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August 29, 2023

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments in Response to Public Meeting and Listening Session for Developing the Food and Drug Administration's Center for Tobacco Products' Strategic Plan, Docket No. FDA-2023-N-2873, 88 Fed. Reg. 47,509 (July 24, 2023)

The Campaign for Tobacco-Free Kids (Tobacco-Free Kids) submits these comments in response to the above-referenced Listening Session on the development of the Strategic Plan for the Center for Tobacco Products (CTP).

INTRODUCTION

Tobacco-Free Kids appreciates the opportunity to participate in the Listening Session on August 22, as well as to provide written comments. We also commend CTP for engaging in this Strategic Planning process, for seeking public input and for establishing the end of 2023 as its target date for issuing a 5-year Strategic Plan.

Before turning to the four "goal areas" on which FDA has sought comments, it is important to articulate two overarching realities that provide the necessary backdrop for the development of a Strategic Plan to address each of those goals.

First, the regulation of tobacco products, as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) is fundamentally different from the regulation of other products, like drugs, food and medical devices, subject to FDA jurisdiction under the Food, Drug & Cosmetic Act (FDCA). The TCA was enacted as a response to decades of predatory conduct by the tobacco industry, conduct that resulted in a finding by a federal court that the industry had violated federal anti-racketeering laws by engaging in a massive conspiracy to defraud the American public by lying about the health effects of smoking and the marketing of cigarettes to children.[1] Significantly, the court also determined that the

[1] *U.S. v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009).

companies were likely to continue their predatory conduct into the future.[2] The Congressional findings in the TCA make specific reference to the court's factual findings[3] and make clear that the legislation is intended "to address the public health crisis created by actions of the tobacco industry."[4]

Thus, the mission of FDA under the TCA is to protect the public, and particularly America's children, from a predatory industry that markets harmful and addictive products. Whatever the shortcomings of the other industries regulated by FDA, the fact is that they have long supplied many products that enhance public health and welfare. In contrast, tobacco regulation is directed at an industry that has caused enormous harm to public health through its predatory practices. In this case the very product being regulated is the cause of the harm that prompted Congress to act. Any CTP Strategic Plan must reflect the reality that the policies and processes developed by FDA to regulate other products may not function to protect public health when applied to the tobacco industry and its products. A primary goal of the TCA is to protect the public from the tobacco industry's products, including the industry's history of introducing new products that increased the number of tobacco users and decreased the number of people who quit using tobacco.

Second, it should be apparent that Congress has given CTP powerful regulatory tools to protect the public from the tobacco industry. From a public health standpoint, it is encouraging that CTP is beginning to use its broad authority to issue rules that can implement product standards to fundamentally change the nature of tobacco products, making them less appealing, addictive and hazardous to health. It also is encouraging that FDA is beginning to use its broad premarket review authority to deny marketing authorization to flavored e-cigarette products that have proven to be particularly attractive to young people and have undermined our progress in reducing youth usage of tobacco products. It is important that CTP's Strategic Plan build on this progress by fully utilizing the broad authority conferred by Congress to protect the public, and particularly young people, from the harm of tobacco products.

DISCUSSION OF PROPOSED STRATEGIC GOALS

I. <u>Develop, Advance and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance</u>

A. Failure to Use Broad Rulemaking Authority

The power to issue regulations imposing product standards to make tobacco products less appealing, addictive and harmful is potentially CTP's most significant tool to reduce the disease and death caused by tobacco products. For most of CTP's history, however, this authority has been underutilized. In its first thirteen years, CTP issued only one proposed product standard—to

[2] *Id.* at 909.
[3] TCA, Pub. L. No. 111-31 § 2(47)-(49), 123 Stat. 1781 (2009).
[4] *Id.* § 2(29), 123 Stat. at 1778.

reduce the carcinogen NNN in smokeless tobacco[5]—and that rule has yet to be issued in final form. Although the proposed rules banning menthol as a characterizing flavor in cigarettes[6] and banning all characterizing flavors in cigars[7] are significant steps forward, those rules were issued in proposed form in 2022 only after public health groups brought a lawsuit alleging "unreasonable delay" by the agency in responding to an earlier Citizen Petition seeking a menthol cigarette ban.[8] CTP's Strategic Plan should, as a central objective, seek to more fully utilize the broad authority to issue product standards conferred by the TCA.

B. Delays in Exercising Rulemaking Authority

The Strategic Plan also should seek to minimize delays in the rulemaking process of the kind that have historically hampered CTP. Even when CTP has been required by statute to issue regulations, or has indicated its intent to do so, the rulemaking process has been encumbered by significant delays, with important public health consequences:

- The Deeming Rule. FDA first indicated in 2011 its intent to issue a deeming rule subjecting all tobacco products, including e-cigarettes, to its regulatory jurisdiction. The agency did not issue its final rule until 2016.[9] During those intervening years, many thousands of entirely unregulated e-cigarettes entered the market, including many flavored products that contributed to an epidemic of youth e-cigarette use.

- The rule limiting the carcinogen NNN in smokeless tobacco products. This rulemaking was initiated in January 2017 and the comment period on the proposed rule closed in April 2017. Six years later, the Rule has yet to be issued in final form.

- The rule requiring graphic health warnings for cigarettes. The TCA requires FDA to issue a rule requiring the placement of large, graphic health warnings on

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[5] Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8,004 (proposed Jan. 22, 2017), https://www.govinfo.gov/content/pkg/FR-2017-01-23/pdf/2017-01030.pdf.

[6] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (proposed May 4, 2022), https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08994.pdf.

[7] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. 26,396 (proposed May 4, 2022), https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08993.pdf.

[8] *See* Compl. (Doc. No. 1) at 41, *Afr. Am. Tobacco Control Leadership Council v. U.S. Dep't of Health & Human Servs.*, 571 F.Supp.3d 1144 (N.D. Cal. 2021), https://ashorg.wpenginepowered.com/wp-content/uploads/2020/06/ASH-AATCLC-Complaint.pdf.

[9] 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, 81 Fed. Reg. 28,974 (May 10, 2016), https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

cigarette packs and advertising. After FDA's initial rule was struck down by the U.S. Court of Appeals for the D.C. Circuit in 2012[10] and the rulemaking was remanded to FDA, FDA did not issue a second graphic warnings rule until a federal court in Boston, pursuant to a lawsuit filed by Tobacco-Free Kids and other public health groups and several pediatricians, ordered FDA to issue a second rule. The court found that FDA had "unlawfully withheld and unreasonably delayed" issuance of the rule.[11] Pursuant to that court order, FDA issued a final rule on March 18, 2020.[12]

- The proposed rule prohibiting menthol as a characterizing flavor in cigarettes. The Tobacco Product Scientific Advisory Committee (TPSAC) issued its report recommending removal of menthol cigarettes from the market in 2011,[13] which the industry then challenged. Their lawsuit produced a lower court ruling barring use of the report by FDA, which was later overturned.[14] The FDA issued its own menthol report in 2013 concluding, as TPSAC did, that menthol cigarettes likely "pose a public health risk above that seen with nonmenthol cigarettes."[15] Despite these conclusions, advanced notices of proposed rulemakings issued in 2013 and 2018,[16] and an FDA Commissioner's announced intention to issue a notice of proposed rulemaking,[17] FDA did not actually propose the menthol cigarette product standard until May 2022, over two years after a lawsuit was initiated by public health groups charging FDA with "unreasonable delay" in taking action on menthol cigarettes.[18]

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[10] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. U.S. Dept. of Agric.*, 760 F.3d 18 (D.C. Cir. 2014).
[11] *Am. Acad. of Pediatrics v. FDA*, 330 F.Supp.3d 657 (D. Mass. 2018).
[12] However, industry lawsuits against the rule postponed the rule's effective date pending resolution of those cases. *R.J. Reynolds Tobacco Co. v. FDA*, No. 6:20-cv-00176 (E.D. Tex.); *Philip Morris USA, Inc. v. FDA*, No. 1:20-cv-01181 (D.D.C.). The rule was vacated in *R.J. Reynolds Tobacco Co. v. FDA*, 6:20-cv-00176, 2022 WL 17489170 (E.D. Tex. Feb. 6, 2023).
[13] TPSAC, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (2011), https://wayback.archive-it.org/7993/20170405201731/https:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.
[14] *R.J. Reynolds Tobacco Co. v. FDA*, 810 F. 3d 827 (D.C. Cir. 2016).
[15] FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Non-Menthol Cigarettes* (2013), https://www.fda.gov/media/86497/download.
[16] Menthol in Cigarettes, Tobacco Products; Request for Comments, 78 Fed. Reg. 44,484 (July 24, 2013), https://www.govinfo.gov/content/pkg/FR-2013-07-24/pdf/2013-17805.pdf; Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018), https://www.govinfo.gov/content/pkg/FR-2018-03-21/pdf/2018-05655.pdf.
[17] https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers
[18] Compl., *supra* note 8.

