Commentary to the Reagan Udall Foundation
Regarding the Operational Evaluation of the U.S. Food and Drug Administration's Center for Tobacco Products' Programs
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Members of the Reagan Udall Foundation expert panel:

Thank you for the opportunity to discuss the issue of regulating and taxing vapor products. My name is Martin Cullip, and I am a Research Fellow at The Taxpayers Protection Alliance's (TPA) Consumer Center. TPA is a non-profit, non-partisan organization dedicated to educating the public through the research, analysis, and dissemination of information on the government's effects on the economy. TPA's Consumer Center focuses on providing up-to-date information on adult access to goods including alcohol, tobacco and vapor products, as well as regulatory policies that affect adult access to other consumer products, including harm reduction, technology, innovation, antitrust and privacy.

TPA's Consumer Center welcomes the opportunity to provide oral and written comments to the panel of independent experts in guidance of their review for the Center for Tobacco Products (CTP) at the U.S. Food and Drug Administration (FDA), especially concerning their role in authorization of novel tobacco products through the premarket tobacco product application process (PMTA). Below are further details of the oral comments provided to the panel on October 21, 2022.

CTP Arbitrarily Ignores Products Youth Are Using, Data on Youth Vaping Declining and Reasons for Youth E-Cigarette Use

In reviewing applications and determining any products' appropriateness for the protection of public health, FDA should prioritize products on both the basis of reduced harms and the likelihood of youth usage of such products.

There are a plethora of different e-cigarette product types including open tank systems, closed refillable pod systems, and the growing disposable e-cigarette product category. All are vapor products and thus are significantly less harmful than combustible cigarettes as they produce a vapor rather than smoke and eliminate combustion. Nonetheless, some of these products are more likely to be used by youth than other products.

For example, according to the 2022 National Youth Tobacco Survey (NYTS), among middle and high school students that had reported using an e-cigarette product on at least one occasion in the 30 days prior to the survey, 55.3 percent had used a disposable e-cigarette, 25.2 percent had used

a pod device and 6.7 percent reported using open tanks.[1] The FDA's priority of reviewing applications for e-cigarette products must take this into account, but instead, the FDA has issued arbitrary denial orders for the products youths are least likely to use.

CTP is also ignoring the national data finding youth vaping has declined significantly in the years since e-cigarette manufacturers were required to submit PMTAs.

In 2022, 3.3 percent of middle schoolers and 14.1 percent of high schoolers reported past-month vapor product use. This is defined as having used a vapor product on at least one occasion in the 30 days prior to the survey. Between 2019 and 2022, past-month vapor product use declined by 48.7 percent among high school students and by 68.6 percent among middle school students.

Moreover, the CTP has denied nearly all flavored e-cigarette applications citing youth use, yet flavors are not the main reason why youth are using e-cigarettes.

According to the 2021 NYTS, among middle and high school students that reported ever trying e-cigarettes, 57.8 percent had used them because a friend had, 47.6 percent cited curiosity as a reason for use, 25.1 percent cited feelings of anxiety, depression and stress, 23.3 percent had used them to get a buzz from nicotine and only 13.5 percent cited flavors "such as menthol, mint, candy, fruit or chocolate" as a reason for trying e-cigarettes.[2]

Among middle and high school students that were past-month users, 43.4 percent cited using e-cigarettes because they were "feeling anxious, stressed, or depressed," 42.8 percent cited using them to get a buzz from nicotine, 28.3 percent had used them because a friend had, and only 13.2 percent cited using e-cigarettes because they were available in flavors.

Contrary, adult users of e-cigarettes overwhelmingly cite the use of flavors as a reason for both quitting combustible cigarettes and maintaining smoking cessation.

Analysis of EcigIntelligence's 2019 user survey found that fruits, sweets and candy, and desserts and bakery flavors "are among the most preferred flavors across all age groups."[3] Use of tobacco flavor was preferred by less than 5 percent of those who vape. If legal sales were restricted to tobacco flavor only, 69 percent of respondents said they would try to acquire their flavors from alternative methods and 25 percent stated that they would be willing to drive over 100 miles to obtain supply. This illustrates that flavors are important to the appeal of vaping over smoking and that proposals to ban flavored vaping products are more an attempt at prohibition by stealth than a serious public health measure.

