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Submitted by e-mail.

Dear Ms. Winckler:

On behalf of the Campaign for Tobacco-Free Kids (Tobacco-Free Kids), I wish to express our thanks to the Reagan-Udall Foundation (the Foundation) for affording us the opportunity to address the Independent Expert Panel (the Panel) evaluating aspects of FDA's tobacco program and to submit these written comments. We have organized our written discussion around the questions posed by the Foundation in its Stakeholder Portal established to receive public comments. We respectfully request that our comments be transmitted to the members of the Panel for their consideration in formulating their recommendations for FDA.

We recognize that the purpose of this evaluation of FDA's tobacco program is to address operational issues concerning FDA's Center for Tobacco Products (CTP), not policy issues. To the extent that our comments touch on policy issues, it is only to provide necessary background to explicate our views on operational issues.

Before turning to the questions posed for public input, we want to make one overarching comment that should guide the Panel's consideration of FDA's tobacco operations and its work in formulating recommendations for all areas of FDA's tobacco regulation. 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 regulation 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 companies were likely to continue their predatory conduct into the future.² The Congressional findings in the TCA make specific

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).

² *Id.* at 909.

reference to the court's factual findings³ and make clear that the legislation is intended "to address the public health crisis created by actions of the tobacco industry."⁴

Thus, there is no question that the mission of FDA under the TCA is to protect the public, and particularly America's children, against 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. In contrast, with tobacco regulation, the industry is the one that has created the public health problem through its long history of predatory marketing of deadly products and its distortion of evidence and manipulation of science to ensure the economic viability of the industry. Thus, the processes and procedures used by FDA to regulate other products may not function to protect public health when applied to the tobacco industry and its products. This key reality should guide all of the Panel's deliberations and recommendations on the operations of CTP.

WHAT RECOMMENDATIONS DO YOU HAVE TO IMPROVE FDA'S TOBACCO PROGRAM OPERATIONS?

I. Application Review

Before turning to specific recommendations to improve CTP's application review process, several introductory comments are needed for context.

A. Statutory Purpose and Structure

First, 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. Of particular concern to Congress were products sold for use to reduce the risks of tobacco products when in fact their use may perpetuate the use of tobacco products.⁵ Thus, with certain exceptions, Section 910 of the statute 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."⁶ 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).⁷

Second, 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 in many cases is intended to prevent the industry from introducing new products that may increase the harm to the public, in part by expanding the number of people who are and/or become addicted to products that are harmful and/or by discouraging people who smoke cigarettes from quitting altogether. The TCA makes clear that, first and foremost, the public

³ Tobacco Control Act, Pub. L. No. 111-31 § 2(47)-(49), 123 Stat. 1781 (2009).

⁴ *Id.* § 2(29), 123 Stat. 1778.

⁵ *Id.* § 2(36)-(43), 123 Stat. 1779-1780.

⁶ 21 U.S.C. § 387j.

⁷ 21 U.S.C. § 387k.

health review of new 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.

Third, and of greatest importance, FDA’s public health review of new products is to occur *before* the products are introduced into commerce. Indeed, the statute does not contemplate that a new product can be on the market *for a single day* without having met the statutory standard. The only reason so much focus has been on products already on the market is that FDA took so long to assert its jurisdiction over these products and its failure to enforce the law subsequent to the adoption of the Deeming Rule that prohibited products from entering the market after that date without an FDA order. Our operational recommendations are largely intended to address the current reality that many thousands of varieties of highly addictive e-cigarette products, including flavored products found by FDA to be especially attractive to young people, have been on the market for many years without having met the statutory public health standard. As a consequence, youth usage of e-cigarettes remains at unacceptable levels.⁸ It is critical that FDA move promptly to prevent the marketing of any product that has not already undergone FDA review and end the industry practice of introducing products first and asking for FDA review later. *As to e-cigarettes, what was intended by the statute to be premarket review has become post-market review – that must change.*

B. The Breakdown of E-Cigarette Premarket Review

Despite the statutory requirement of *premarket* review, FDA currently faces the extraordinary situation of many thousands of e-cigarettes remaining on the market for years without having gone through premarket review. In order to make recommendations on how FDA should address its responsibilities to review new tobacco products, the Panel must understand how this occurred. It was due to the confluence of several factors, all of which involve the industry’s success in exploiting CTP’s failure to bring products creating substantial public health harm under strict science-based regulation.

