Commentary to the Center for Tobacco Products
U.S. Food and Drug Administration
Regarding Development of the Center's Strategic Plan
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Center for Tobacco Products
Food and Drug Administration
Document Control Center
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Dr. Brian King, Director, Center for Tobacco Products, FDA:

Thank you for your time today to discuss the issue of the development of an improved strategic plan for the Center for Tobacco Products (CTP) at the U.S. Food and Drug Administration (FDA). My name is Lindsey Stroud and I am Director of 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.

The Tobacco Control Act Severely Limits Marketplace and Small Businesses

CTP is one of the newest agencies at the FDA and in its infancy has struggled to adapt to changing technologies – notably the introduction and responsible marketing of tobacco harm reduction products. This has happened because of the language of the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) which restricts the agency to draconian standards and regulatory processes.[1]

[1] 111th Congress, "FAMILY SMOKING PREVENTION AND TOBACCO CONTROL AND FEDERAL RETIREMENT REFORM," Public Law 111-31, Jun. 22, 2009, https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.

In 2009, when the TCA was signed, the marketplace for tobacco products – especially novel products – was relatively small. A handful of manufacturers were marketing e-cigarettes. Other products (including heated tobacco) had yet to be introduced to market.

The TCA was designed to curtail tobacco manufacturers, not encourage and promote the use of tobacco harm reduction products.

Line 6 of the TCA states:

> Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.[2]

Indeed, numerous commentaries published during the passage of the TCA found a complete disdain for tobacco manufacturers. Yet, interestingly, large tobacco manufacturers seem to be the only companies able to market new tobacco products.

Upon signing the TCA, then-president Barack Obama remarked that "kids" are "aggressively targeted as customers by the tobacco industry … exposed to a constant and insidious barrage of advertising where they flavor, they learn, and where they play. Most insidiously, they are offered products with flavorings that mask the taste of tobacco."[3]

In a 2009 commentary describing the strengths and weaknesses of the TCA, Stanton Glantz (a well-known advocate against tobacco and vapor products) remarked that the new law includes "[t]obacco interests that have violated US racketeering law [and] are inappropriately represented on the Scientific Advisory Committee that influences FDA regulations."[4]

In a 2009 article in *The New York Times*, it was reported that the TCA was actually supported by one major tobacco company, while others worried that the legislation was a "cunning ploy … to

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[2] *Ibid*.

[3] Office of the Press Secretary, "Remarks by the President at the signing of the family smoking prevention and tobacco control act," The White House, Jun. 22, 2009, https://obamawhitehouse.archives.gov/the-press-office/remarks-president-signing-family-smoking-prevention-and-tobacco-control-act.

[4] Glantz, Stanton A., Richard Barnes, and Sharon Y. Eubanks, "Compromise or Capitulation? US Food and Drug Administration Jurisdiction Over Tobacco Products," *PLOS Medicine*, e1000118, (2009): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2709428/.

seal the company's dominant position."[5] Understandably, competitors noted that the FDA "is unlikely to approve many new tobacco products [and] combined with the legislations' broader restrictions on tobacco advertising and marketing, would lock in [tobacco company's] market dominance."[6]

If the FDA is to represent the interests of public health, it is essential regulations don't pick and choose winners by not allowing smaller companies to exist on the marketplace. Many novel tobacco products are products introduced by individuals who quit smoking by innovation that was able to flourish prior to the FDA establishing massive regulations on each product.

The 2007 marketing date fails to recognize already-existing products and hinders bringing them to market.

The TCA was signed in 2009, two years after the introduction of e-cigarettes to the marketplace and long before novel products (heated tobacco and nicotine pouches) were introduced. As such, the authors of the legislation determined that products that came to market after February 15, 2007 (the predicate date) were subject to register with the FDA, as well as be subject to other draconian regulations found in the TCA. One such regulation is applying to the agency for marketing authorization to legally sell new products in the United States (U.S.).

Currently, there are only two pathways to bring new tobacco products to market: the substantial equivalent (SE) pathway, and the premarket tobacco product application (PMTA) pathway.

The SE process was designed to bring products to market which are "substantially equivalent" to a product on the market as of February 15, 2007. The FDA defines substantially equivalent as the product "being compared to the predicate tobacco product … has the same characteristics as the predicate product; or … has different characteristics and the information submitted contains information that if deemed necessary by the [FDA] Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health."[7]

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[5] Duff Wilson, "Philip Morris's Support Casts Shadow Over a Bill to Limit Tobacco," *The New York Times*, Mar. 31, 2009, https://www.nytimes.com/2009/04/01/business/01tobacco.html

[6] *Ibid.*

[7] 111th Congress, *supra* note 1.

Essentially, the SE pathways applies to combustible and smokeless products that were on the market long prior to the predicate date and do not significantly affect health risks and/or addictiveness or accompany an increase in youth use.

The SE process fails to capture the innovation brought forth by the numerous tobacco harm reduction products introduced after February 15, 2007. For example, between 2019 and 2022, FDA authorized 421 SE orders for various tobacco products including:[8]

- 173 SE orders for pipe tobacco products
- 126 SE orders for combustible cigarette products
- 60 SE orders for cigar products
- 31 SE orders for roll your own tobacco products
- 17 SE orders for waterpipe products
- 14 orders for smokeless tobacco products

The premarket tobacco product application process favors larger manufacturers, stunts innovation in harm reduction

Most (if not all) of novel tobacco harm reduction products were brought to market post February 15, 2007 and are subject to undergo the premarket tobacco product application process. This was essentially promulgated in 2014 when FDA decided to deem products not included in the TCA as tobacco products – namely electronic cigarettes and heated tobacco.

