Dear Commissioner Gottlieb:

The Food and Drug Administration (FDA) has issued an advanced notice of proposed rulemaking “to obtain information related to the role that flavors play in tobacco products.” It is The Heartland Institute’s understanding that FDA is seeking information on the potential harmful effects, especially to children, of including flavors in smokeless tobacco products, electronic cigarettes and vaping devices, and heat-not-burn (HNB) products. Heartland urges FDA acknowledge these products are tobacco harm reduction (THR) tools and have been shown to have a positive impact public health. FDA should also be aware of the many industry efforts to prevent underage users from accessing such products.

**Tobacco Harm Reduction**

Of the estimated 39 million adult smokers in the United States, approximately 480,000 die each year from smoking-related illnesses. If this persists, an estimated 9.6 million Americans will die because of tobacco-related diseases during the next 20 years. Anti-tobacco campaigns and tax increases have tried to curb the use of tobacco products, but they only offer a strategy of “quit or die.” There is another approach: tobacco harm reduction, which explicitly includes the continued use of tobacco or nicotine, and is designed to reduce the health effects of tobacco use.

Research shows it is the smoke created by burning tobacco, rather than nicotine, that creates the harmful risks associated with combustible tobacco. There are numerous THR products currently on the market in the United States—including snus, electronic cigarettes and vaping devices, and HNB products—all of which effectively deliver nicotine in a less harmful way than combustible cigarettes.

**The Proof of Tobacco Harm Reduction**

The efficacy of smokeless tobacco, electronic cigarettes and vaping devices, and HNB products as THR tools has been made evident in recent years by the growing support of THR products by public health groups and researchers.
Smokeless tobacco products have been consumed for centuries and were “the dominant form of tobacco used in the U.S. until early in the 20th century.” Today, the most popular forms of smokeless tobacco include moist snuff, chewing tobacco, and American and Swedish snus.

Data from Sweden and other countries provides significant evidence that smokeless tobacco poses considerably fewer risks than combustible cigarettes. Dr. Brad Rodu, a senior fellow at The Heartland Institute, has conducted more than 20 years of research on the effects of smokeless tobacco. Analyzing data from Sweden, Rodu notes that although Swedish men have the highest rate of smokeless tobacco use in Europe, they have the lowest smoking rate. As a result, Rodu points out, “Swedish men also have the lowest rates of lung cancer and other smoking-related diseases in Europe.” Rodu concludes that smokeless tobacco is “at least 98 percent safer even though most Americans are misinformed about the differences in risk.”

Electronic cigarettes have been examined extensively over the past several years, and numerous public health organizations have urged their use as a replacement for combustible cigarettes. In 2015, in one of the first monumental studies conducted by a public health organization on the safety of e-cigarettes, Public Health England (PHE) declared the use of e-cigarettes to be “around 95% safer than smoking.” The following year, the Royal College of Physicians echoed PHE’s claim, stating electronic cigarette use “unlikely to exceed 5% of the harm from smoking tobacco,” and urged public health groups “to promote the use of e-cigarettes.” In late 2016, Cancer Research U.K. commented on the harm reduction provided by e-cigarettes, noting “it is important that regulation does not [stifle] their development.”

In 2017, NHS Health Scotland reported there “is now agreement based on the current evidence that vaping e-cigarettes is less harmful than smoking tobacco.” Another 2017 study in BMJ’s peer-reviewed journal Tobacco Control examined health outcomes using “a strategy of switching cigarette smokers to e-cigarette use … in the USA to accelerate tobacco control progress.” The authors concluded that replacing e-cigarettes “for tobacco cigarettes would result in an estimated 6.6 million fewer deaths and more than 86 million fewer life-years lost.”

Earlier in 2018, the National Academies of Sciences, Engineering and Medicine reported e-cigarette use resulted in “reduced short-term adverse health outcomes in several organs.” Also earlier in 2018, PHE released its landmark 2015 study, which concluded that health risks associated with e-cigarette use was minimal and that “switching completely from smoking to vaping conveys substantial health benefits.” Additionally, the American Cancer Society, which has often been a staunch critic of electronic cigarettes, acknowledged the health benefits associated with vaping devices, noting “exclusive use of e-cigarettes is preferable to continuing to smoke combustible cigarettes.”