First, FDA’s delay in issuing the Deeming Rule subjecting e-cigarettes to its regulatory jurisdiction allowed the e-cigarette market to become a “wild, wild West” of unregulated, highly addictive, flavored products marketed to young people.

Second, in August, 2017, FDA issued a Guidance which purported to suspend operation of premarket review as to e-cigarettes already on the market as of the effective date of the Deeming Rule for several years, extending the deadline for Premarket Tobacco Product Applications (PMTAs) for four years (until August, 2022), and allowing products to remain on the market indefinitely until FDA denied the application. As the result of a lawsuit brought by Tobacco-Free Kids and other public health groups, a Maryland federal court vacated the Guidance, finding that suspending the premarket review process exceeded FDA’s authority

⁸ CDC Press Release, *More than 2.5 Million Youth Reported E-Cigarette Use in 2022*, (Oct. 6, 2022). <https://www.cdc.gov/media/releases/2022/p1007-e-cigarette-use.html#:~:text=A%20study%20released%20today%20from,and%203.3%25%20of%20middle%20school.>

under the TCA.⁹ The court also noted the industry’s intentional failure to engage the regulatory process until absolutely required to do so,¹⁰ a failure to recognize the legitimacy of FDA regulation that further distinguishes tobacco companies from companies that market other FDA-regulated products. The court set new dates by which companies had to file PMTAs (September 9, 2020), and FDA had to issue marketing orders (September 9, 2021) for products to remain on the market without being subject to FDA enforcement.¹¹

Third, FDA was deluged with a flood of applications far in excess of what it anticipated. In 2019, CTP Director Mitch Zeller had estimated the number of anticipated e-cigarette marketing applications to be in the thousands.¹² Instead, the agency received applications for more than 6.5 million products, though one company’s applications accounted for more than 4.5 million products.¹³ It is apparent that the industry submitted applications for millions of products which did not represent serious efforts to marshal the science necessary to meet the statutory standard, but rather were intended to cripple the agency’s premarket review process. It is also apparent that CTP did not have an accurate understanding of the e-cigarette market sufficient to prepare it for the volume of applications submitted.

Fourth, there have been lengthy delays in FDA decision-making on e-cigarettes, allowing many of the products with the largest market shares to remain on the market far after the September 9, 2021 deadline set by the court. According to periodic status reports filed by FDA with the Maryland federal court, FDA will not complete its review of these products until June 2023,¹⁴ almost two years after the deadline set by the court for decisions on all e-cigarette products with applications filed by the September 9, 2020 deadline.

Fifth, the agency has delayed decisions on menthol-flavored products, citing “unique considerations” applicable to those products, even though the data shows significant youth usage of menthol e-cigarettes.¹⁵ This moratorium on menthol-product decisions appears to have come

⁹ *Am. Acad. of Pediatrics (“AAP”) v. FDA*, 379 F.Supp. 3d 461, 492 (D. Md. 2019), *appeal dismissed sub nom.*, *In re Cigar Ass’n of Am.*, 812 F.App’x 128 (4th Cir. 2020).

¹⁰ *AAP v. FDA*, 399 F.Supp. 3d 479, 485 (D. Md. 2019) (“[T]he record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings.”)

¹¹ *Id.* at 487, *modified by subsequent order*, Doc. No. 182 (D. Md. Apr. 22, 2020).

¹² Decl. of Mitchell Zeller, Doc No. 120-1, at 13-15 (filed June 12, 2019), *AAP*, 399 F.Supp. 3d 479 (D. Md. 2019).