Prior to the deeming regulations, per the TCA, new rules and regulations were only subject to cigarettes, cigarette tobacco, roll you own tobacco and smokeless tobacco products. The deeming rules were finalized in May 2016 and brought additional tobacco products under FDA's regulatory authority. These products include:

- Electronic cigarettes, e-cigarettes, and/or vaping devices; referred to as Electronic Nicotine Delivery Systems by FDA
- Cigars
- Pipe Tobacco
- Waterpipe (hookah) tobacco
- Nicotine gels and dissolvables
- Chewing tobacco and snuff

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[8] Center for Tobacco Products, Marketing Orders for SE," U.S. Food and Drug Administration, Apr. 7, 2023, https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se.

Including premarket review (PMTA or SE), newly deemed tobacco products are also subject to other TCA regulations including age restrictions, health warning label requirements, registering with the FDA (including reporting ingredients in new products), a prohibition on free samples, and making health-related (modified risk) claims on the new product without FDA authorization.

Some of the products today are substantially equivalent to products on the market prior to February 15, 2007, yet many novel harm reduction products have no substantial equivalent and as such must submit a PMTA in order to legally market their products.

The PMTA process is arduous, expensive and has essentially shut down thousands of small businesses across the United States due to excessive costs associated with the applications.

Manufacturers of e-cigarettes (and other newly deemed products) were required to submit PMTAs by September 2020 to legally market their products in the U.S. Manufacturers were required to submit extensive data and evidence to prove the new product's safety, addictiveness, and potential health impacts including likelihood of creating new users of combustible cigarette and products and youth appeal. The FDA then reviews the submitted application – completed and tested by the manufacturer of the said product – and will issue either a marketing granted order and/or marketing denial order.

To date, the FDA has authorized 45 marketing orders under the PMTA pathway including:[9]

- 23 PMTA orders for e-cigarettes
- 8 PMTA orders for smokeless tobacco products
- 7 PMTA orders for combustible cigarette products
- 4 orders for tobacco products deemed as "other"
- 3 orders for heated tobacco products

More notably, the FDA has issued marketing denial orders for hundreds of thousands of product applications for a variety of e-cigarette products, from e-liquids to devices.

In August 2021, FDA issued the first marketing denial orders to one e-cigarette firm for nearly 55,000 PMTAs for flavored e-liquid. In the announcement, then-acting FDA Commissioner Janet Woodcock remarked that "flavored tobacco products are very appealing to young people,

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[9] Center for Tobacco Products, "Premarket Tobacco Product Marketing Granted Orders," U.S. Food and Drug Administration, Jun. 14, 2023, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders.

therefore assessing the impact of potential or actual youth use is a critical favor in our decision-marking process about which products may be marketed."[10]

By September 2021, the FDA has issued nearly 1 million denial orders (946,000) for flavored e-cigarette products, which the agency even noted "many of which were already on the market."[11]

In April 2022, Congress implemented a new law that permitted the FDA to "regulated tobacco products containing nicotine from any source, including non-tobacco nicotine (NTN) or synthetic nicotine."[12] By May 2022, the FDA received almost 1 million applications for synthetic nicotine products. In October 2022, the agency had remarked that majority of the new NTN product applications (889,000) were issued letters that the agency refused to accept their application, essentially issuing marketing denial orders.

Between October 2021 and August 20203, the FDA has issued a very limited number (23) PMTA marketing orders for e-cigarette products and only to merely three different manufacturers – all of which are owned by large tobacco manufacturing corporations. For comparison, 27 different companies have received SE orders to market over 400 tobacco products between 2019 and 2022.

The FDA Is Fundamentally Challenged in Bringing Small Business's Products to Market; Regulating an Everchanging Marketplace

The PMTA has been a difficult process for American small business owners who manufacturer e-cigarette products. According to FDA requirements, all newly deemed tobacco products were required to be on market by August 8, 2016, or were to have submitted a PMTA or SE

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[10] Center for Tobacco Products, "FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health," *FDA News Release*, U.S. Food and Drug Administration, Aug. 26, 2021, https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence.

[11] Janet Woodcock and Mitch Zeller, "FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted," *FDA Statement*, U.S. Food and Drug Administration, Sept. 9, 2021, https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90.

[12] Center for Tobacco Products, "FDA Completes Initial Review of 95% of Non-Tobacco Nicotine Product Applications; Agency Has Issued Over 60 Warning Letters to Manufacturers, Including for Products with a Submitted Application and Negative Action," U.S. Food and Drug Administration, Oct. 14, 2022, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-completes-initial-review-95-non-tobacco-nicotine-product-applications-agency-has-issued-over-60.

application prior to being introduced to the market. As such, many of the denial orders were issued for products which had been on the U.S. marketplace for over half a decade.

There are numerous constraints for small businesses because of the PMTA including:

- Massive and often unattainable financial burden for firms without significant market share, including a lack of access to resources needed to complete PMTA scientific and data requirements
- Scientific data required is too complex as the PMTA process itself demands a high level of data and evidence on product characteristics, safety, addictiveness, and the potential health impacts.
- The FDA's lack of authorization has led to major market uncertainty with many choosing to exit the market caused by FDA's lacking authorization process. Further, some small businesses have chosen to operate without authorization. While these firms face the possibility of enforcement actions, their illegitimacy undermines the efforts of responsible firms attempting to get FDA authorization.
- There is a major fundamental competitive disadvantage to small, new firms who don't have the resources of established tobacco firms with access to more capital and resources.
- An ever-changing e-cigarette market undermines established businesses attempting to provide tobacco harm reduction options for adult consumers.

Per FDA regulations, e-cigarettes (and other newly introduced products) were to be on the marketplace by August 8, 2016 in order to legally market their products.[13] A recent court decision forced the FDA to begin the PMTA authorization process in September 2020.

FDA's Must Determine the Appropriate Number of Youth Use As Zero-Sum Is Unattainable, Harms Adults Who Smoke

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

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[13] U.S. Food and Drug Administration, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," Rule 81 FR 28973, May 10, 2016, https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.

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 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:[14]

- 55.3 percent reported using disposable vapor products
- 25.2 percent reported using prefilled and/or refillable pods/cartridge systems
- 6.7 percent reported using tanks/mod vapor products
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Interestingly – and alarmingly – 12.8 percent reported not knowing the type of vaping device they were using.

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.

The threshold for youth usage must be considered.

In 1992, Congress enacted the Synar Amendment to curb sales of tobacco products to youths, requiring states to "reduce the extent to which tobacco products are available to individuals under the age of 18."[15] The amendment also required states to conduct unannounced compliance inspections, which would be reported annually as part of the Annual Synar Report.[16]

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[14] Cooper, Maria *et* al., "*Notes from the Field*: E-cigarette Use Among Middle and High School Students — United States, 2022," *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention, Oct. 7, 2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7140a3.htm.

[15] DiFranza, Joseph R. and G.F. Dussault, "The federal initiative to halt the sale of tobacco to children—the Synar Amendment, 1992–2000: lessons learned," *Tobacco Control*, Volume 14, Issue 2, (2005): https://tobaccocontrol.bmj.com/content/14/2/93.

[16] Clark Hagen, "Synar Program Annual Reports: Youth Tobacco Sales," Substance Abuse and Mental Health Services Administration, Apr. 14, 2022, https://www.samhsa.gov/synar/annual-reports.

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 (HHS) contingent upon states enacting and enforcing prohibition on the sale to minors."[17] Prior to the Synar Amendment, of then-tobacco compliance checks, approximately 76 percent result in sales to minors. Per the Synar Amendment, Congress required HHS to reduce certain percentages of block grants to non-compliant states. In 1996, HHS 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."[18]

If 20 percent is a threshold for tobacco products to be sold to minors, the FDA must determine the correct percentage of youth using such products is ideal for the marketing of tobacco harm reduction products. The results from the NYTS 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.[19] 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, they do not need to as youth vaping has significantly declined since then. In 2022, only 9.4 percent middle and high school students reported past-month e-cigarette use.[20] 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 means there 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 unable to quit, and impact the 480,000 annual smoking-related deaths each year.

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[17] DiFranza, Joseph R *et* al., *supra* note 15.

[18] *Ibid.*

[19] Wang, Theresa *et* al., "Tobacco Product Use and Associated Factors Among Middle and High School Students – United States, 2019," *Morbidity and Mortality Weekly Report*, U.S. Centers for Disease Control and Prevention, Dec. 6, 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6903396/pdf/ss6812a1.pdf.

[20] Cooper, Maria *et* al., *supra* note 14.

The PMTA process for authorizing new e-cigarette products has focused entirely too much on the risks of youth vaping while both not setting a viable standard of acceptable youth use rates, as it will be impossible to reduce youth e-cigarette use to zero.

Moreover, the agency is ignoring another useful step: postmarket surveillance of newly authorize products that can both address youth use and bad actors, as well as provide the agency with needed data on the patterns of adult use of e-cigarette products.

FDA Must Not Continue to Ignore Science on Adults and the Role of Flavors, E-Cigarettes in Reducing Combustible Cigarette Use

When the TCA came into effect, an estimated 400,000 Americans were dying each year due to smoking-related illnesses. Unfortunately, in 2022, according to data from the Centers for Disease Control and Prevention, an estimated 480,000 Americans were dying annually due to smoking – or an 80,000 increase since the FDA began regulating tobacco products.

The efficacy of e-cigarettes should no longer be ignored by a massive public health agency which claims to want to reduce smoking-related harms.

In 2021, according to data from the CDC's Behavioral Risk Factor Surveillance System (BRFSS) survey, 16.1 million adults, or 6.7 percent of US adults 18 years or older, were currently using vapor products (defined as having used in the past 30 days).[21] This is a 32.6 percent increase from 2017 when 4.6 percent of US adults were current vapers. In terms of absolute numbers, approximately 4.6 million more adults were using vapes in 2021 than in 2017. Nearly half of the adults (46.4 percent) who were vaping in 2021 were between 25 and 44 years of age, the largest contingent. This proportion has increased by 6.8 percent since 2017, when 42.6 percent of adult vapers were in this age range.

While the CDC does not provide data for nationally the number of adults who were formerly or currently smoking and using e-cigarettes, some states have listed their own specific data finding many e-cigarette users are current and/or former cigarette users.

According to data from New York's 2021 BRFSS, among adults who were currently using e-cigarettes that year, more than 77.7 percent reported current and/former combustible cigarette

[21] Taxpayers Protection Alliance, "Adult & Youth E-Cigarette Use: 50 State Analysis," 2023, https://www.protectingtaxpayers.org/adult-youth-e-cigarette-use-50-state-analysis/.

use.[22] Only 22.2 percent of current adult e-cigarette users in New York reported not having smoked.

According to Vermont's 2021 BRFSS, 42 percent of adults who were currently smoking reported current e-cigarette use. Among current e-cigarette users, "those who currently smoke … use e-cigarettes at the highest rates."[23]

Further, youth use of e-cigarette is on a marked decline. The CTP has reported that the agency has quit using the term "epidemic" to describe youth vapor product use. In February 2023, CTP director remarketed that the CTP "has not used that (youth vaping epidemic) terminology for the most recent estimates of youth use" as the "science has shown a decline in the number of youth users."[24]

According to numerous state and national youth surveys – youth vaping has halved since 2019.

Recent national surveys from the CDC, FDA, and the University of Michigan, all which monitor youth tobacco and e-cigarette use, found a large decrease in youth vaping in recent years.