Although industry litigation obviously has played a role in delaying FDA action on life-saving regulations, much of the delay was unrelated to that litigation. Indeed, in the case of the graphic warnings rule and the menthol cigarette rule, it took litigation by public health groups to bring about FDA action. Avoiding unnecessary delay in rulemaking should be a key tenet of any CTP Strategic Plan.

C. Highest Priority Rules

The Strategic Plan should make clear that CTP's highest short-term priorities include issuance of final rules prohibiting menthol as a characterizing flavor in cigarettes and prohibiting all characterizing flavors in cigars. It should also place a priority on issuing and finalizing a product standard limiting nicotine in cigarettes and other combustible products to non-addictive or minimally addictive levels.

1. Menthol Cigarette Rule

Few actions CTP could take in exercising its authority under the TCA would have as great an impact in preventing tobacco-caused mortality, avoiding suffering from tobacco addiction and disease, and reducing persistent and tragic health disparities in the U.S. as the proposed rule prohibiting menthol as a characterizing flavor in cigarettes. The science supporting this product standard has been clear for over a decade and has grown stronger with each passing year.[19] In seeking comments on tobacco regulations to guide development of its Strategic Plan, CTP has highlighted "efforts to advance health equity."[20] Given the decades of industry targeting of the Black community in its marketing of menthol cigarettes, and the resulting disproportionate toll of tobacco-related disease and death on that community, prohibiting menthol cigarettes would be the most important single step CTP could take to advance health equity.

It has now been a full year since the comment period closed on the proposed menthol rule. The Spring 2023 Unified Regulatory Agenda shows August, 2023 as the planned date for issuance of a final rule.[21] We strongly urge CTP to ensure that the final rule is issued within the next 30 days.

2. Flavored Cigar Rule

CTP should also issue its final rule prohibiting all characterizing flavors in cigars. There is no question that the tobacco industry has deliberately developed and marketed flavored cigars to appeal to youth, resulting in more high school boys now smoking cigars than smoke

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[19] *See generally* Comments of Over 100 Public Health, Medical, Educational and Civil Rights Organizations in Docket No. FDA-2021-N-1349, *Tobacco Product Standard for Menthol in Cigarettes* (Aug. 2, 2022), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Support_Prohibiting_Menthol_Cigarettes_8_2_2022.pdf

[20] 88 Fed. Reg. at 47,510.

[21] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI60.

cigarettes.[22] The industry has particularly targeted Black youth with flavored cigars, resulting in Black high school students smoking cigars at a much higher rate than white high school students (4.4% vs. 2.8%).[23] Issuance of the flavored cigar rule in final form thus will be a substantial step toward greater health equity. Moreover, because consumers substitute cigarettes and cigars, particularly little or filtered cigars, issuance of the flavored cigar rule in conjunction with the menthol cigarette rule, will enhance the beneficial public health impact of both rules.[24]

It is now one year since the comment period closed. There is no reason for further delay in issuing the flavored cigar rule in final form. The Unified Regulatory Agenda lists August 2023 as the indicated date for this final rule.[25] Like the menthol cigarette rule, it should be issued within the next 30 days.

3. Nicotine Reduction Rule

CTP's Strategic Plan also should establish firm deadlines for a rulemaking to establish a product standard reducing nicotine in cigarettes to non-addictive or minimally addictive levels. Such a rule would have historic public health benefits. It would prevent young people who experiment with smoking from becoming addicted and save them from a lifetime of addiction, tobacco-caused disease and premature death. It also would reduce the level of nicotine dependence in adult smokers, making it easier for them to quit.[26] In 2018, CTP estimated that reducing nicotine levels in combusted tobacco products would prevent more than 33 million youth and young adults from initiating regular smoking by the year 2100.[27] In addition, within

[22] Eunice Park-Lee et al., *Tobacco Product Use Among Middle and High School Students – United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1429, 1432 tbl.1 (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7145a1-H.pdf.
[23] *Id.*
[24] *See* Comments of Over 100 Public Health, Medical, Educational and Civil Rights Organizations in Docket No. FDA-2021-N-1309, *Tobacco Product Standard for Characterizing Flavors in Cigars*, at 23-24 (Aug. 2, 2022), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Support_Prohibiting_Flavored_Cigars_8_2_2022.pdf.
[25] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI60
[26] *See generally* Comments by 40 Public Health, Medical and Other Organizations in Docket No. FDA-2017-N-6189, *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes* (July 16, 2018), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2018_07_16_Nicotine_Standard_ANPRM.pdf.
[27] Benjamin J. Apelberg, et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 NEW. ENG. J. MED. 1725 (2018), https://www.nejm.org/doi/full/10.1056/NEJMsr1714617; *see also* Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Advanced Notice of Proposed Rulemaking, 83 Fed. Reg. 11,818 (Mar. 16, 2018), https://www.govinfo.gov/content/pkg/FR-2018-03-16/pdf/2018-05345.pdf.

five years, it would cause 13 million smokers to quit, including five million within the first year.[28] Ultimately, over 8 million lives would be saved by the end of the century.[29]

Given CTP's own estimates of the extraordinary lifesaving impact of a nicotine reduction product standard, the Strategic Plan should reflect a sense of real urgency about moving this rule forward. A nicotine reduction product standard has been under active consideration by CTP since it was presented as part of FDA Commissioner Gottlieb's plan for comprehensive nicotine regulation in July of 2017.[30] CTP issued an Advance Notice of Proposed Rulemaking over five years ago[31] and, over one year ago, Commissioner Califf announced the agency's plans to issue a proposed rule, listing it on the Administration's Unified Regulatory Agenda.[32] In September of 2022, over seventy public health, medical and professional organizations wrote to Commissioner Califf in strong support of his announcement.[33] However, the indicated date for issuance has slipped from May, 2023 to December, 2023. The Strategic Plan should provide for issuance of a proposed rule by December, 2023 and should specify a date certain in 2025 for a final rule.

D. Other Important Rulemaking Proceedings

The Strategic Plan also should provide for action to move forward, and complete, rulemakings in the following areas:

- Issue rule mandating creation of track and trace system to deter illicit trade. In March, 2013, the New York City Department of Health and Mental Hygiene, joined by Tobacco-Free Kids and other public health organizations, filed a Citizen Petition urging FDA to fulfill the mandate in the TCA to create a track and trace system to reduce the illicit trade in tobacco products.[34] Ten years later,

[28] *Id.* at 11,837
[29] *Id.*
[30] FDA News Release, *FDA's Plan for Tobacco and Nicotine Regulation* (July 2017), https://web.archive.org/web/20180125072524/https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm
[31] 83 Fed. Reg. 11,818.
[32] FDA News Release, *FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products* (June 21, 2022), https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco#:~:text=Today%2C%20the%20Biden%2DHarris%20Administration,and%20certain%20other%20combusted%20tobacco
[33] Letter from Public Health, Medical and Community Groups to Dr. Robert Califf, Comm'r., FDA, supporting FDA Announcement of Proposed Rule to Reduce Nicotine Level in Cigarettes (Sept. 12, 2022), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2022_09_12_Coalition-Letter-Support-Nicotine-Standard.pdf
[34] N.Y.C. Dep't of Health & Mental Hygiene, et al., Citizen Petition to FDA Requesting Track and Trace System for Tobacco Products, Docket No. FDA-2013-P-0285 (Mar. 6, 2013),

FDA has yet to act on this Petition, even though, in 2015, reports issued by the National Research Council and the Institute of Medicine, and by the Centers for Disease Control and Prevention (CDC), provide strong support for a track and trace system.[35] Given the industry's continued assertion that tobacco control measures like the menthol cigarette rule will create an illicit market, the Strategic Plan should include a timeline for a rulemaking creating a track and trace system.

- Rule to regulate online sales. The TCA requires FDA to issue rules on the sale and marketing of tobacco products that do not occur through a face-to-face transaction at a retailer based at a physical location.[36] In 2011, FDA issued an advanced notice of proposed rulemaking on the subject,[37] but has never issued a proposed rule. Since the passage of the TCA, Congress has enacted the Prevent All Cigarette Trafficking (PACT) Act to regulate online and other non-face-to-face sales of cigarettes and smokeless tobacco[38] and, in 2021, it amended the PACT Act to also cover online retailers of e-cigarette products.[39] Although CTP has indicated that other laws, including state laws, may achieve the same objectives as a new regulation governing online sales,[40] the Inspector General (OIG) of the Department of Health and Human Services (HHS) has concluded that "completing this rulemaking is an important step toward FDA's goal of preventing youth access to tobacco products."[41] OIG has requested that "FDA clarify how and when it intends to complete its rulemaking on non-face-to-face tobacco sales."[42] We agree with this request for greater clarity and suggest that CTP set a date certain for issuance of a proposed rule.

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https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2013-03-6%20Track%20&%20Trace%20Citizen%20Petition%20(Partners).pdf

[35] *See generally* Letter from N.Y.C. Dep't of Health & Mental Hygiene and various public health groups to Mitchell Zeller, Dir., FDA, CTP (Apr. 5, 2016), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Track%20and%20Trace%20Letter%20to%20FDA%204.5.16.pdf

[36] 21 U.S.C. § 387f(d)(4)(A).

[37] Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products, 76 Fed. Reg. 55,835 (Sept. 9, 2011), https://www.govinfo.gov/content/pkg/FR-2011-09-09/pdf/2011-23096.pdf.

[38] P.L. No. 111-154 (enacted March 10, 2010).

[39] Consolidated Appropriations Act, 2021, P.L. 116-260, Division FF, Title VI, Section 602 (enacted Dec. 27, 2020), amending 15 U.S.C. §376.

[40] See HHS, Office of Inspector General, *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement*, at 18 (Dec. 2022), https://oig.hhs.gov/oei/reports/OEI-01-20-00241.pdf.

[41] *Id.*

[42] *Id.*

- Finalize rule reducing NNN in smokeless tobacco. Over six years ago, CTP issued a proposed rule limiting the carcinogen NNN in smokeless tobacco.[43] Yet the agency still has not advanced the rule to final issuance, even though the lifesaving benefits of the rule are firmly established by the relevant science.[44] The Strategic Plan should set a date certain in 2023 for issuance of the final rule.

- Issue new rule mandating larger warnings for cigars. In *Cigar Association of America v. FDA*, 964 F.3d 56 (D.C. Cir. 2020), the Court struck down FDA's rule mandating larger textual warnings for cigars, on the ground that the agency had not shown that the warnings would reduce smoking prevalence, as required by the TCA. The Court remanded the rule to FDA for further proceedings. Given the health harms of cigars, their substantial use by youth and the widespread misperception that they are safer than cigarettes, FDA should issue a new rule, with a stronger administrative record establishing the likelihood that larger, more prominent warnings will reduce the use of cigars and thus will survive industry legal challenge.

E. Coordination with CDER on Cessation-Related Strategies

Between its Center for Drug Evaluation and Research (CDER) and CTP, FDA has regulatory jurisdiction over the full range of nicotine products. Because FDA has been slow to regulate companies who are marketing nicotine products, like e-cigarettes, as recreational products, market incentives have favored such products, with substantial disincentives for companies to devote their resources to meeting the safety and effectiveness standards for drug approval by CDER under the FDCA.[45] It is encouraging that CTP, through the premarket review process, has denied marketing authorization for many flavored e-cigarettes that have posed a clear threat to young people, with little evidence that their flavors are necessary to help smokers stop smoking. There is still a need to make the drug approval pathway more viable for responsible companies seeking to develop products that can be scientifically shown to help smokers quit.[46] Of course, this is the responsibility of CDER, but CTP also has a key role to play

[43] 82 Fed. Reg. 8,004 (Jan. 23, 2017).
[44] *See generally* Comments of Public Health and Medical Organizations in Docket No. FDA-2016-N-2527, *Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products* (July 10, 2017), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/Coalition%20Comments%20on%20NNN%20Proposed%20Rule%207.10.17.pdf.
[45] *See* Comments of Public Health Organizations in Docket No. FDA-2019-D-0297, Draft Guidance, *Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products: Guidance for Industry* (Apr. 23, 2019), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2019_04_23_Comments_NRT_Guidance.pdf.
[46] Neal L. Benowitz et al., *How the FDA Can Improve Public Health – Helping People Stop Smoking*, 388 NEW. ENG. J. MED. 1540 (2023),

in advocating for, and participating in, a coordinated agency-wide nicotine regulation program that will prevent the marketing of nicotine products that pose a threat to public health, while encouraging the development of innovative new drug therapies that meet CDER's standards of safety and effectiveness. The Strategic Plan should reflect a commitment by CTP to play that role.

II. Ensure Timely, Clear and Consistent Product Application Review to Protect Public Health

The premarket review provisions of the TCA were enacted against the backdrop of the industry's long and tragic history of introducing new products that were more hazardous, addictive and appealing than their predecessors.[47] Congress was concerned both about products sold for use to reduce the risks of tobacco products when in fact their use may perpetuate the use of tobacco products, and the introduction of new versions of traditional products, such as cigarettes, whose impact is to expand or sustain the marketplace by encouraging new users or providing an alternative to quitting for existing smokers. [48] Thus, with certain exceptions, Section 910 of the FDCA, as amended by the TCA, requires that, before any new tobacco product (i.e., products introduced or modified after February 15, 2007) may be marketed it must undergo FDA review and must demonstrate that it is "appropriate for the protection of the public health."[49] Section 911 requires separate premarket review for products to be sold with implicit or explicit claims that they are less harmful than other tobacco products or expose the consumer to reduced levels of harmful substances (modified risk products).[50]

The purpose of premarket review for tobacco products differs from that of other FDA-regulated products. Based on the industry's past history, tobacco product premarket review is intended to prevent the industry from introducing new products that may increase the harm to the public, both by expanding the number of people who become addicted and/or by discouraging people who use tobacco products from quitting altogether. The TCA makes clear that, first and foremost, the public health review of new products and of modified or new versions of existing products is to be rigorous and the burden is on the applicant to demonstrate that the introduction of its product into the market measurably enhances the public health to prevent new products from causing or contributing to the harm tobacco companies are already causing.

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https://www.nejm.org/doi/10.1056/NEJMp2301700?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

[47] *See generally* Campaign for Tobacco-Free Kids, *Designed for Addiction* (2014), https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/product_manipulation/2014_06_19_DesignedforAddiction_web.pdf

[48] TCA § 2(36)-(43), 123 Stat. at 1779-1780.

[49] 21 U.S.C. § 387j.

[50] 21 U.S.C. § 387k.

A. Premarket Tobacco Product Applications (PMTAs)

1. FDA Review Must Occur *Premarket*

The TCA requires CTP's public health review of new tobacco products and modifications to existing products to occur *before* the products are introduced into commerce. Indeed, the statute does not contemplate that a new or modified product can be on the market *for a single day* without having met the statutory public health standard. FDA's undue delay in issuing a Deeming Rule asserting its jurisdiction over e-cigarettes and its subsequent failure to enforce the law that prohibits products from entering the market without an FDA order has allowed thousands of e-cigarettes to remain on the market for years without having gone through premarket review. As a consequence, youth usage of e-cigarettes remains at unacceptable levels,[51] even though CTP Director King recently has acknowledged that "youth use of tobacco products in any form, including e-cigarettes, is unsafe."[52] As to e-cigarettes in particular, what was intended by the statute to be premarket review has become post-market review. That must change.

FDA's failure to properly administer and enforce the premarket review requirements for new and modified tobacco products under the TCA is not limited to e-cigarettes that already were on the market when the Deeming Rule was issued in 2016. As public health groups have repeatedly reported to FDA, there are many examples of cigarettes, smokeless tobacco and cigars that have been promoted as "new" to the market after February 15, 2007 and yet appear to have no marketing orders, including substantial equivalence orders.[53] Indeed, even though FDA has proposed rules banning menthol cigarettes and flavored cigars, it has allowed the continued introduction of new menthol cigarettes ("Newport Boost") and flavored cigars ("White Owl Chocolate and Vanilla Swirl" and other various White Owl flavors) without marketing orders.[54] To our knowledge, FDA has taken no enforcement action against any of the companies that have introduced these products; nor has the agency offered an explanation for why products which the

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[51] Maria Cooper et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1283, 1284 tbl. (2022), https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf (9.4% of youth, including 14.3% of high school students, reported current use of an e-cigarette product in 2022).

[52] Brian A. King & 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 (2023), Https://doi.org/10.1111/add.16296.

[53] *See, e.g.*, Letter from 37 Public Health, Medical and Community Groups to Mitchell Zeller, Dir., FDA, CTP, on Marketing of Tobacco Products as "New" Products Without Premarket Orders (Feb. 26, 2016), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/Coalition Letter re New Tobacco Products 2.26.16.pdf

[54] Letter fromPublic Health, Medical and Community Groups to Mr. Mitchell Zeller, Dir., FDA, CTP, on Continued Introduction of New Menthol Cigarettes and Flavored Cigars Without FDA Marketing Authorization (Aug. 9, 2021), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2021_08_10_FDA_Letter_Newport.pdf.

companies themselves promote as "new" to the market have been able to avoid premarket review.

CTP's Strategic Plan must include a strategy to implement a true *premarket* review system for marketing applications of cigarettes, cigars, e-cigarettes and other new and modified products, as envisioned by the statute,. CTP must implement more systematic monitoring of the market to allow early identification of new products introduced without marketing orders. It should make clear to manufacturers, distributors, and retailers that all tobacco products on the market without marketing orders are subject to enforcement. The agency must then bring sufficient enforcement actions to make the threat of enforcement credible.

2. Expedite Decision-Making on Currently Pending, Timely Filed PMTAs

As addressed more fully in Part III of these comments ("Ensure Compliance of Regulated Industry and Tobacco Products Utilizing All Available Tools, Including Robust Enforcement Actions"), FDA appears to have an unstated policy of exercising across-the-board discretion to not enforce the law against products with pending PMTAs, despite the fact that these products have no more legal right to be on the market than products that have never filed a PMTA. FDA's enforcement policy also runs counter to a federal court order establishing a date (September 9, 2021) by which marketing orders must be issued for products to stay on the market without being subject to FDA enforcement.[55]

The most impactful step FDA could take to remedy this situation is to immediately enforce against all illegal products, regardless of whether they have a timely filed PMTA pending with the agency. However, if FDA is unwilling to take such action, the agency must expedite decision-making on timely filed PMTAs for both tobacco-derived and synthetic nicotine e-cigarette products that are on the market, including menthol-flavored products. While FDA has decided many of the PMTAs, reviews for some of the products with the largest market share and that are most popular with youth, including Juul and R.J. Reynolds' Vuse Alto, remain incomplete. As part of its Strategic Plan, CTP must ensure that decisions on all timely filed PMTAs are issued by December 31, 2023, which aligns with the intended timeline FDA has provided in court filings.[56]

3. Increased Transparency About the Bases for Marketing Decisions

It is important for all stakeholders, and particularly the public at large, to be as informed as possible about the rationale for FDA decisions both denying and granting marketing orders for new tobacco products. Transparency provides industry with important guidance in developing other new products and in seeking FDA authorization for those products. Transparency is crucial for the public to assess whether FDA's decisions are consistent with the statutory requirement that no new products be authorized unless they are "appropriate for the protection of the public health." It is also important for the public to have accurate and complete information about the

[55] *American Academy of Pediatrics ("AAP") v. FDA*, 399 F.Supp.3d 479, 487 (D. Md. 2019), *appeal dismissed sub nom., In re Cigar Ass'n of Am.*, 812 F.App'x 128 (4th Cir. 2020).
[56] Status Report (Doc. No. 215, filed July 24, 2023), *AAP*, No. 8:18-cv-00883, 399 F.Supp.3d 479 (D. Md. 2019)

characteristics of products for which marketing orders have been granted, including any public health risks created by those products.

From a transparency standpoint, it has been helpful that FDA posted on its website a model Technical Project Lead (TPL) Review of flavored e-cigarettes, which revealed the agency's general analysis of these products. However, FDA has been inconsistent in releasing information about its decisions both denying and granting marketing orders for e-cigarettes, particularly for menthol and unflavored (i.e., tobacco-flavored) products. To obtain more disclosure, it is our understanding that both applicant companies and the public have had to use Freedom of Information Act requests, some of which have been granted by the agency while others have been denied.[57]

It should also be recognized that FDA's failure to provide the public with more information about its decisions on PMTAs is often at the behest of the industry applicants, who regularly assert their interest in protecting from disclosure purported trade secrets and confidential business information. We believe that FDA is too accommodating to the industry in this regard, particularly as to products already on the market, resulting in heavily redacted FDA decisions and their supporting documents. We are particularly concerned about a recent trend toward companies, without objection from FDA, filing their appeals of marketing denial orders in court entirely under seal, making it impossible for the public to understand both the bases of FDA's decisions and the nature of industry objections to those decisions.[58] The Strategic Plan must include a commitment to greater transparency. The premarket review process should not be conducted in secret; nor should the judicial process.

This lack of transparency also extends to other types of tobacco marketing orders. For example, following the introduction of its new "Non-menthol" flavored cigarettes, R.J. Reynolds disclosed in litigation that these the products were the subject of FDA "Found Exempt" marketing orders, meaning FDA determined that these products are exempt from having to demonstrate that they are substantially equivalent to a legally marketed predicate product and may themselves be marketed.[59] However, none of the "Found Exempt" orders posted on FDA's

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[57] *See e.g.*, *Wages & White Lion Invs., L.L.C. v. FDA*, 41 F.4th 427, 448 n.7 (5th Cir. 2022) (Jones, J., dissenting); Stanton Glantz, *Juul knows why FDA denied its request to legally sell its ecigs. Why won't FDA tell the rest of us*, STANTON GLANTZ BLOG (Aug. 10, 2022), https://profglantz.com/2022/08/10/juul-knows-why-fda-denied-its-request-to-legally-sell-its-ecigs-why-wont-fda-tell-the-rest-of-us/.

[58] In several recent cases, public health groups have entered the cases as *amici curiae*, challenging these filings in court under seal. See Medical, Public Health and Parent Groups' Motion to Unseal, *Fontem US, LLC v. FDA*, No. 22-1076 (D.C. Cir. Oct. 6, 2022); Brief of Campaign for Tobacco-Free Kids as *Amicus Curiae* Opposing Petitioner's Motion to Seal, *Logic Technology Development LLC v. FDA*, No. 22-3030 (3d Cir. Nov. 14, 2022). In *Logic*, the Third Circuit ordered the parties to file a publicly available version of the pleadings, cautioning them "not to redact more information than is truly necessary to protect information that meets the high threshold for sealing." Order, *Logic*, No. 22-3030, ECF 60 (3d Cir. Jan. 27, 2023).

[59] Decl. Edward Patrick Swan Jr., Ex. B. (filed July 28, 2023), *R.J. Reynolds Tobacco Co. v. Bonta*, No. 23CEG01734 (Cal. Sup. Ct.)

website[60] correspond to the names of the R.J. Reynolds products or the dates on which the orders were issued. This lack of transparency makes it impossible for the public and other stakeholders to know if the products are legal to market in the United States. Moreover, when a company informs FDA that it has changed the name of its product after that product has been authorized, it does not appear that FDA updates its marketing orders lists with the updated product name. CTP's Strategic Plan must provide for greater transparency in the premarket review process, as well as for the bases of FDA's decisions on premarket orders of all types.

4. Involvement of TPSAC in Major PMTA Decisions

TPSAC has been underutilized in recent years, particularly with respect to its statutorily required role in modified risk tobacco product (MRTP) application proceedings.[61] However, in addition to an increased role in MRTP proceedings, CTP should also seek input from TPSAC on PMTAs for products not yet on the market that present novel scientific or technological issues, such as the recently submitted Juul PMTA seeking authorization for a Bluetooth-enabled device.[62] This type of technology raises significant questions that FDA must thoroughly consider prior to making any authorization decisions.[63] For example, it would give tobacco companies access to significant data about individual users that could be used to enhance addiction by controlling nicotine delivery. Through the TPSAC process, the public would also be able to submit comments that the committee—and FDA—could use to inform its assessments. This was an approach endorsed by the recent Reagan-Udall Report on FDA's Tobacco program.[64]

B. Modified Risk Tobacco Product (MRTP) Applications

MRTP applications are governed by the standards set out in Section 911 of the FDCA, as amended by the TCA (21 U.S.C. § 387k). Section 911 was enacted as a response to the tragic history of false and misleading tobacco industry claims that certain tobacco products were less

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[60] https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se.

[61] Letter from Public Health Groups to FDA on The Role of the Tobacco Products Scientific Advisory Committee in Modified Risk Tobacco Product Proceedings (Oct. 19, 2020), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2020_10_10_Letter-to-FDA-on-TPSAC-role-MRTP-proceedings.pdf.

[62] Jenifer Maloney, "Juul Has a New High-Tech Vape and Hopes the FDA Won't Ban It," WALL ST. J. (July 19, 2023), https://www.wsj.com/articles/juul-has-a-new-high-tech-vape-and-hopes-the-fda-wont-ban-it-655bd16a.

[63] Letter from Public Health Groups to Mitchell Zeller, Dir., FDA, CTP, on Bluetooth Technology in Tobacco Products (July 16, 2020), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2020_07_16-Letter-to-FDA-re-Bluetooth-Technology-in-Tobacco-Products.pdf.

[64] OPERATIONAL EVALUATION OF CERTAIN COMPONENTS OF FDA'S TOBACCO PROGRAM: A REPORT OF THE TOBACCO INDEPENDENT EXPERT PANEL, at 16 (Dec. 2022), https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_Dec.%202022.pdf ("Reagan-Udall Report").

dangerous than other products, which persuaded health-conscious smokers to switch to the "reduced risk" products instead of quitting altogether.

In the Tobacco Control Act, Congress made specific findings about the potential public health harm from modified risk claims. Congress found that "unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health. . . ."[65] Congress also found that "the dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk products are complete, accurate, and relate to the overall disease risk of the product."[66] Congress determined that it is "essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products."[67] These congressional findings—and the history upon which the findings are based—should guide FDA in its consideration of any MRTP application.

1. Require Applicants to Show that People Do Not Misinterpret Reduced *Exposure* Messages to Mean Reduced *Risk*

Section 911 expressly distinguishes claims of reduced levels of a substance or reduced exposure to a substance ("reduced exposure" claims) from claims that the product "presents a lower risk of tobacco-related disease or is less harmful" than one or more other tobacco products ("reduced risk" claims). Reduced exposure and reduced risk claims are governed by different evidentiary standards.[68] The TCA makes clear that a product is eligible to be marketed with reduced exposure claims only if the scientific evidence is insufficient to meet the standards for demonstrating reduced risk.[69] Although a reduced exposure order under section 911(g)(2) does not require a showing of reduced risk, the statute requires the applicant to present sufficient evidence to allow FDA to make "additional findings" not required for a reduced risk order.[70] This evidence includes consumer perception studies demonstrating that the reduced exposure claim will not mislead consumers into believing that the product has been shown to be less

[65] TCA § 2(37), 123 Stat. at 1,780.
[66] *Id.* § 2(37).
[67] *Id.* § 2(36)
[68] *See generally* Comments of Tobacco-Free Kids in Docket No. FDA-2019-N-0001, *Tobacco Products Scientific Advisory Committee; Notice of Meeting re 22nd century Group Inc's Modified Risk Applications for VLN™ King and VLN™ Menthol King*, at 3-6 (Feb. 7, 2020), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2020_07_07_CTFK_comments_TPSAC_VLN_cigarettes_modified_risk.pdf#asset:509569%3Aurl.
[69] 21 U.S.C. § 387k(g)(2)(A). For modified exposure claims, the TCA requires a showing that the scientific evidence that is available without conducting long-term epidemiological studies "demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies." 21 U.S.C. § 387k(g)(2)(A)(iv).
[70] 21 U.S.C. § 387k(g)(2)(B).

harmful or to present a lower risk of disease than another tobacco product.[71] Thus, since a reduced exposure order would not be issued unless the currently available science is insufficient to show reduced risk from the product, the applicant must demonstrate that the claim does not cause consumers to believe that use of the product actually reduces risk.

Despite this explicit statutory requirement, FDA has repeatedly authorized modified exposure claims even when the applicant has failed to demonstrate that consumers do not misinterpret such claims to mean reduced risk.[72] The Strategic Plan must reflect CTP's commitment to permit only modified exposure claims where the applicant has demonstrated a minimal risk of misinterpretation by the public.

2. Need for TPSAC to Vote on All Key Scientific Issues

The TCA requires that MRTP applications be submitted to TPSAC and that TPSAC provide FDA with its recommendations on the applications before FDA issues or denies MRTP orders.[73] As documented by public health organizations,[74] TPSAC's role, however, has been increasingly marginalized. It has not been asked, nor provided an opportunity, to indicate whether applications meet the required scientific standards, and more recently, it has not been provided with an opportunity to vote on the most important scientific issues necessary for it to make recommendations concerning that determination. At its most recent meeting on an MRTP application, filed by 22nd Century for its Very Low Nicotine cigarettes, TPSAC was not asked to vote on any specific scientific questions and the Committee meeting functioned as essentially a discussion forum on the issues raised.[75] This is not consistent with the letter and spirit of the TCA. The Strategic Plan should provide for TPSAC to play the role properly assigned it by the TCA.

C. Issues Relevant to Both PMTAs and MRTP Applications

There are several overarching issues regarding both PMTA and MRTP applications that should be addressed in the Strategic Plan. First, the Strategic Plan should make clear that no

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[71] 21 U.S.C. § 387k(g)(2)(B)(iii).

[72] *See, e.g.*, Letter from Public Health Groups to Mitchell Zeller, Dir., FDA, CTP, re Request to reconsider the exposure modification orders granted to VLN™ and VLN™ Menthol very low nicotine cigarettes, at 3-4 (Mar. 7, 2022), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2022_03_07_VLN-MRTP-Letter-FDA.pdf; Comments of Public Health Groups in Docket No. FDA-2021-N-0408, *Modified Risk Tobacco Product Application for the IQOS 3 System Holder and Charger Submitted by Philip Morris Products S.A.*, at 7-10 (Dec. 10, 2021), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2021_12_10_IQOS-3-MRTPA-Comments.pdf.

[73] 21 U.S.C. § 387k(f)(2).

[74] Letter from AAP et al. to Mitchell Zeller, Dir., FDA, CTP, on Role of the Tobacco Products Scientific Advisory Committee in Modified Risk Tobacco Product Proceedings (Oct. 19, 2020), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2020_10_10_Letter-to-FDA-on-TPSAC-role-MRTP-proceedings.pdf.

[75] *Id.* at 6.

PMTA or MRTP application will be authorized if it does not include adequate youth perception data. Second, in creating its Strategic Plan, CTP must resist any efforts to "streamline" its application review process in a way that would lessen the burden on applicants to meet the relevant statutory standards.

1. Need for Direct Evidence of the Potential Impact of Specific Products and Modified Risk Claims on Youth and Adolescents

Youth usage of tobacco products is inherently harmful and produces no public health benefit. Yet FDA has repeatedly issued both marketing orders and modified risk orders for products without sufficient evidence of how the products and modified risk claims may affect American youth and adolescents. Given the unambiguous mandate in the TCA to provide sufficient evidence, on a premarket basis, of the population-wide impact of the introduction of a product,[76] and of any modified risk claims,[77] such an impact cannot be assessed without direct evidence of the impact on nonusers, especially youth. Using data from other countries, or extrapolating from young adult data, does not suffice.

The presentation of such direct evidence should be expressly required for all PMTAs and MRTP applications and FDA should establish the necessary protocols and safeguards needed to ensure that youth and young adult subjects are sufficiently protected in the conduct of such studies and that the data are objective and reliable.[78] The Strategic Plan should specify a process, and timeline, for development of those protocols and safeguards. By not requiring such data before issuing marketing and modified risk orders, FDA is effectively permitting the industry to "experiment" on the nation's youth with new products and modified risk claims. This must no longer be permitted.

2. Application Process Should Not Be Made Less Demanding

The tobacco industry has long argued that the PMTA and MRTP requirements are too burdensome and must be simplified to ensure new products are able to quickly enter the market, and to ensure companies are able to make comparative health claims about products they allege are less harmful. In formulating its Strategic Plan, FDA must resist these efforts to undermine the TCA standards.

As an initial matter, Congress intended for FDA review of new tobacco product applications and MRTP applications to be rigorous. As the U.S. Court of Appeals for the D.C. Circuit noted, in enacting the TCA's premarket review provisions, Congress "took the then-

[76] 21 U.S.C. § 387j(c)(4).
[77] 21 U.S.C. §387k(g)(1)(B).
[78] *See* Comments of AAP et al. in Docket No. FDA-D-2019-4188, *Draft Guidance for Industry titled "Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intension Studies*" (Dec. 28, 2020), https://www.regulations.gov/comment/FDA-2019-D-4188-0011; *see also* Bonnie Halpern-Felsher et al., *The Importance of Including Youth Research in Premarket Tobacco Product and Modified Risk Tobacco Product Applications to the Food and Drug Administration*, 67 J. ADOLESCENT HEALTH 331 (2020), https://pubmed.ncbi.nlm.nih.gov/32674965/.

current tobacco product market as a baseline from which to ratchet down tobacco products' harm to public health."[79] Moreover, in the Findings of the TCA (§ 2(36)), Congress noted that it "is essential" that prior to "marketing products to reduce risks or exposures associated with tobacco products," "manufacturers . . . be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole. . . ."

We applaud FDA for its interpretation of the statutory "appropriate for the protection of public health" standard to require applicants to demonstrate that their products provide a net public health benefit.[80] With respect to flavored e-cigarette products in particular, FDA has correctly required applicants to provide "reliable and robust evidence" that their flavored e-cigarettes are more effective than unflavored (i.e., tobacco-flavored) products in helping adult smokers to quit cigarettes, so as to outweigh the known risks to youth posed by these products,[81] a standard courts have repeatedly upheld as reasonable.[82]

As noted above, the problem FDA must address is not that tobacco products beneficial to public health are being kept off the market, but rather that products that have not met the public health standard are still on the market.

There are also serious issues concerning FDA's legal authority to make any substantial alterations or simplifications to the premarket review process that may affect the applicant's statutory burden of showing that the product under review is appropriate for the protection of the public health, as generally required by the TCA. For example, although FDA has employed the concept of a "supplemental" application, there is nothing in the TCA about "supplemental" applications or establishing the agency's authority to consider them.[83]

III. Ensure Compliance of Regulated Industry and Tobacco Products Utilizing All Available Tools, Including Robust Enforcement Actions

A. Enforce the TCA's Prohibition Against the Introduction of New Tobacco Products Prior to Premarket Review

The most impactful action FDA can take to improve compliance and enforcement is to adopt policies to strongly enforce the TCA's prohibition against the introduction of new tobacco

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[79] *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019).
[80] *See, e.g.*, FDA Sample Technical Project Lead (TPL) Review at 4, https://www.fda.gov/media/152504/download?attachment ("Sample TPL").
[81] *Id.* at 3.
[82] *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Gripum LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3rd Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657 (9th Cir. 2023); *Magellan Tech., Inc. v. FDA*, 70 F.4th 622 (2d Cir. 2023); *Prohibition Juice Co., v. FDA*, 45 F.4th 8 (D.C. Cir. 2022).
[83] *See* Comments of AAP et al. in Docket No. FDA-2021-N-0408, *Modified Risk Application for the IQOS 3 System Holder and Charger Submitted by Philip Morris Products, S.A.*, at 2-3 (Dec. 10, 2021), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2021_12_10_IQOS-3-MRTPA-Comments.pdf.

products prior to premarket review. As detailed in Part II of these comments ("Ensure Timely, Clear and Consistent Product Application Review to Protect Public Health"), the TCA is clear that before any new tobacco product may be introduced into commerce, it must undergo premarket review and receive FDA marketing authorization.[84] Despite the clear statutory language, FDA has for years allowed unauthorized new tobacco products, including cigarettes, smokeless tobacco products, cigars, and e-cigarettes, to be introduced to the market, apparently free from FDA scientific review or enforcement. It is critical to the agency's public health mission that CTP's Strategic Plan include a commitment and strategy to clear the market of illegal products and ensure that only FDA-authorized products are permitted to be introduced into commerce. To that end, we offer the following recommendations.

1. List of Authorized Products

Today, FDA finds itself in a situation in which thousands of unauthorized tobacco products are sold by manufacturers, distributors, and retailers that either are not aware, or do not care, that they are selling illegal products. To remedy this, CTP's Strategic Plan should include the creation and distribution of a list of authorized products and clear communication to manufacturers, distributors, and retailers that FDA and its enforcement partners are prepared to bring enforcement actions (e.g., possible seizure, injunctions and substantial civil penalties) against any product that is not on that list. Creating and distributing a list of authorized products —coupled with actual enforcement against products not listed—is an efficient and relatively simple way for FDA to satisfy its statutory obligations to establish a well-regulated marketplace for tobacco products and to prevent the introduction of any unauthorized product to the market. The Reagan-Udall Report endorsed this idea of a list of legally marketed products to facilitate industry compliance.[85]

2. Enforcement Actions Against All Parties in the E-Cigarette Supply Chain

CTP's Strategic Plan must include a strategy—in conjunction with its enforcement partners, including the U.S. Department of Justice (DOJ) and U.S. Customs and Border Protection (CBP)—to take appropriate enforcement actions against all parties in the supply chain, including manufacturers, distributors, importers and retailers, that sell e-cigarette products without marketing orders. To date, FDA's enforcement actions—primarily warning letters—have mainly been targeted at retailers and manufacturers, and primarily relate to products with minimal market share. To transform the e-cigarette landscape into a well-regulated marketplace, CTP and its enforcement partners should bring enforcement actions against all parties that sell unauthorized products, including wholesalers and distributors. On this point, we agree with the Reagan-Udall Report that such "high profile [enforcement] actions against wholesalers and distributors who are handling illegally marketed products . . . could help clear the downstream distribution pathways of illegal products and deter those who might bring new products to the market without marketing authorization."[86]

[84] 21 U.S.C. § 387j.
[85] Reagan-Udall Report, *supra* note 64, at 23, 25.
[86] *Id.* at 24.

3. Implement More Systematic and Rapid Market Surveillance to Identify Unauthorized Products

As discussed, the e-cigarette market is dominated by illegal, unauthorized products—many of which are available in kid-friendly flavors. However, as also discussed, this problem is not limited to e-cigarettes. Many cigarettes, smokeless tobacco and cigars have also been promoted as "new" yet appear to have no marketing orders. As part of its Strategic Plan, CTP should implement more systematic and real-time monitoring of the tobacco product market to allow for early identification of new products that have been introduced without marketing orders.

We were pleased to see the announcement in June 2023 that FDA and the National Institutes of Health had awarded funding for a new Center for Rapid Surveillance of Tobacco that will "enhance CTP and the research community's ability to understand, document, and quantify changes in the tobacco product marketplace and tobacco use patterns."[87] The Strategic Plan should include concrete plans and a timeline for bringing the new Center to its full operational capability as quickly as possible.

B. Enforcement Priorities

1. End Implicit Exercise of Enforcement Discretion for New E-Cigarette Products with Pending PMTAs

It does not appear that FDA has taken enforcement actions against any e-cigarette products with a timely filed pending PMTA, despite these products having no more legal right to be on the market than products that have received a negative decision or that never filed PMTAs. Many of the products with pending PMTAs—that FDA has failed to enforce against—are products with demonstrated public health harm. For example, FDA is still reviewing marketing applications for some of the products most popular with youth, including Juul and Vuse Alto.[88] As Judge Paul W. Grimm of the U.S. District Court for the District of Maryland stated in April 2022, and which remains true today, although "FDA reports that it has completed millions of phased product reviews . . . the popular products used by young people remain on the market unreviewed, which is inconsistent with the purpose of the Court's [earlier] judgment."[89] There is no basis for continued enforcement discretion for these products. CTP's Strategic Plan should commit to ending any exercise of enforcement discretion for products with pending PMTAs—whether made of tobacco-derived or synthetic nicotine—by December 31, 2023 at the latest.

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[87] CTP, *FDA and NIH Award Funding for New Center for Rapid Surveillance of Tobacco* (June 1, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-and-nih-award-funding-new-center-rapid-surveillance-tobacco.

[88] Cooper et al., *supra* note 51, at 1284 tbl (Vuse and Juul, respectively, are the second and third most popular e-cigarette brands among youth). Although FDA has issued decisions on some Vuse product lines, it has not ruled on applications for Vuse Alto products, the most popular Vuse line.

[89] Letter Order (Doc. No. 201), at 2, *AAP*, No. 8:18-cv-00883 (D. Md. Apr. 15, 2022) (emphasis added) (footnote omitted).

2. Prioritize Enforcement Against Unauthorized Flavored E-Cigarette Products

As FDA has repeatedly recognized, flavored e-cigarettes, including menthol, "have a known and substantial risk with regard to youth appeal, uptake, and use" over and above the risk presented by tobacco-flavored products.[90] The use of flavored e-cigarettes by youth is not confined to one product type. Instead, as FDA has properly acknowledged in its marketing denial orders for flavored e-cigarettes, "the role of flavor is consistent" "across. . . different device types."[91] In short, youth will gravitate to whatever kind of e-cigarette device offers the desired flavors.

The most recent National Youth Tobacco Survey data continues to demonstrate the popularity of flavored e-cigarettes among youth, with 84.9% of current youth e-cigarette users reporting use of a flavored product.[92] Flavors are continuing to drive the high rates of youth e-cigarette use—in 2022, over 2.5 million middle and high school students reported using an e-cigarette in the past month.[93] To meaningfully drive down these youth use numbers, the Strategic Plan must prioritize enforcement against all flavored e-cigarette products that lack marketing authorization yet remain on the market. Moreover, given the role of FDA's federal law enforcement partners, including the DOJ and CBP, FDA should communicate and ensure prioritization of these products by its enforcement partners.

C. More Systematic and Aggressive Use of Full Range of Enforcement Tools

Given the continued presence on the market of many thousands of illegal products and the evidence that the tobacco industry does not take FDA enforcement seriously, the Strategic Plan must include an enforcement strategy to go beyond warning letters and use the other available tools, namely civil money penalties, no-tobacco-sale orders, seizures, injunctions, or in extreme situations, criminal prosecution.[94]

According to the agency's website, FDA has sought injunctions against six companies and filed civil monetary penalty complaints against 21 companies for illegally selling unauthorized e-cigarettes.[95] All of these actions were taken in the last year, and while it is an encouraging sign, it pales in comparison to the scope of the problem. Given that thousands of e-cigarettes remain on the market, more aggressive and frequent enforcement action is required.

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[90] *E.g.*, FDA News Release, *FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (Jan. 24, 2023), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-e-cigarette-products-following-determination-they-do-not-meet.
[91] Sample TPL, *supra* note 80, at 7.
[92] Cooper et al., *supra* note 51, at 1283.
[93] *Id.* at 1284 tbl.
[94] FDA, *Compliance, Enforcement & Training* (last updated Apr. 5, 2022), https://www.fda.gov/tobacco-products/compliance-enforcement-training.
[95] FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products* (last updated Aug. 10, 2023), https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#4.

For example, with respect to the injunctions FDA has sought, the proceedings were initiated only against certain companies that failed to submit PMTAs by the court-ordered September 9, 2020 deadline.[96] Moreover, in each of these cases, more than one year passed between the time FDA sent a warning letter to the companies informing them of their violative conduct and when injunction proceedings were initiated.[97] During such time, the companies profited off the sale of their illegal products, which included kid-appealing flavored products like SUPER VAPE'Z Premium E-Liquid Apple Mango.[98] This sparing use of enforcement tools stronger than warning letters, coupled with the long lag between FDA's identification of the violative conduct and the initiation of injunction proceedings, has created a perverse financial incentive for companies to disregard FDA and the law, which holds obvious and immediate negative public health consequences. It is particularly critical for FDA to go beyond warning letters for illegal products like flavored e-cigarettes and other products with demonstrated health harm to young people.

Additionally, with respect to the CMPs it issued, FDA appears to be charging companies with only a *single* violation of the TCA seeking only $19,192—the inflation-adjusted maximum penalty for a single violation—from each company.[99] As explained in a letter from Tobacco-Free Kids' outside counsel to CTP Director King, the statute provides FDA with the authority to charge a manufacturer with multiple violations, up to $1.2 million, in a single proceeding.[100] It is difficult to believe that FDA observed only a single violation in each of these cases. To create real incentives to comply with the law, FDA must be willing to levy more severe penalties.

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[96] FDA News Release, *FDA, DOJ Seek Permanent Injunctions Against Six E-Cigarette Manufacturers* (Oct. 18, 2022), https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers.

[97] Compl. (Doc. No. 1) at 7-8, *U.S. v. Lucky's Convenience & Tobacco, LLC*, Civil No. 22-1237 (D. Kan. Oct. 18, 2022); Compl. (Doc. No. 1) at 7-8, *U.S. v. Morin Enterprises, Inc.*, Civil No. 22-cv-2592 (D. Minn. Oct. 18, 2022); Compl. (Doc. No. 1) at 5-6, *U.S. v. Seditious Vapours LLC*, Case No. 22-cv-01777 (D. Ariz. Oct. 18, 2022); Compl. (Doc. No. 1) at 7-8, *U.S. v. Soul Vapor, LLC*, Civil No. 1:22-cv-00458 (S.D.W. Va. Oct. 18, 2022); Compl. (Doc. No. 1) at 5-6, *U.S. v. Vapor Craft LLC*, Civil No. 4:22-cv-00160 (M.D. Ga. Oct. 18, 2022); Compl. (Doc. No. 1) at 6, *U.S. v. Super Vape'z LLC*, Case No. 3:22-cv-05789 (W.D. Wa. Oct. 18, 2022).

[98] *Id.* at 6.

[99] FDA News Release, *FDA Files Civil Monetary Penalty Complaints Against Four E-Cigarette Product Manufacturers* (Feb. 22, 2023), https://www.fda.gov/news-events/press-announcements/fda-files-civil-money-penalty-complaints-against-four-e-cigarette-product-manufacturers.

[100] Letter from Bill Schultz to Dr. Brian King, Dir., FDA, CTP, re Effective Use of Civil Monetary Penalties to Control Illegal Marketing of E-Cigarette Products (June 30, 2023), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2023_06_30_Civil-Monetary-Penalties-Letter.pdf.

Finally, FDA has repeatedly stated that "a majority of warning letter recipients voluntarily take corrective action."[101] However, that does not appear to hold true for the tobacco industry. For example, a STAT news investigation that reviewed 120 warning letters issued to e-cigarette companies between August 2021 and May 2022 found that of the 274 products named in the warning letters, at least 139 of the products—more than 50%—were still being sold.[102] The investigation also found that FDA had issued "close-out" letters to (1) companies that were still selling the illegal products mentioned in the letter and (2) a company that stopped selling the named products but, as acknowledged by FDA in the close-out letter, continued to sell other illegal products.[103] This is unacceptable. The Strategic Plan must reflect a strong CTP commitment to use the agency's full range of enforcement tools more frequently, aggressively and systematically.

D. Simplify and Expedite Enforcement Proceedings

CTP has struggled to enforce the law even against products that are clearly illegal and have no plausible claim to enforcement discretion, such as flavored e-cigarettes that have received marketing denial orders.[104] The Reagan-Udall Report found that although FDA has "not been transparent regarding the reasons it has failed to the clear the market of illegal products," one factor it pointed to was that the "current process of bringing enforcement actions [beyond warning letters] is cumbersome."[105] The Report describes a series of steps that FDA and DOJ must take before DOJ can file actions for injunctions and civil monetary penalties.[106] It is critical that FDA, DOJ, and any of FDA's other law enforcement partners, such as CBP and the Bureau of Alcohol, Tobacco, Firearms, and Explosives, simplify and expedite this process. CTP's Strategic Plan must make the simplification and expedition of enforcement proceedings an *immediate* priority.

Relatedly, as discussed in the context of FDA's recent injunctive actions, CTP has been too slow to follow up warning letters with more severe penalties, such as injunctions or CMPs. In the cases of the companies against which FDA sought injunctions, FDA waited more than one year between issuing the warning letters and seeking injunctive relief. The Strategic Plan should commit FDA to completing mandatory reinspections—within a specified time period —of any firm that has received a warning letter or has otherwise been found to have violated the law.

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[101] *E.g.*, CTP, *FDA Puts Distributors on Notice for Illegal E-Cigarettes Popular with Youth, Inclulding Elf Bar/EB Design and Esco Bars* (July 27, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-puts-distributors-notice-illegal-e-cigarettes-popular-youth-including-elf-bareb-design-and-esco.

[102] Nicholas Florko & Elissa Welle, *The FDA Stands by as the Vaping Industry Flouts Its Orders*, STAT NEWS (Aug. 24, 2022), https://www.statnews.com/2022/08/24/the-fda-stands-by-as-the-vaping-industry-flouts-its-orders/.

[103] *Id.*

[104] Letter from Public Health Groups to Dr. Brian King, Dir., FDA, CTP re Lack of FDA Enforcement Against Products Subject to Marketing Denial Orders (July 26, 2022), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2022_07_26_Letter-to-FDA-re-MDO-enforcement.pdf.

[105] Reagan-Udall Report, *supra* note 64, at 22.

[106] *Id.*

E. Increase Transparency of Enforcement Actions

We were encouraged to see that in response to the Reagan-Udall evaluation, Dr. King stated CTP's intention to "be more transparent about its compliance and enforcement activities" including through the creation of a new "comprehensive webpage for all enforcement activities for products that are illegally marketed without FDA authorization."[107] While this new website[108] has been helpful in understanding some of FDA's enforcement actions, the public still does not have access to certain critical compliance and enforcement information. For example, FDA currently has two databases of tobacco warning letters—one for letters issued to online retailers and manufacturers[109] and another for letters issued to traditional "brick and mortar" stores.[110] Both databases lack key information.

With respect to the online retailer and manufacturers database, it is often not clear whether the firm receiving the warning letter is a retailer and/or manufacturer of the violative product(s), or even which products are subject to the warning letters.[111] It also is not clear whether the product's manufacturer applied for authorization, received a negative decision on its application, or still has an application under review. This lack of transparency makes it extremely difficult for the public to be fully informed about the exercise of enforcement discretion by CTP. It also is difficult for the public to discern whether, and how often, FDA follows these warning letters with stronger enforcement for continued violations or whether companies even respond to the warning letters. CTP should commit to posting on its warning letters database all responses to warning letters, all close-out letters, and any subsequent enforcement actions taken against a firm.

The database with warning letters issued to brick-and-mortar retailers contains even less information. For example, it does not contain copies of the underlying warning letters, and does not list the type of violation (e.g., sale of an unauthorized product, sales to an underage buyer, etc.), the specific products at issue, or any follow-up actions taken. This lack of information undermines the utility of the database. CTP should increase the transparency of the enforcement actions it has taken to allow the public to fully understand the nature of the violations and whether warning letters led to compliance or subsequent stronger enforcement actions.

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[107] Dr. Brian King, *An All-Center Approach: CTP's Response to the Reagan-Udall foundation Evaluation Report* (Feb. 24, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report.

[108] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products.

[109] FDA, *Warning Letters*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

[110] FDA, *Compliance Check Inspections of Brick and Mortar Tobacco Product* Retailers, https://timp-ccid.fda.gov/; *see generally* FDA, *Tobacco Retailer Warning Letters* (April 29, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tobacco-retailer-warning-letters.

[111] To allow the public and researchers to easily identify which products are subject to the warning letters, it would be particularly helpful to add columns to the search entry table that list the specific products and product type (e.g., ENDS, cigarette, cigar) subject to the letters.

IV. Improve Public Health by Enhancing Knowledge and Understanding of CTP Tobacco Regulation and the Risks Associated with Tobacco Product Use

According to CTP, beginning in 2020 it has prioritized public education efforts aimed at educating youth about the health harms and addictiveness of e-cigarettes.[112] Given that e-cigarette usage among youth had quickly reached epidemic levels by 2018-2019, and that more than 2.5 million high school and middle-school students currently use these products,[113] the Strategic Plan should retain this public education priority.

On the other hand, industry representatives frequently argue that FDA's public education efforts should be largely devoted to countering public misperceptions, particularly among adult smokers, about the health hazards of nicotine. There is substantial evidence that the public incorrectly believes, for example, that nicotine is carcinogenic. Some argue that such misperceptions about the health hazards of nicotine may discourage adult smokers from switching to e-cigarettes, which generally contain nicotine and many at high concentrations, and that it should be an FDA priority to engage in public education about the relative safety of e-cigarettes versus combustible cigarettes.

Before engaging in a broad-based public education campaign with the message that nicotine is not harmful, CTP must perform a rigorous scientific evaluation of how the public will perceive the messages and respond to them. As CTP Director King has asserted, the agency should take a "data-driven approach" that assesses both "the benefits among the intended population (i.e. adult smokers) and risks among unintended populations (e.g. youth)."[114] This includes testing among key segmented audiences, including not only adult smokers, but also unintended audiences such as youth. There is no doubt the industry will misuse such government messaging to try to attract new users to e-cigarette products; smokers also may respond to such messages by engaging in prolonged dual use of cigarettes and e-cigarettes instead of quitting entirely. This would not serve the interests of public health.

Particularly given the continued high prevalence of e-cigarette use among young people, and the evidence that young people are largely unaware that e-cigarettes contain nicotine, that it is powerfully addictive, and that it causes lasting damage to the still-developing adolescent brain,[115] FDA would be ill-advised to undertake broad-based public education campaigns designed to minimize the perceived dangers of nicotine in e-cigarettes and emphasizing the relative safety of e-cigarettes versus cigarettes. There is a substantial risk that such efforts could not be targeted only to adult smokers and that the messages would reach young people, making them more likely to initiate or continue e-cigarette use.

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[112] FDA, *Public Health Education Campaigns*, https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns (last visited Aug. 21, 2023).
[113] Cooper et al., *supra* note 51, at 1285.
[114] King & Toll, *supra* note 52, at 1.
[115] RACHEL BOYKAN ET AL., FLAVORED E-CIGARETTES AND ADOLESCENT HEALTH 6-7 (July 19, 2022), https://www.massgeneral.org/assets/mgh/pdf/children/flavored-e-cigs-and-adolescent-health-white-paper.pdf.

Finally, although there is great value in science-based public education campaigns carefully targeted at audiences where they can have the greatest impact in reducing the use of tobacco products, FDA should be mindful that its primary responsibility under the TCA is to prevent the public health harms of tobacco products through science-based regulation of the tobacco industry. Thus, the agency's allocation of resources under the Strategic Plan should not devote those resources to public education at the expense of strong regulation of the industry, but should endeavor to use its resources efficiently to serve both public education and regulatory objectives.

V. Advance Operational Excellence

We are particularly pleased that CTP's view of operational excellence includes a commitment to diversity, equity, inclusion and accessibility. In that regard, CTP's recent hiring of its first Senior Advisor for Health Equity is an important step forward. Given the reality that the scourge of tobacco use imposes a disproportionate health burden on certain populations, and the benefits of reducing tobacco use are unevenly distributed throughout society, the Strategic Plan should specify that health equity concerns should be regarded as relevant to CTP decision-making across the board, whether as to regulations, applications, enforcement or public education. All CTP functions should be evaluated, on a continuing basis, for their impact on existing health disparities.

CONCLUSION

CTP's request for written comments asks several specific questions as to each "goal area." We summarize our comments by providing answers to certain of those questions that we believe are particularly important in developing a Strategic Plan that ensures the full possible use of agency resources to protect public health.

Regulatory Priorities. CTP asks for "feedback on specific regulations and guidance document FDA should pursue and how they should be prioritized." As indicated above, the Strategic Plan should attach the highest short-term priority to the menthol cigarette and flavored cigar rules and similar priority to the nicotine reduction rule, while acknowledging a somewhat longer timeline for that rule.

Short and long-term Outcomes. CTP asks for "measurable short-and long-term outcomes over the next 2-5 years." In the regulatory arena, within the next five years, the menthol, flavored cigar and nicotine reduction rules should be fully in effect, with substantial resulting diminished use of combustible tobacco products, particularly by populations now suffering disproportionately from tobacco-caused disease and mortality. As to e-cigarettes, the active implementation of premarket review, combined with vigorous use of all available enforcement tools, should clear the market of all illegal products, particularly the flavored products that have been a continuing threat to young people. The only e-cigarettes on the market should be those that CTP has found to be "appropriate to the protection of the public health."

Most significant impact. CTP asks for the actions it could take in the next five years "that would have the most impact in significantly reducing tobacco-related death and disease." We believe those actions are: (1) implementing a rule reducing the nicotine in cigarettes and other

combustible tobacco products to non-addictive levels; (2) implementing rules prohibiting menthol as a characterizing flavor in cigarettes and all flavors in cigars; and (3) clearing the market of all illegal e-cigarette products and allowing the marketing only of e-cigarettes that meet the statutory public health standard for new products.

Respectfully submitted,

Campaign for Tobacco-Free Kids