¹³ FDA Statement, *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* (Sep. 9, 2021), <https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90#:~:text=FDA%20Statement,.FDA%20Makes%20Significant%20Progress%20in%20Science%2DBased%20Public%20Health%20Application.D deemed%20New%20Tobacco%20Products%20Submitted&text=Statement%20From%3A,Janet%20Woodcock%2C%20M.D.>

¹⁴ Status Reports, Doc Nos. 205 (filed May 13, 2022), 207 (July 28, 2022), 209 (Oct. 26, 2022), *AAP*, 399 F.Supp. 3d 479 (D. Md. 2019).

¹⁵ 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, 1283 (2022), <https://www.cdc.gov/mmwr/volumes/71/wr/mm7140a3.htm>

to an end on October 26, 2022, as FDA announced marketing denial orders (MDOs) for several menthol products marketed by Logic Technology Development LLC.¹⁶

Sixth, FDA has yet to take any enforcement actions against products with pending PMTAs, even though they have no more legal right to be on the market than products that have never filed a PMTA. Yet there appears to be an unstated FDA policy of exercising across-the-board enforcement discretion protecting these products, even though the Maryland court established 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.

Finally, when companies began marketing products with nicotine not derived from tobacco (synthetic nicotine) in a brazen effort to evade FDA regulation, Congress acted to close this loophole by extending FDA's tobacco regulatory authority to those products, including the premarket review requirement.¹⁷ However, FDA does not appear to be enforcing the new statute consistent with Congressional intent. As public health groups have argued to FDA,¹⁸ Congress enacted the new law to clear the market of synthetic products after a brief transition period during which companies with those products already on the market could submit PMTAs and FDA could review them. That transition period ended for all synthetic products on July 13, 2022. Although FDA has issued warning letters to some manufacturers of these products, including brands popular among youth like Puff Bar,¹⁹ many synthetic products remain readily available to youth and it is not clear that the agency intends to bring enforcement actions against any synthetic nicotine product manufacturers with pending PMTAs.

This recent history of industry exploitation of FDA's regulatory failures and delays should inform the Panel's recommendations for improving the application process going forward and requiring FDA to adopt procedures so that "pre-market" review becomes just that – review before the product goes on the market.

C. Incomplete Application of Premarket Review to Other Products

FDA's failure to properly administer and enforce the premarket review requirements for new 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

¹⁶ FDA News Release, *FDA Denies Marketing of Logic's Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (Oct. 26, 2022), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-logics-menthol-e-cigarette-products-following-determination-they-do-not-meet>.

¹⁷ Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Division P, Title I, Subtitle B, § 111, 136 Stat. 49, 789-90 (2022).

¹⁸ Letter from AAP et al. to Dr. Brian King, Dir., FDA CTP, on FDA Enforcement Policy Toward Illegal Synthetic Nicotine Products (Sep. 22, 2022), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2022_09_22_Letter-to-FDA-enforcement-policy-illegal-synthetic-nicotine-products.pdf

¹⁹ FDA, *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* (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>.

been promoted as new to the market after February 15, 2007 and yet appear to have no marketing orders.²⁰ Indeed, even though FDA has proposed rules banning menthol cigarettes and flavored cigars, it has recently 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.²¹ 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 companies themselves promote as new to the market have been able to avoid premarket review.

D. Need for Requirement of Direct Evidence of Potential Impact of Specific Products on Youth and Adolescents

FDA has repeatedly issued both marketing orders and modified risk orders for products without sufficient evidence of how those products are used and perceived by youth and adolescents. Given the unambiguous mandate in the TCA to provide sufficient evidence, on a premarket basis, of the product’s population-wide impact, such an impact cannot be assessed without direct evidence of a tobacco product’s impact on nonusers, especially youth. The presentation of such evidence should be expressly required for all PMTAs and modified risk 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.²²

E. Marginalization of the Role of the Tobacco Products Scientific Advisory Committee in Evaluating Modified Risk Tobacco Product (MRTP) Applications

The TCA requires that MRTP applications be submitted to the Tobacco Products Scientific Advisory Committee (TPSAC) and that TPSAC provide FDA with its recommendations on the applications before FDA issues or denies MRTP orders. As documented by public health organizations,²³ 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

²⁰ See, e.g., Letter from Action on Smoking & Health et al. to Mr. Mitchell Zeller, Dir., FDA, CTP (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

²¹ Letter from Action on Smoking & Health et al. to Mr. Mitchel 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.

²² 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/>.

²³ Letter from AAP et al. to Mr. Mitchell Zeller, Dir., FDA CTP, on Role of the Tobacco Products Scientific Advisory Committee in Modified Risk Tobacco Product Proceedings (Oct. 19, 2020), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2020_10_10_Letter-to-FDA-on-TPSAC-role-MRTP-proceedings.pdf

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.²⁴ This is not consistent with the letter and spirit of the TCA.

F. Application Review – Specific Recommendations

In order to bring the PMTA and MRTP application processes into alignment with the TCA, and remedy the presence of many thousands of new tobacco products being marketed without having met the statutory standards, FDA should take the following concrete steps:

- (1) Expedite its decision-making on PMTAs submitted for tobacco-derived and synthetic nicotine e-cigarette products, including menthol-flavored products;
- (2) Make it clear to manufacturers, distributors, and retailers that all e-cigarette products on the market without marketing orders are subject to enforcement, regardless of whether they have pending PMTAs, and bring sufficient enforcement actions to reinforce that message to the industry.
- (3) Going forward, make it clear that no new tobacco product, including all tobacco-derived and synthetic nicotine e-cigarette products, will be permitted on the market unless a PMTA has been filed and the product has undergone full public health review and a marketing order has been issued, with no exceptions and with no exercise of agency enforcement discretion.
- (4) FDA should implement a more systematic monitoring of the tobacco market sufficient to allow the early identification of new products introduced without marketing orders.
- (5) Given that FDA has determined that youth usage of tobacco products, including e-cigarettes, is inherently harmful and produces no public health benefit, FDA should require that every PMTA and MRTP application include specific data on youth use and youth perception of the product based on American data. FDA should develop and require the necessary protocols and safeguards companies must implement to ensure that youth and young adults are sufficiently protected during the conduct of such studies and that the data are objective and reliable.
- (6) In considering MRTP applications, FDA must provide TPSAC with the opportunity to vote on each of the scientific issues that must be resolved to determine whether MRTP applications meet the statutory public health standard. In addition, TPSAC voting members should be instructed to vote on whether an application meets the scientific standards for granting the MRTP applications.

²⁴ *Id.* at 6.

II. Compliance and Enforcement

A. FDA Must 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 products prior to premarket review. As detailed in our discussion of Application Review above, 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.²⁵ 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 for public health that FDA clear the market of these 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. *FDA Should Create a List of Authorized Products and Communicate to All Parties that the Sale or Distribution of Any Product Not Listed is Illegal and Will Lead to Enforcement Actions*

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 breaking the law. To remedy this, FDA must begin by making crystal clear which products are legal to sell²⁶ – through the creation and distribution of a list of authorized products – and to communicate clearly to manufacturers, distributors, and retailers that it is prepared to bring enforcement actions (e.g., possible seizure, injunctions) against any unlisted product. Creating and distributing a list of authorized products – coupled with actual enforcement against products not listed – is an efficient and straightforward 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.

2. *FDA Must End Its Policy of Enforcement Discretion That Has Allowed Unauthorized Products to Be on the Market and Must Clearly Communicate that It is Prepared to Bring Enforcement Actions Against Such Products*

As discussed above, it does not appear that the FDA has taken enforcement actions against any product with a pending PMTA, despite these products having no more legal right to

²⁵ 21 U.S.C. § 387j.

²⁶ FDA currently publishes on its website separate lists of the products that have received Premarket Tobacco Product Marketing Granted Orders (<https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>), Substantial Equivalence (“SE”) Orders (<https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se>), and SE Exemption Orders (<https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se>). To the extent FDA does not currently have a list of “pre-existing tobacco products” that are legal to market, it should develop one.