- According to the National Youth Tobacco Survey, only 9.4 percent of U.S. middle and high school students reported current e-cigarette use, a 53 percent decline from 20210 when 20 percent were using e-cigarettes.[25]
- According to the CDC's Youth Risk Behavior Survey, in 2021, 18 percent of high school students reported current e-cigarette use, a 45 percent decline from 2019 when 32.7 percent reported current e-cigarette use.[26]

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[22] New York State Department of Health, "Behavioral Risk Factor Surveillance System (BRFSS)," Feb. 2023, https://www.health.ny.gov/statistics/brfss/.

[23] Vermont Department of Health, "Adult Populations Who Smoke Cigarettes at Higher Rates Than the Statewide Rate (2021 BRFSS)," https://www.healthvermont.gov/sites/default/files/document/HSI_2023_2021_Tobacco_Disparities_Charts_VT_Adults.pdf.

[24] American Vapor Manufacturers, "Factual, candid concessions like these and more were made during our interview with director King this past Friday -- when he was finally, at long last, pressed with genuinely probing questions, ones the FDA beat writers have routinely failed to ask." Twitter. Feb. 28, 2023, https://twitter.com/VaporAmerican/status/1630609040744275968/photo/1.

[25] Cooper, Maria *et* al., *supra* note 14.

[26] U.S. Centers for Disease Control and Prevention, "1991-2021 High School Youth Risk Behavior Survey Data," Accessed Aug. 2023, https://nccd.cdc.gov/Youthonline/App/Default.aspx.

- According to the University of Michigan's Monitoring the Future Survey, in 2022, 17.3 percent of U.S. middle and high school students reported currently vaping, a 23.9 percent decrease from 2019 when 22.7 percent reported current e-cigarette use.[27]

Further, FDA continues to deny adults from access flavored e-cigarette products, citing youth appeal, yet, the agency does not have a standard definition of what constitutes a "youth appealing product."

There is no definition for youth appealing in the TCA, but the language refers to various marketing techniques they claim "attract young persons to use tobacco products" including:

- "Advertising, marketing, and promotion of tobacco products" including advertising which "often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.[28]
- The use of sports and other marketing sponsorships
- Use of tobacco products in films and television programming

In regard to e-cigarette marketing authorization, FDA and public health groups have looked at more explicit marketing techniques including:

- Flavored e-cigarette and tobacco products
- Disguised and/or colorful, flashy designs
- Social media marketing

For the past several years, the agency has issued warning letters and enforcement actions against flavored e-cigarettes which the agency claims are causing an epidemic among youth.

In a January 2020 press release, the agency declared that due to "the epidemic levels of youth use of e-cigarettes and the popularity of certain products among children," the FDA issued new

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[27] University of Michigan, "Tables and Figures," Monitoring the Future, Accessed Aug. 2023, https://monitoringthefuture.org/results/data-products/tables-and-figures/.

[28] 11th Congress, *supra* note 1.

policies "prioritizing enforcement against certain unauthorized flavored e-cigarette products that appeal to kids," namely, flavored cartridge-type e-cigarette products.[29]

With the massive round of denials for products that submitted PMTAs after the flavored cartridge ban, the FDA has essentially regulated all flavored e-cigarette products out of existence. Worse, the FDA is ignoring massive amounts of survey data indicating flavors are not the most cited reason among youth for using e-cigarettes.

According to the 2022 National Youth Tobacco Survey, among U.S. middle and high school students who reported current e-cigarette use:[30]

- 43.4 percent cited using e-cigarettes because they were feeling anxious, depressed, and/or stressed
- 42.8 percent cited using e-cigarettes to get a "high or buzz" from nicotine
- 28.3 percent cited using e-cigarettes because a friend and/or family member used them
- 19.5 percent cited "other" as a reason for using e-cigarettes
- 13.2 percent cited using e-cigarettes because they were available in flavors

The FDA is actively ignoring the role flavors play in tobacco harm reduction products for adults.

- A 2018 survey examined nearly 70,000 American adult vapers, with 95 percent reporting having ever smoked.[31] The survey found that the "majority had quit smoking." Among all participants, 83.2 percent and 72.3 percent reported vaping fruit and dessert flavors, respectively.
- A 2019 user survey found that fruits, candy, dessert, and beverage flavors were preferred across all age groups and that less than 5 percent of vapers preferred tobacco-flavored e-cigarettes.[32]

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[29] Center for Tobacco Products, "FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint," *FDA News Release*, U.S. Food and Drug Administration, Jan. 2, 2020, https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children.

[30] Cooper, Maria *et* al., *supra* note 14.

[31] Konstantinos Farsalinos, "Submitting to the FDA the findings of the largest ever survey on e-cigarette flavors use by US vapers," *E-Cigarette Research*, Aug. 11, 2018, http://www.ecigarette-research.org/research/index.php/whats-new/2018-2/266-us-flav.

[32] Consumer Advocates for Smokefree Alternatives Association, "ECigintelligence User Survey 2019," Aug. 25, 2020, https://casaa.org/ecigintelligence-user-survey-2019/.

- A 2020 cohort study of nearly 18,000 participants found that "adults who began vaping non-tobacco-flavored e-cigarettes were more likely to quit smoking than those who vaped tobacco flavors."[33]

The fact that the e-cigarette marketplace is full of flavors also indicates that adults are using them.

According to a CDC analysis examining retail scanner data from e-cigarette sales between January 2020 and December 2022, overall unit sales increased by 46.6 percent during the period.[34] The percent of tobacco and mint-flavored products decreased by 22.9 percent and 41.6 percent, respectively. During the same period, sales of other flavors increased by 41.4 percent.

Again, during the same period, youth vaping was significantly decreasing, while the percentage of adults who were vaping in the U.S. increased by over 30 percent between 2017 and 2021.

FDA's Denial of Majority of Products Allowed Illicit Market to Flourish

E-cigarettes have been available for retail sale in the U.S. 2007 and even prior to being deemed tobacco products by the FDA in 2014, experienced tremendous innovation and growth. Unfortunately, because of the FDA's defacto flavor ban, a growing market of illicit products is harming the regulatory process.

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.[35] In March

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[33] Friedman, Abigail S. and SiQing Xu, "Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation," *JAMA Network Open*, e203826, (2020): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7275248/.

[34] Ali, Fatma Romeh M., *et* al., "E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022," *Morbidity and Mortality Weekly Report*, U.S. Centers for Disease Control and Prevention, Jun. 23, 2023, https://www.cdc.gov/mmwr/volumes/72/wr/mm7225a1.htm.

[35] U.S. Food and Drug Administration, "CBP, FDA Seize Counterfeit, Unauthorized E-Cigarettes," *FDA News Release*, Jan. 13, 2021, https://www.fda.gov/news-events/press-announcements/cbp-fda-seize-counterfeit-unauthorized-e-cigarettes.

2021, U.S. Customs and Border Protection (CBP) officers in Chicago seized $1.5 million in counterfeit vapes.[36]

Understandably, CBP is not actively seeking out illicit vapor products, yet a surge of these unregulated products is being seen globally. This year, officials in Australia,[37] China,[38] Singapore[39], and the UK[40] 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.[41]

The FDA itself has recently responded to the massive increases in both legitimate products and counterfeit vapor products.

In July 2020, the agency issued warning letters to 10 companies ordering them to remove their flavored disposable products from market.[42]

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[36] U.S. Customs and Border Protection, "CBP Officers in Chicago Capture $1.5 Million in Counterfeit Vaping Pens," *Local Media Release*, Mar. 11, 2021, https://www.cbp.gov/newsroom/local-media-release/cbp-officers-chicago-capture-15-million-counterfeit-vaping-pens.

[37] Mary Ward, "More than $2 million worth of vapes seized in state health crackdown," *The Sydney Morning Herald*, Feb. 14, 2022, https://www.smh.com.au/national/nsw/more-than-2-million-worth-of-vapes-seized-in-state-health-crackdown-20220128-p59s0m.html.

[38] Diane Caruana, "Hong Kong Customs Seize Thousands of Vape Products Worth a Total of HK$10 Million," *VapingPost*, Jun. 6, 2022, https://www.vapingpost.com/2022/06/06/hong-kong-customs-seize-thousands-of-vape-products-worth-a-total-of-hk10-million/.

[39] "Singapore Seizes Nearly $1 Million in Illegal Vapes," *VaporVoice*, Jun. 2, 2022, https://vaporvoice.net/2022/06/02/singapore-seizes-nearly-1-million-in-illegal-vapes/?utm_source=rss&utm_medium=rss&utm_campaign=singapore-seizes-nearly-1-million-in-illegal-vapes.

[40] Charlotte Lillywhite, "Massive £100k shipment of dodgy vapes seized near Heathrow Airport," *MyLondon*, Aug. 9, 2022, https://www.mylondon.news/news/west-london-news/massive-100k-shipment-dodgy-vapes-24708471.

[41] Kiran Paul, "Elf Bar helps close 20 counterfeit factories in China, seizing million fake vapes," *Asian Trader*, Jul. 15, 2022, https://www.asiantrader.biz/elf-bar-helps-close-down-20-counterfeit-factories-in-china-seizing-over-a-million-fakes/.

[42] U.S. Food and Drug Administration, "FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization," *FDA News Release*, Jul. 20, 2020, https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth.

In May 2023, the FDA issued warning letters to the manufacturers of two popular disposable vapor products as well as issuing an import alert for one brand of disposable vapes.[43] Following up, FDA later issued warning letters to 30 retailers and one distributor for see selling two different brands of disposable e-cigarettes without marketing authorization authority.[44] In June, the agency reported having issued more than 180 warning letters to retailers for selling two particular disposable e-cigarette brands that did not have market authorization orders.[45]

Again, the FDA is ill equipped to handle the massive influx of new products that have arisen to due to FDA regulations which turned the existing marketplace into an illicit, unregulated and unauthorized market. One study fund that even amid massive denial orders, between June 2021 and June 2022, the number of unique e-cigarette products available increased by over 300 percent from 453 to 2,023.[46]

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

FDA's Regulatory Language and Inaction Adds to Misperception of Tobacco Harm Reduction

Unfortunately, one of the worse flaws of the TCA is the language permitted to be used when allowing for the marketing of new tobacco products.

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[43] Center for Tobacco Products, "FDA Puts Firms Responsible for Esco Bars and Breeze — Two Popular Disposable E-cigarette Brands — on Notice," U.S. Food and Drug Administration, May 25, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-puts-firms-responsible-esco-bars-and-breeze-two-popular-disposable-e-cigarette-brands-notice.

[44] U.S. Food and Drug Administration, "FDA Conducts Retailer Inspection Blitz, Cracks Down on Illegal Sales of Popular Disposable E-cigarettes," *FDA News Release*, May 31, 2023, https://www.fda.gov/news-events/press-announcements/fda-conducts-retailer-inspection-blitz-cracks-down-illegal-sales-popular-disposable-e-cigarettes.

[45] U.S. Food and Drug Administration, "FDA Inspection Blitz Leads to More Than 180 Warning Letters to Retailers for the Illegal Sale of Youth-Appealing Elf Bar and Esco Bars E-Cigarettes," *FDA News Release*, Jun. 22, 2023, https://www.fda.gov/news-events/press-announcements/fda-inspection-blitz-leads-more-180-warning-letters-retailers-illegal-sale-youth-appealing-elf-bar.

[46] Truth Initiative, "E-cigarette products sold on the market quadruple in just one year," Mar. 15, 2023, https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarette-products-sold-market-quadruple-just-one.

Section 46 of the TCA states:

> "If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is *approved* or inspected by [FDA] or complies with [FDA] standards are likely to be confused and misled."

