United States and is responsible for more than 480,000 deaths annually.

### **Current Trends in Tobacco Use**

Recent trends in tobacco use are of great concern. Among high school students, current electronic cigarette (e-cigarette) use increased by 78 percent in the last year, and among middle school students, current e-cigarette use rose by 48 percent.<sup>1</sup> Use of e-cigarettes, hookah, non-cigarette combustible tobacco, or smokeless tobacco by youth is associated with cigarette smoking one year later.<sup>2</sup> Furthermore, the risk of progressing to conventional cigarette smoking is increased with use of multiple forms of non-cigarette tobacco, suggesting that novel tobacco products have the potential to undermine public health gains in combatting the smoking epidemic.<sup>1</sup> During 2017–2018, overall tobacco product use (cigarettes, cigars, smokeless tobacco, e-cigarettes, hookahs, tobacco pipes, snus, dissolvable tobacco, and bidis) increased by 38 percent among high school students and by 29 percent among middle school students.<sup>1</sup> Reports indicating that preliminary data from the National Youth Tobacco Survey show an increase in high school student use of combustible cigarettes from 7.6 percent in 2017 to 8.1 percent in 2018 are concerning. E-cigarette use among youth and young adults is a public health concern, and coordinated efforts are needed to protect young people from a lifetime of nicotine addiction.

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<sup>1</sup> Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018*. *MMWR* 2018; 67:1276–1277.

<sup>2</sup> Watkins SL, Glantz SA, Chaffee BW. Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013–2015. *JAMA Pediatr.* 2018;172:181–187.

## **Preventing Youth Tobacco Use**

The AMA recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and has pledged to work with the FDA and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices. The AMA believes that while it is important to consider drug therapies for youth who are already addicted, preventing youth tobacco use and nicotine addiction must be the priority. The AMA has encouraged the enactment of laws that would set the minimum age for purchasing tobacco products, including e-cigarettes, at 21 years and urges strict enforcement of laws prohibiting the sale of tobacco products to minors.

AMA policy also calls for the FDA to prohibit the use of flavoring agents in tobacco products, including e-cigarettes. With flavored e-cigarette products still available on the market, it is important that youth access is closely monitored. The AMA urges the FDA to create a non-addictive nicotine level standard for all tobacco products, including cigarettes, smokeless tobacco and e-cigarettes. Given that combustible cigarettes are not the only addictive form of tobacco, applying this standard across all tobacco products is essential.

## **Evidenced-Based Tobacco Cessation in Youth**

The U.S. Preventive Services Task Force (USPSTF) recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents. The USPSTF found adequate evidence that behavioral counseling interventions, such as face-to-face or phone interaction with a health care provider, print materials, and computer applications, can reduce the risk of smoking initiation in school-aged children and adolescents. While the FDA has approved several smoking cessation products, including nicotine replacement therapy (NRT) and non-nicotine pharmacotherapies, none of these medications are currently approved by the FDA for tobacco cessation in children and adolescents. Furthermore, studies evaluating behavioral interventions plus medication (sustained-release bupropion alone or combined with NRT) in youth showed no statistically significant benefit from the medication.<sup>3</sup>

## **More Research is Needed**

Given the trends in youth tobacco use, additional research is needed. While current research in this area is very limited, it also almost exclusively focuses on the use of combustible cigarettes. We have little understanding of the trajectory of nicotine dependence for e-cigarette users. Furthermore, it is not clear if behavioral interventions and drug therapies for combustible cigarettes are effective in e-cigarette users. While drug therapies for youth tobacco cessation are needed given the current public health epidemic of youth e-cigarette use, behavioral interventions that can reduce the risk of initiating e-cigarette use are essential.

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<sup>3</sup> Patnode CD, O'Connor E, Whitlock EP, Perdue LA, Soh C. Primary Care Relevant Interventions for Tobacco Use Prevention and Cessation in Children and Adolescents: A Systematic Evidence Review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 97. AHRQ Publication No. 12-05175-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; December 2012.

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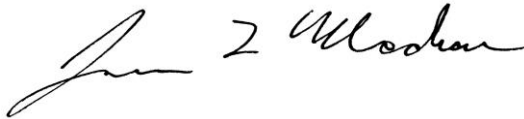
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We recognize that there are ethical concerns and limitations to conducting research and clinical trials involving youth. Given the current epidemic of youth e-cigarettes use we are facing, it will be important to adequately address these barriers.

We look forward to working closely with you and other agencies to prevent another generation from developing nicotine dependence. If you have questions, please contact Margaret Garikes, Vice President, Federal Affairs at [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org) or 202-789-7409. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD