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November 25, 2019

Dockets Management Staff
U.S. Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Premarket Tobacco Product Applications and Recordkeeping Requirements, Docket No. FDA-2019-N-2854-0001

On behalf of The Society of Thoracic Surgeons (STS), I write to thank you for the opportunity to provide comments on requirements for premarket tobacco product applications (PMTAs). Founded in 1964, STS is a not-for-profit organization representing more than 7,300 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. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The Family Smoking Prevention and Tobacco Control Act of 2009 gave FDA the authority to review new tobacco products and evaluate whether their marketing will negatively impact public health. Since all tobacco products (new or existing in the marketplace) are harmful to public health, FDA's usual "safe and effective" standard for evaluating medical products does not apply. Instead, FDA issues marketing orders, or authorization to market a product, for PMTAs. This proposed rule will help to ensure that PMTAs contain adequate information for FDA to determine whether a marketing order should be issued for a new tobacco product.

STS appreciates the thoroughness of these proposed requirements, especially as they pertain to protecting children and young people from nicotine addiction. The current youth electronic cigarette (e-cigarette) epidemic is deeply concerning. STS has supported many FDA proposals to address it, including those contained in the proposed rule, Modifications to Compliance Policy for Certain Deemed Tobacco Products. Nicotine exposure is harmful to the developing adolescent brain, impacting learning, memory, and attention, and increasing the risk for future addiction to other drugs.[1] It is therefore crucial that new tobacco products do not disproportionately target or impact young people.

FDA is proposing to require the submission of reports on health risk investigations to ensure it understands the full scope of what is known about the potential health risks of a new tobacco product. STS strongly supports this requirement, and urges FDA to require that health risk reports be included in all product marketing so that the public can see the risks of each product.

[1] "Know the Risks of E-cigarettes For Young People," U.S. Surgeon General's Report, https://e-cigarettes.surgeongeneral.gov/knowtherisks.html

STS supports requiring PMTAs to include the impacts on tobacco use initiation by nonusers, especially youth. In particular, STS supports requiring PMTAs to contain full reports of investigations regarding the likelihood that youth and young adults who have never used tobacco products will initiate use of the tobacco product. FDA's proposal to withdraw a marketing order if more nonusers of tobacco products are initiating use with the product than expected is also important. This interpretation of the Appropriate for the Protection of Public Health (APPH) standard is apt as it allows FDA to respond rapidly to changes in the tobacco product marketplace and tobacco product use behaviors in the midst of the youth vaping epidemic. In addition to studying initiation among nonusers, STS urges FDA to require health risk investigations into the effects of secondhand exposure to the smoke/aerosol released by new tobacco products in PMTAs.

STS appreciates that, in addition to health risk investigations, FDA is proposing to require marketing plans in PMTAs in order to limit youth exposure to the labeling, advertising, marketing, or promotion of a new tobacco product. FDA must have a clear understanding of how tobacco companies plan to market their products in order to protect public health. To ensure this specificity, FDA plans to differentiate between test marketing and commercial marketing. FDA defines test marketing as "distributing or offering a tobacco product for sale in the United States (U.S.) for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which the product is offered in a limited number of regions; offered for a limited time; or offered to a chosen set of the population or specific demographic group." FDA defines commercially marketed as "offering a tobacco product for sale to consumers in all or in parts of the U.S." These distinctions are necessary because test marketing is much more controlled. Commercially marketing a new product may have unintended consequences in the real world that did not become apparent under test marketing conditions. STS is in favor of including definitions of the terms "test marketing" and "commercial marketing" in the final rule. STS also urges FDA to require information about commercial marketing, not test marketing alone, in PMTAs in order to meet the APPH standard. Finally, STS urges FDA to require information about secondhand exposure to the smoke/aerosol of new products in marketing plans so that the public is aware of any potential risks.

Thank you for working to protect the nation from the harmful effects of nicotine addiction by ensuring that all new tobacco products are carefully reviewed. If you have any questions or would like additional clarification, please contact Courtney Yohe Savage, Director of Government Relations, at cyohe@sts.org or 202-787-1222.

Sincerely,

Robert S.D. Higgins, MD
President