FDA is essentially unable to "approve" new products, only "authorize" the sale of them. The agency has yet to "approve" an e-cigarette as a smoking cessation device. There is no indication the FDA will ever approve an e-cigarette. This is despite evidence of e-cigarettes (and other tobacco harm reduction products) being significantly less harmful and useful in helping adults quit smoking.

According to a July 2023 FDA webpage on e-cigarettes, the agency notes that:

> "While certain e-cigarettes may adults who smoke to transition completely away from, or significantly reduce their use of, more harmful cigarettes, no e-cigarette product has been approved by FDA as a smoking cessation device."[47]

As such, public health groups who wage active campaigns against tobacco harm reduction products can confuse policymakers and the public in the safety and efficacy of e-cigarettes and other alternatives to cigarettes. Groups using FDA inaction on cessation claims use such statements to push for bans and draconian regulations include:

- Truth Initiative: "While some adults have used e-cigarettes to switch completely from combustible cigarettes, the FDA has not approved any e-cigarette as a cessation intervention, and nearly half of adults who use e-cigarettes also use cigarettes."[48]
- American Lung Association: "Despite what … e-cigarette companies want you to believe, switching to vaping (e-cigarettes) is not quitting smoking. E-cigarettes are still tobacco products, and FDA has not approved any e-cigarette as a quit smoking device."[49]

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[47] U.S. Food and Drug Administration, "Facts About E-Cigarettes," *Rumor Control*, Jul. 26, 2023, https://www.fda.gov/news-events/rumor-control/facts-about-e-cigarettes/.

[48] Truth Initiative, "Action Needed: E-Cigarettes," Nov. 2020, https://truthinitiative.org/sites/default/files/media/files/2021/06/Truth_E-Cigarette%20Factsheet%20update%20JUNE%202021_FINAL.pdf.

[49] American Lung Association, "Don't Just Switch, Quit Tobacco For Good," May 31, 2023, https://www.lung.org/quit-smoking/e-cigarettes-vaping/quit-dont-switch.

- American Medical Association (AMA): "AMA has called for a total ban on all e-cigarette and vaping products that do not meet FDA approval as cessation tools."[50]
- American Heart Association: "The lack of long-term scientific safety data on e-cigarette use, along with the potential for the addiction to e-cigarette products seen among youth, are among the reasons the American Heart Association does not recommend e-cigarette use for cessation efforts."[51]

There is ample evidence that e-cigarettes are associated with decreases in smoking rates and cessation.

- A 2017 user survey of nearly 70,000 American adult vapers found nearly 95 percent of participants were ever smokers, and 74.6 percent were former smokers who had used e-cigarettes at the time of smoking cessation.[52]
- A 2019 randomized trial comparing e-cigarettes to FDA approved nicotine replacement therapy found e-cigarettes to be "more effective for smoking replacement than nicotine-replacement therapy."[53]
- A 2022 Cochrane Review of 78 studies examining e-cigarette use and smoking cessation determined that participants were "more likely to stop smoking for at least six months using nicotine e-cigarettes than nicotine replacement therapy, or e-cigarettes without nicotine."[54]

> The misperception of nicotine and the reduced harm reduction potential of novel tobacco products is rampant in the years of authorizing (and issuing massive denials) of marketing orders

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[50] American Medical Association, "E-cigarettes and vaping: A public health epidemic," Accessed Aug. 2023, https://www.ama-assn.org/delivering-care/public-health/e-cigarettes-and-vaping-public-health-epidemic.

[51] American Heart Association, "Current evidence identifies health risks of e-cigarette use; long-term research needed," Jul. 17, 2023, https://newsroom.heart.org/news/current-evidence-identifies-health-risks-of-e-cigarette-use-long-term-research-needed.

[52] Konstantinos Farsalinos, *supra* note 31.

[53] Hajek, Peter *et* al., "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy," *The New England Journal of Medicine*, 380:629-637, (2019): https://www.nejm.org/doi/full/10.1056/nejmoa1808779.

[54] Hartmann-Boyce, J., *et* al., "Can electronic cigarettes help people stop smoking, and do they have any unwanted effects when used for this purpose?," *Cochrane Library*, (2022): https://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-do-they-have-any-unwanted-effects-when-used.

for e-cigarette products, public confusion over the differing associated risks of tobacco products is harming American adult consumers, especially those who smoke.

The AMA recently updated guidelines accepted among its association (as well as other public health trade associations), which was repeated by numerous media out lets and reported that doctors "increasingly discourage vaping amid mounting health concerns."[55]

AMA's updated guidelines state "[a]lthough e-cigarettes increase the likelihood of successful smoking cessation compared with nicotine replacement therapy, because of the lack of long-term safety data … e-cigarettes are not recommended as a first-line therapy for smoking cessation."[56] While the authors of the report note identify at least 29 randomized control trials indicating efficacy in cessation, they ascertain that only five are "at a low risk of bias." The guidelines again repeat to not recommend e-cigarettes a "first-line therapy for smoking cessation," and urge that patients with chronic coronary disease who use e-cigarettes "be warned about risks of developing long-term dependence and encouraged to quit use of e-cigarettes promptly to avoid potential long-term risks."[57]

A recent global survey of more than 15,000 doctors representing 11 different countries came to the alarming conclusion with 74 percent of participants "incorrectly [believing that] nicotine causes a range of illnesses from lung cancer to COPD."[58] According to the survey administers, more than two-thirds (77 percent) of doctors "mistakenly believe nicotine causes lung cancer."[59]

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[55] Adesola Oje, "Doctors increasingly discoursing vaping amid mounting health concerns," *ABC News*, Jul. 31, 2023, https://abcnews.go.com/Health/doctors-increasingly-discourage-vaping-amid-mounting-health-concerns/story?id=101784059&cid=social_twitter_abcn.