A 2020 study found an association between flavors and smoking cessation. In a cohort study of more than 17,900 participants, the authors found that "adults who began vaping nontobacco-flavored e-cigarettes were more likely to quit smoking than those who vaped tobacco flavors."[4]

A Zero-Youth Vaping Threshold Is Unachievable, FDA Should Use Existing Thresholds As Measures

The threshold for youth usage must be considered. In 1992, Congress enacted the Synar Amendment in an effort to curb sales of tobacco products to youths. This required states to "reduce the extent to which tobacco products are available to individuals under the age of 18" and requiring states to conduct unannounced compliance inspections, which would be reported annually as part of the Annual Synar Report.[5]

To get states to comply, Congress made "block grants to states from the Substance Abuse and Mental Health Services Administration (SAMHSA) under the Department of Health and Human Services (DHHS) contingent upon states enacting and enforcing prohibition on the sale to minors." Prior to the Synar Amendment, of then-tobacco compliance checks, approximately 76 percent result in sales to minors. Per the Synar Amendment, Congress required DHHS to reduce certain percentages of block grants to non-compliant states. In 1996, DHHS determined that violation rates – i.e. sales to minors – must be reduced to 20 percent of all checks. In 1996, four states had already reached that goal, and the "remaining states were assigned individualized declining interim annual targets allowing up to seven years to reach 20 percent."

If 20 percent is a threshold for tobacco products to be sold to minors, what percentage of youth using such products is ideal for the marketing of tobacco harm reduction products? The results from the 2022 National Youth Tobacco Survey indicate tremendous declines in youth use of vapor products.

In 2019 an estimated 5.4 million middle and high school students reported past-month vapor product use, or 20 percent of American youth. This is the same percentage allowed under the Synar Amendment in terms of youth accessing tobacco products. But even if the FDA did choose to follow the 20 percent rule, it would be unnecessary because youth vaping has significantly declined since then. In 2022, only 9.4 percent middle and high school students reported past-month e-cigarette use. In fact, there are nearly 2.75 million fewer youth vapers in 2022 than in 2019, and between 2019 and 2022, past-month vapor product use has declined by 48.7 percent among high schoolers and by 68.6 percent among middle schoolers.

This brings up the larger question of the intent of PMTAs and the FDA's role in reviewing applications of novel tobacco harm reduction products that will benefit the millions of American

adults who are still smoking and are unable to quit. Many of these people will become part of the 480,000 annual smoking-related deaths each year.

The PMTA process for authorizing new e-cigarette products has focused almost entirely on the risks of youth vaping without setting a viable standard of acceptable youth use rates. This is unrealistic as it will be impossible to reduce youth e-cigarette use to 0. Moreover, the agency is ignoring another useful tool: post market surveillance of newly authorize products that can both address youth use and bad actors, as well as provide the agency with useful data on the patterns of adult use of e-cigarette products.

CTP Lack of Authorization Has Helped Illicit Products Flourish

The e-cigarette marketplace has exploded in the United States and despite FDA's denial orders, a massive market of illicit products from foreign countries saturate the marketplace and will continue to do so.

In January 2021, the FDA applauded itself as it worked with other federal agencies and seized 42 different shipments of counterfeit disposable vapor products from China to Texas.[6] In March 2021, U.S. Customs and Border Protection (CBP) officers in Chicago seized $1.5 million in counterfeit vapes.[7]

Understandably, CBP is not actively seeking out illicit vapor products, yet a surge of these unregulated products is being experienced globally. This year, officials in Australia,[8] China,[9] Singapore,[10] and the UK[11] have all reported massive seizures of counterfeit vapor products. The illicit products are so prevalent that a vapor product company has been actively working with government officials in China and has successfully shut down more than 20 factories manufacturing counterfeit vapes.[12]

Due to a global marketplace that evolves faster than FDA's own regulations, these products will remain in place. Rather than arbitrarily denying the entire flavored e-cigarette marketplace, the FDA would better serve public health by allowing and regulating long-existing American companies. Again, post market surveillance among products that cause an issue to public health and/or youth can only be conducted on products given FDA authorization.

CTP Authorization Process Impedes Product Introduction and Innovation

In the UK and Europe, vaping products are regulated under a notification process whereby safety and quality standards are set by the regulator and if manufacturers meet these criteria, they may bring the product to market. It is also worth noting that despite availability of a wide array of flavors, the UK and Europe does not have high levels of youth vaping.

In the United States, the authorization process creates a huge amount of unnecessary and expensive bureaucracy. It bakes in failure for balanced and proportionate regulation and almost encourages political interference. There is nothing in the legislation which would stop the FDA moving to a fair and transparent notification system which lays out to all industry exactly what is demanded by the regulator.

Other Centers at the FDA currently regulate other consumer products under a notification process, for example dietary supplements, so there is already a template for such an approach. This would also improve FDA efficiency and encourages innovation – for example, product improvements could be fast tracked instead of requiring an entire new application - instead of the PMTA process which guarantees that products will be almost obsolete by the time they gain authorization.

Conclusion

CTP should be given the authority to utilize enforcement discretion when authorizing novel tobacco harm reduction products (including e-cigarettes) for market sale in the United States.

Currently, the office is hindered by political influences that disregard science and the overwhelming evidence that since PMTAs were due, youth vaping has halved in the United States. A zero-sum youth vaping policy is unattainable, yet it seems to be the policy the CTP aspires to due to outside political influence.

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