

April 30, 2019

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket ID: FDA-2019-D-0661, Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry; Availability**

To Whom It May Concern:

The American Association for Cancer Research (AACR), with over 42,000 members and residing in 120 countries, is the first and largest scientific organization in the world dedicated to the prevention and cure of cancer through research, education, communication, collaboration, science policy and advocacy, and funding for cancer research. We appreciate the opportunity to provide comments in response to the U.S. Food and Drug Administration's (FDA) Draft Guidance, "Modifications to Compliance Policy for Certain Deemed Tobacco Products."

**The Dangers of Tobacco Use:**

Tobacco use is the leading preventable cause of premature mortality in the United States and globally. In 2016, active and secondhand smoking was responsible for about a half million deaths in the U.S., accounting for about 1 in 10 deaths from multiple causes. Globally, the number is even more striking, as tobacco use accounted for more than 7.1 million deaths in 2016.

Specifically, tobacco use accounts for 30 percent of all cancer deaths and incidence and is causally associated with 18 different human cancers including, among other cancer types: lung, head and neck, stomach, pancreas, colon, and cervical cancers. Additionally, continued use of tobacco products by cancer patients currently undergoing treatment as well as by cancer survivors who previously completed treatment, are at an increased risk of dying from cancer, developing a second malignancy, or suffering from severe cancer treatment toxicity.

Tobacco use in any form is one of the strongest threats to public health; therefore, to curb this epidemic, we must enforce existing laws, implement evidence-based policies to stem tobacco use with greater vigor, and invest in more research to understand nicotine addiction to inform effective control measures. As outlined in the 2014 Surgeon General's Report, efforts to reduce the use of combustible products, either by reducing their appeal and/or addictiveness, are

important to substantially reduce the burden of tobacco-caused death and disease. Currently, there are a number of tobacco products on the market, with combustible products being the most harmful. However, greater attention must now be given to novel tobacco products, such as e-cigarettes, because of the increasing uptake of these products by young people.

### **The AACR Recommends More Research on the Safety and Efficacy of E-cigarettes as a Cessation Tool**

Given the paucity of data regarding the safety of e-cigarettes in relation to complete cessation and the lack of data on their long-term health effects, we cannot currently endorse the use of these products as first-line cessation therapies for current adult smokers until there is a better understanding of the potential benefits for cessation and the development of best practices for the use of e-cigarettes in tobacco cessation (e.g., combined with behavioral counseling). We believe that, since e-cigarettes are not currently an FDA-approved smoking cessation method, their use in lieu of currently validated methods (i.e., pharmacotherapy combined with counseling) should be discouraged. Instead, patients should be counseled to use the proven efficacious methods. We recognize that some patients have opted on their own to use e-cigarettes to quit the use of combustibles and are unwilling to try known methods of quitting with additional behavioral support or changes to their pharmacotherapy. In such cases, providers should work with patients using e-cigarettes to offer counseling and support and transition patients back to known methods if the e-cigarettes are not working. We believe that e-cigarettes should not be recommended to the patients as a smoking cessation device as primary therapy in lieu of exhausting recommendation guidelines that include multiple "lines" of therapy and counseling. However, we are disinclined to support the enactment of policies that would create undue barriers to adult cessation attempts using these products.

While the 2018 National Academies of Sciences, Engineering, and Medicine (NASEM) report, *Public Health Consequences of E-cigarettes*, states that there is insufficient evidence to support the effectiveness of e-cigarettes as cessation aids, the expert committee from the NASEM also reported that “there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.” Additionally, “there is substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.”<sup>1</sup> Therefore, for individuals who have been unable to quit smoking through currently available FDA-approved medications and behavioral therapy, complete switching to these products might be a means of reducing harm. E-cigarettes may be a less risky alternative than smoking combustible products,

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<sup>1</sup>National Academies of Sciences, Engineering, and Medicine. 2018. Consensus Report: Public Health Consequences of E-Cigarettes.

but the evidence for use of e-cigarettes in cessation therapy, although accumulating, is not yet definitive.

### **The AACR's Response to the FDA's Draft Guidance**

The AACR applauds the FDA for considering modifications to the compliance policies for premarket review requirements for certain deemed tobacco products. Since we would not want another generation of youth to succumb to nicotine addiction, we strongly support efforts to reduce the use of these products by tobacco-naïve youth and young adults.

In response to the FDA's Federal Register announcement, and in recognition of the significant knowledge content within the FDA's Center for Tobacco Products (CTP), the AACR provides comments on the following points raised in the Federal Register notice:

- *The FDA requests comments on other examples of products that are offered for sale in ways that pose greater risk for minors to access such products.*

We believe that access to any tobacco product should be restricted for youth and that age should be verified upon purchase. However, we are concerned that, by moving e-cigarette products to restricted areas while leaving combustible products on display behind convenience store counters, the FDA would be making the most harmful products (i.e., combustible products) more accessible to youth than comparatively less harmful products (i.e., e-cigarettes) which would be sequestered in age-restricted areas. If age-restricted areas are required for e-cigarettes, we suggest that all combustible cigarettes be moved to restricted areas as well.

- *FDA solicits comments on whether there are any technologies or other measures that would be well tailored to address youth access to ENDS products, as well as any additional data that would be relevant to FDA's formulation of its enforcement priorities.*

It is our understanding that there are products in development to disallow e-cigarette use on school properties (e.g., Bluetooth technologies and Wi-Fi enabled geofencing). Implementing the use of these technologies may increase the price of these products initially, but we believe that competition in the market will encourage these products to be priced so that these products will be accessible to current smokers of a lower socioeconomic class. We understand that there are important privacy issues involved with the use of these technologies, but feel that the benefit of protecting children outweighs any potential privacy concerns. We urge companies to create products in a way that protects youth and is the least invasive regarding privacy issues.

- *FDA requests comments on whether to adjust the premarket review compliance date to August 8, 2021 for all ENDS products, including mint, menthol, and tobacco-flavored ENDS products.*

We agree with moving the premarket review compliance date to August 8, 2021 to reduce the number of and labelling of products that are appealing to youth. While we believe that flavors in addition to tobacco, mint, and menthol should be available to adult smokers because of the evidence showing the use of flavored products among smokers who are trying to quit smoking may be helpful, changing the labeling of these flavors should be implemented so that they do not appeal to youth. For example, instead of labels like Gummy Bear and Strawberry Daquiri, the label Fruit could be used. Furthermore, FDA should consider issuing product standards for e-cigarettes to reduce any undue toxicity of the product (e.g., metals, materials used for the coils, unnecessary toxicants in e-fluids, level of power, etc.).

In conclusion, the AACR commends the FDA for reevaluating the compliance policy for certain deemed tobacco products. Thank you very much for considering our input on this important issue. These comments are based on careful discussion and evaluation of the extant literature on tobacco use and its effects by the AACR's Subcommittee on Tobacco Products and Cancer (roster attached), and are approved by the Subcommittee on Tobacco Products and Cancer and the Science Policy and Government Affairs Committee. If the AACR can provide any additional information or assistance to the FDA, please do not hesitate to contact Nicole Boschi, PhD, Senior Science Policy Analyst, at 215-446-7275 or [nicole.boschi@aacr.org](mailto:nicole.boschi@aacr.org).

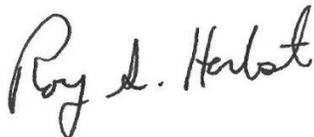
Sincerely,



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