[56] Virani, Salim S., *et* al., "2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines," *Circulation*, American Heart Association, Jul. 20, 2023, https://www.ahajournals.org/doi/10.1161/CIR.0000000000001168.

[57] *Ibid.*

[58] Foundation for a Smoke-Free World, "Nearly 80% Of Doctors Worldwide Mistakenly Believe Nicotine Causes Cancer, Thwarting Efforts To Help One Billion Smokers Quit," 2023, https://www.smokefreeworld.org/newsroom/nearly-80-of-doctors-worldwide-mistakenly-believe-nicotine-causes-lung-cancer-thwarting-efforts-to-help-one-billion-smokers-quit/.

[59] *Ibid.*

Further, among American physicians, 70 percent "moderately" agreed nicotine was the source for "lung, bladder, and head/neck/gastric cancer."[60]

This misperception of nicotine's role in causing cancer is nothing new.

A 2018 study examining a 2017 government health information survey of American adults found that 53 percent believed that nicotine is what caused most of the cancer related to smoking.[61] A 2020 Rutgers-led survey of more than 1,000 physicians determined that 80 percent of respondents "believe it is the nicotine directly that causes cancer."[62] Recently, a 2022 study estimated that 61.2 percent of adults who smoke believe that nicotine causes cancer.[63]

Recently, the FDA responded with commentary to a research study in the journal *Addiction*, which found common misperceptions among adults who smoke and do not smoke on the harm reduction of cigarettes. According to the article published in May 2023, in the U.S. "most adults who smoke cigarettes and young adult non-smokers do not appear to think that e-cigarettes have fewer harmful chemicals than cigarettes."[64]

In the response commentary, the CTP Director remarked that the study's findings "suggest opportunities exist to educate adult smokers about the relative risks of tobacco products."[65] Unfortunately, the agency continued to point out the need for adults to first use the minimal

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[60] *Ibid.*

[61] Richard Craver, "Study finds majority of adults erroneously link nicotine to cancer," *Winston-Salem Journal*, Mar. 4, 2018, http://www.journalnow.com/business/study-finds-majority-of-adults-erroneously-link-nicotine-to-cancer/article_d249b427-3993-5c35-a044-bc6334617f07.html.

[62] Modest Alobawone, "Researchers say physicians need to understand accurate nicotine risks better to assist patients addicted to the most harmful tobacco products," Rutgers, Sep. 8, 2020, https://www.rutgers.edu/news/rutgers-led-national-survey-uncovers-doctors-misconceptions-about-nicotine-risks.

[63] Weiger, Caitlin *et* al., "Beliefs and Characteristics Associated With Believing Nicotine Causes Cancer: A Descriptive Analysis to Inform Corrective Message Content and Priority Audiences," *Nicotine & Tobacco Research*, 1264–1272, (2022): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9278833/.

[64] Wackowski, Olivia A., *et* al., "Perceptions about levels of harmful chemicals in e-cigarettes relative to cigarettes, and associations with relative e-cigarette harm perceptions, e-cigarette use and interest," *Addiction*, May 23, 2023, https://onlinelibrary.wiley.com/doi/full/10.1111/add.16258.

[65] King, Brian A., and Benjamin A. Toll, "Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers," *Addiction*, Aug. 15, 2023, https://onlinelibrary.wiley.com/doi/full/10.1111/add.16296.

FDA-approved products (which most adult e-cigarettes have already used and failed with), and the need for aggressive action to prevent youth e-cigarette use.

Yet, the FDA has been failing for the past half decade in explaining to the public – as well as manufacturers of reduced risk products – the continuum of harm in which tobacco products exist.

In 2017, FDA announced a radical plan to strike "an appropriate balance between regulation and encouraging the development of innovative tobacco products that may be less dangerous than cigarettes."[66] In the statement, the FDA reported that a "key piece" of the agency's "approach is demonstrating a greater awareness that nicotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes."

In 2019, the agency authorized the first-ever modified risk tobacco product orders (MRTPs) for eight smokeless snus products, noting that "FDA recognizes that tobacco products exist on a continuum of risk, with combustible cigarettes being the deadliest."[67]

Again, in the recent commentary about misperceptions, the CTP director notes that although "there are no safe tobacco products, the available scientific evidence indicates that tobacco products exist on a continuum of risk, with cigarettes being the most harmful."[68]

because of FDA's inactions and continued denial of massive amounts of e-cigarette products, reforms should include public health awareness campaigns on the reduced risks associated with the varying tobacco harm reduction products.

FDA's Budget Relies on Combustible Cigarette, Need For Financial Reform

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[66] U.S. Food and Drug Administration, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death," *FDA News Release*, Mar. 23, 2018, https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

[67] Center for Tobacco Products, "FDA Authorizes Modified Risk Tobacco Products," U.S. Food and Drug Administration, "May 4, 2020, https://www.fda.gov/tobacco-products/advertising-and-promotion/fda-authorizes-modified-risk-tobacco-products.

[68] Center for Tobacco Products, "CTP Director Discusses Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products Among Adults Who Smoke," U.S. Food and Drug Administration, Aug. 15, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-director-discusses-opportunities-and-considerations-addressing-misperceptions-about-relative.

Unfortunately, because of the language in the TCA, CTP is "solely funded by tobacco user fees" which are applied to a limited amount of tobacco products.[69]

Currently, CTP collects user fees on only six categories of tobacco products and collected nearly $712 million in user fees in FY 2023.[70] Of the products which the agency collected user fees from, the amount collected and percent allocation by class of tobacco product were:

- Cigarettes: $148.9 million (83.6 percent)
- Cigars: $25.6 million (14.4 percent)
- Snuff: $2.3 million (1.3 percent)
- Pipe Tobacco: $1 million (0.6 percent)
- Chewing Tobacco: $102,350 (0.06 percent)
- Roll-Your-Own Tobacco: $65,080 (0.04 percent)

Relying on the sale of combustible cigarettes for most of the funding for the Center is irresponsible and flies in the face of promoting the protection of public health. Such budgetary constraints make the agency beholden to the sale of combustible cigarettes.

