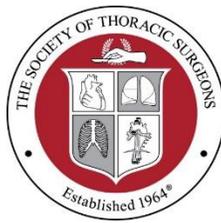


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April 10, 2019

*Submitted electronically to regulations.gov*

Mitch Zeller, J.D.  
Director  
Center for Tobacco Products  
U.S. Food and Drug Administration  
Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**RE: FDA-2019-D-0661-0003; Modifications to Compliance Policy for Certain Deemed Tobacco Products**

Dear Director Zeller,

On behalf of The Society of Thoracic Surgeons (STS), I write to strongly support the Food and Drug Administration's (FDA) recent draft guidance document titled *Modifications to Compliance Policy for Certain Deemed Tobacco Products* as published in the Federal Register on March 14, 2019. The Society commends the FDA for its ongoing efforts to protect youth from the harms of nicotine and help adult smokers quit.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Studies show that, while tobacco use among adults is decreasing, the usage of electronic nicotine delivery systems (ENDS) has increased among our nation's youth.<sup>1</sup> The 2016 Surgeon General Report on e-cigarettes and other ENDS products concluded that flavoring is among the most commonly cited reasons why youth and young adults use e-cigarettes.<sup>2</sup> Therefore, STS strongly supports the FDA's efforts to prioritize enforcement regarding the following: flavored ENDS products sold in ways that pose a greater risk for minors such as those sold in locations that minors can enter at any time; products targeting minors using television, radio, and social media advertisement; and products that do not have a premarket application submitted to the FDA by 2021.

Although the Guidance Document asserts that minors do not favor mint or menthol as much as they prefer fruit flavors in ENDS products, we also urge the FDA to expand its enforcement activity to include mint

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<sup>1</sup> Wang TW, Asman K, Gentzke AS, et al. Tobacco Product Use Among Adults- United States, 2017. *MMWR Morb Mortal Wkly Rep* 2018; 67:122-1232. DOI: <http://dx.doi.org/10.15585/mmwr.mm6744a2>

<sup>2</sup> HHS, E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General, 2016.

Director Mitch Zeller, J.D.

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and menthol. While these flavors may not be as popular among the youth population, they are still being used and should not be excluded from the agency's enforcement activities.

We urge the FDA to expedite the implementation of these policies to allow for oversight of these products as soon as possible. While we recognize it will require considerable resources and time to develop the infrastructure necessary to enforce these proposals, we believe we must act quickly to stem this emerging public health crisis among our nation's youth.

Thank you for working to protect young people from the harmful effects of nicotine addiction. The Society welcomes the opportunity to be a resource to the FDA as you finalize this draft guidance. Please contact Courtney Yohe Savage, STS Director of Government Relations, at [cyohe@sts.org](mailto:cyohe@sts.org) or 202-787-1222 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink that reads "Robert S.D. Higgins". The signature is written in a cursive style with a large initial "R".

Robert S.D. Higgins, MD

President