HNB devices, such as iQOS by Philip Morris International, are relatively new, but evidence indicates they are effective THR products. HNB devices are unique because they have the “ability to regulate and distill flavor and nicotine at lower temperatures,” thus generating less harmful components. A 2016 study in Toxicology in Vitro compared “the biological impact of heated tobacco aerosol from the tobacco heating system … and smoke for a combustible cigarette.” Examining bronchial epithelial cultures exposed to iQOS vapor, the study found significant reductions in biological markers compared to when cigarette smoke is regularly inhaled.
**The Role of Flavors in Tobacco Harm Reduction Products**

Flavors are an important component of THR products and vital to helping many smokers cease using combustible tobacco. Current evidence indicates smokeless tobacco product users prefer flavored products over non-flavored THR products. A 2013 study examined data from five studies on smokeless tobacco use to gauge users’ “choice of brand flavor.” Researchers noted that a majority of respondents’ “first and current choice of product was flavored, specifically mint or wintergreen.” The analysis also found a significant number of smokeless tobacco users moved to flavored smokeless tobacco after using nonflavored smokeless tobacco at initiation. Despite growing alarmism, the researchers noted that “flavored products did not appear to lead to greater dependence or increased exposure to nicotine or carcinogens.”

A 2017 study reached similar conclusions, finding that “smokers enrolled in a clinical trial of snus substitution” preferred mint flavored snus. The authors recognized that this was a “conundrum,” as evidence suggests “flavorings make tobacco products more attractive to youth” and adults.

Additional research has been dedicated to the role of flavorings in e-cigarettes and vaping devices. A 2013 study by the Onassis Cardiac Surgery Center concluded flavors in e-cigarettes “appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking.” A 2015 online survey conducted by the Consumer Advocates for Smoke-Free Alternatives Association examined 27,343 Americans over the age of 18. Seventy-two percent of the respondents “credit[ed] interesting flavors with helping them quit.” Of the respondents that were still smoking, “53% say interesting flavors are helping move them toward quitting.”

A 2017 study discovered older adults’ “use of an e-cigarette flavored with something other than tobacco (69.3%) was … significantly higher than the same at initiation (44.1%).” This indicates that electronic cigarette users often first consume tobacco flavored e-liquids and products but then transition to other flavors, helping aid their cessation of combustible cigarettes. Banning flavors would force these individuals to vape only tobacco-flavored e-cigarettes, making them more likely to return to combustible cigarettes.

A 2017 study examined the impact of a flavor ban in electronic cigarettes and vaping devices. The authors concluded banning flavors “would result in increased choice of combustible cigarettes,” and they said they expect e-cigarette use to decline by approximately 10 percent if flavors are banned.

Additionally, a 2018 “systematic review of research examining consumer preference” for flavors concluded adults “in general also preferred sweet flavors.”

**Youth and Tobacco Harm Reduction Products**

Many public health groups have issued warnings about the “dramatic rise” of e-cigarette use among youth. Although flavors in tobacco products may entice youth, the alarmism spread by anti-tobacco organizations dramatizes an unfounded fear. Overwhelming evidence suggests THR products do not lead to combustible cigarette consumption.
Youth are consuming less tobacco, according to data from the National Youth Survey and acknowledged by the Centers for Disease Control and Prevention (CDC). In CDC’s analysis, it concluded from 2015 to 2016, among high school students, there was a “significant decrease in the use of any tobacco product,” including combustibles, e-cigarettes, and hookahs.

Studies analyzing the impact of electronic cigarettes have found only a small percentage of American teenagers use e-cigarettes frequently. For example, a 2017 study in Preventative Medicine Reports examining “cross sectional surveys of school-going youth and young college students in Texas, and young adults and older adults” revealed only 19.5 percent of Texas youth—29.5 percent of youth nationwide—noted ever using an electronic cigarette. Only 7.4 percent of youth were found to be current users of electronic cigarettes.

In a small study, researchers examined the use of electronic cigarettes among Hawaiian youth, finding only 2 percent of respondents reported using e-cigarettes daily or weekly. Seventy-one percent of respondents reported never using e-cigarettes.