E-cigarettes (and other novel tobacco products) are not subject to user fees and thus there is no incentive for the agency to authorize products by new manufacturers. Many of these new tobacco product manufacturers are small business marketing solely products which do not fall beneath the CTP's user fee schedule.

It is also unfair to existing tobacco product manufacturers who are subject to FDA tobacco user fees to be essentially funding the agency's enforcement actions against products not subject to the same fees – as well as products that are not overwhelmingly being used by youth.

Ultimately, FDA will have to reconcile user fees. Currently fees are assessed by market share and not the harm potential of products. As products exist on a continuum of harm, the fees should be represented to recognize this reduced harm.

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[69] Government Accountability Office, "Tobacco Product Regulation:
Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities," GAO-14-561, Jun. 20, 2014, https://www.gao.gov/products/gao-14-561.

[70] Center for Tobacco Products, "Tobacco User Fee Assessment Formulation by Product Class," U.S. Food and Drug Administration, Sep. 28, 2022, https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fee-assessment-formulation-product-class.

It is imperative that FDA policies not only educate the public about reduced harm products, and that the fees do not confuse the public about the reduced harms associated with products.

Lessons from Other Countries Encouraging and Promoting the Introduction and Use of Tobacco Harm Reduction Products

The U.S. is failing at properly regulating a massive new product category which is ultimately a failure to adults who use harmful combusted tobacco products.

Other countries, often with federal governments who endorse the use of vapor products for adults who are unable to quit smoking, are not restricted to a regulatory schematic that permits only a limited number of manufacturers from coming to market.

In the United Kingdom (UK), e-cigarette manufacturers are required to notify the Medicines and Healthcare products Regulatory Agency (MHRA) prior to introducing e-cigarette product to the market. E-cigarette products and e-liquids are subject to certain product standards, including ingredients, limits on nicotine concentration, and emission standards.

The MHRA has established quality and manufacturing standards which manufacturers must adhere to prior to entering the marketplace, including quality control processes and batch testing requirements.

Similar to the U.S., in the UK, e-cigarette products are subject to age restrictions and manufacturers are required to include health warnings and other information including ingredient listings and nicotine content on e-cigarette product labels.

New Zealand e-cigarette regulations are quite similar to the UK in that manufacturers must notify the Ministry of Health prior to introducing products to market, which are then subject to certain regulations.

In the U.S., manufactures are required to get authorization for every single product, despite many e-cigarette products and e-liquids being very similar, if not completely alike. This severely limits the marketplace and fails to respond to consumer demand.

Reforms FDA Should Take To Ensure The U.S. Remains A Leader In Innovation, Protecting Small Businesses, Reducing Youth Use

Vital reforms needed by the FDA to its PMTA process include reassessing the entire process to bring products to market.

There is a fundamental flaw for a public health agency to be authorizing additional combusted tobacco products while denying hundreds of thousands of less harmful e-cigarette products due to extensive requirements imposed upon small businesses. Only 23 e-cigarette products have been authorized for only three different manufacturers – all which have long established marketplaces and massive capital. FDA processes should not be limiting the marketplace to only a handful of companies.

Reforming the PMTA process could include:

- Establishing ingredients that can be brought to market without the need for extensive testing and studies and allowing companies to notify FDA rather than forcing manufacturers to receive authorization
- Simplifying and streamlining the application requirements that could help reduce the costs associated with the premarket review process. This might involve focusing on the most essential scientific data while eliminating redundant or excessive requirements.
- Implementing a tiered review system which could provide a differentiated approach based on the complexity of the product. This would allow simpler products with potentially lower health risks to undergo a more expedited review process.
- Encouraging collaboration among smaller manufacturers or forming industry consortia that could help distribute the costs and resources needed for conducting required studies and data collection.
- Creating specific pathways for innovative products that show potential for reduced harm or novel harm reduction approaches that could encourage the development of new, safer products.

FDA must reconcile youth use of age-restricted products. To date, the agency continues to deny applications for flavored e-cigarette products, citing youth use, yet youth use is decreasing and is at levels far below what is required for persons to sell combustible cigarettes. Youth use should be a factor in FDA considering the authorize a product, yet youth use should not be the main reason for FDA to deny authorization.

FDA should also rely more on post market surveillance in determining the likelihood of youth use of such products. Given the complexity of the different tobacco products on the marketplace, FDA should be focusing on products that appeal to youth, while allowing products not often cited by youth to be on market and monitor youth use. Post market surveillance will also offer

the agency some relief in identifying bad manufacturers who are actively targeting children and permit the FDA to respond in real time to those manufacturers. Relying on post market surveillance will also offer insight to the agency to determine the behaviors of adult users of new products – providing ample evidence to the efficacy of such products helping adults transition to safer alternatives to cigarettes.

FDA must reconcile the funding process for CTP. CTP cannot continue to claim to be agency promoting public health when the agency relies on more than 80 percent of its funding from the sale of combustible cigarettes – i.e., the people who smoke. There is also a fundamental flaw in relying on only certain tobacco products to fund the agency and its activities monitoring other tobacco products.

Finally, FDA must enhance its communication to the public about the continuum of risk that exist among all tobacco products. American adults are essentially misinformed about less harmful alternatives and most of this misperception stems from the agency's lack of communication but also due to FDA not authorizing the many products that have existed on the marketplace since at least 2016.

FDA should continue to reform its tobacco regulatory authority as the agency is failing adults who smoke and falling behind other world leaders in encouraging harm reduction. Any reforms must recognize that the agency needs to evolve to better respond to the marketplace and provide adults with safer alternatives to cigarettes.

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