A larger study investigating youth e-cigarette use concluded only “34 percent of 12th graders, 32 percent of 10th graders, and 21 percent of 8th graders” had tried an e-cigarette. This only tells part of the picture, however. Many young Americans who vape are not vaping nicotine, according to these researchers’ findings. Rather, the authors noted “65-66% in each grade reported vaping ‘just [flavoring]’ at last use.”

Another study noted “a tenth to a fifth of 11-to-16 year olds have tried e-cigarettes, but only 3% or less used them regularly and those were mostly already tobacco smokers.”

Further, there is no valid peer-reviewed evidence concluding youths using electronic cigarettes and vaping devices are highly likely to eventually become regular users of more-dangerous combustible tobacco cigarettes. A 2015 study examined “the causal impact of access to electronic cigarettes … on teen smoking.” The author found “electronic cigarette access reduces teen smoking.” Further analysis of the data found state bans on sales of electronic cigarettes to minors create “a statistically significant 1.0 percentage point increase in recent cigarette smoking rates among 12 to 17 year olds.”

Advertising and E-Cigarettes

There is also great concern about the impact advertising efforts by THR businesses may be having on youth. Although the concern is not totally unwarranted—because some marketing efforts have been found to be youth-oriented—many in the THR community have taken steps to prevent youth marketing of tobacco products.

The Vapor Technology Association (VTA) is a national trade association representing “manufacturers, wholesalers, small business owners and entrepreneurs who have developed innovative and quality vapor products.” VTA “strongly supports efforts to prevent Minors’ access to Vapor Products.” According to VTA’s “Marketing Standards,” VTA members are required to determine whether their product “may appeal or be directed to Minors,” including the names of products, cartoons, other imagery, and promotional items. VTA does not permit any marketing to minors by its members.
Additionally, many traditional tobacco companies with a long history of preventing youth access to tobacco products have in recent years started to sell THR products. These responsible businesses have continued their efforts to prevent underage use of THR tools like e-cigarettes. For instance, the R.J. Reynolds Vapor Company is the manufacturer of Vuse, a brand of electronic cigarette devices. In a 2016 interview, Reynolds American, Inc. noted that the company does not advertise to minors. The company’s advertising of Vuse “is in line with [their] commitment to reducing youth exposure to tobacco-related products and messaging.”

Altria is another company that sells tobacco and THR products, including smokeless tobacco, electronic cigarettes, and HNB devices. Over the past 20 years, Altria has funded programs aimed at reducing underage tobacco usage, including its “Talk. They’ll Listen” campaign on television, radio, and in print; the Parent Resource Center; Teenage Attitudes and Behavior Study; and by implementing an underage tobacco sales prevention policy. In 2013, Altria invested more than $21 million in its Success 360° program, designed to help “organizations better deliver effective programs to middle school kids promoting healthy development and avoiding risky behaviors like tobacco use.”

Most recently, JUUL, the manufacturer of one of the most popular vaping devices, announced its support of “efforts to raise the minimum age for tobacco sales to 21” and said it “will invest $30 million over three years in strategies” to prevent youth access to its e-cigarette.

**Recommended Regulatory Priorities**

The Heartland Institute vehemently opposes an FDA ban on non-tobacco flavors in THR products. If current users of flavored THR products are only permitted to consume tobacco flavors, they are more likely to return to combustible tobacco cigarettes, which are far more dangerous. Evidence continues to indicate THR products deliver nicotine in a method that is significantly less harmful than combustible cigarettes, and FDA should not discourage their use.

It is already illegal to sell THR products to minors, and the THR industry continues to aim to prevent youth access and use of THR products and traditional combustible cigarettes. FDA ought to recognize these industry measures and provide any needed assistance to manufactures and retailers of THR products to help them maintain the efforts they have already undertaken. Imposing additional regulations and restrictions on THR products would likely result in fewer THR users, which means there would likely be more tobacco-related deaths.

Sincerely,

Lindsey Stroud  
State Government Relations Manager  
The Heartland Institute
5 Brad Rodu et al., supra note 2, p. 13.
25 M.B. Harrell et al., supra note 19.