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, until October 26, 2022, FDA had not issued any marketing decisions based on a full scientific review of menthol e-cigarettes, despite the latest data showing that over a quarter (26.6%) of current youth e-cigarette users report using a menthol product.²⁷ Also included in this group of products with pending PMTAs are other products that are very popular with youth and that hold the greatest market share. As Judge Paul W. Grimm of the U.S. District Court for the District of Maryland recently stated, “The FDA reports that it has completed millions of phased product reviews in about 98% of the timely premarket applications ... However, *the popular products used by young people remain on the market unreviewed, which is inconsistent with the purpose of the Court’s [earlier] judgment.*”²⁸

FDA’s public statements about enforcement have not made it clear that the agency intends to take enforcement action against companies marketing unauthorized products. This has arguably emboldened companies to continue violating the law. Take for example FDA’s April 8, 2022 press release announcing MDOs for several myblu e-cigarettes manufactured by Fontem US, LLC.²⁹ That release states in relevant part:

Tobacco products subject to a negative action regarding a premarket submission, including those subject to an MDO, may not be offered for sale, distributed or marketed in the US...Currently, FDA’s highest enforcement priorities are ENDS products for which no application is pending, including, for example, those with an MDO or those for which no application was submitted.

Rather than stating that all new tobacco products without a marketing order are illegal to sell, FDA limited it only to “[t]obacco products subject to a negative action regarding a premarket submission.” Moreover, FDA’s recitation of its “highest enforcement priorities” arguably creates the impression that FDA will not enforce against products that are not part of these priorities, particularly given the agency’s poor track record of enforcement against illegal tobacco products. In fact, shortly after receiving these MDOs, Fontem announced that it had filed an internal administrative appeal of the orders and that “[b]ased on past practice, we expect the *FDA will not seek to enforce the MDOs* while this appeal remains ongoing, and we therefore *expect the products to remain in the market during this period.*”³⁰ To help put an end to this practice of openly marketing illegal products, FDA must make clear that no product without authorization may be sold and that FDA intends to take enforcement actions against such products.

²⁷ Cooper et al., *supra* note 15, at 1283.

²⁸ Letter Order, Doc. No. 201 at 2 (Apr. 15, 2022), AAP, 399 F.Supp. 3d 479 (D. Md. 2019) (emphasis added) (footnote omitted).

²⁹ FDA, *FDA Issues Marketing Denial Orders to Fontem US for myblu Products* (Apr. 8, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-fontem-us-myblu-products>.

³⁰ blu, *Regulation*, <https://www.blu.com/en/US/faqs/regulation/update-blus-response-to-fdas-marketing-denial-order> (last visited Nov. 7, 2022) (emphasis added).

3. *FDA Must Go Beyond Warning Letters and Make More Systematic Use of the Additional Enforcement Tools Congress Provided*

Given the continued presence on the market of many thousands of illegal products and the evidence that the industry does not take FDA enforcement seriously, it is crucial for FDA and the U.S. Department of Justice, its enforcement partner, to go beyond warning letters and use the other tools at their disposal, namely civil money penalties, no-tobacco-sale orders, seizures, injunctions, or in extreme situations criminal prosecution.³¹ We were encouraged by the recent announcement that, for the first time in its history, FDA is seeking an injunction against illegal tobacco products.³²

While this is a positive development, these proceedings were initiated only against certain companies that failed to submit PMTAs by the court-ordered September 9, 2020 deadline.³³ 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.³⁴ During such time, the companies profited off the sale of their illegal products, which included kid-friendly flavored products like SUPER VAPE'Z Premium E-Liquid Apple Mango.³⁵ 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.

FDA should also disclose more information about the enforcement actions it does take, and provide this information in an easy-to-search format. Currently, FDA maintains a database of warning letters.³⁶ However, it is not always 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 to assess whether FDA has adopted an unstated policy of enforcement discretion as to particular categories of products. It also is difficult for the public to discern whether, and how often, FDA follows these warning letters with stronger enforcement for continued violations. And if FDA begins enforcing against

³¹ FDA, *Compliance, Enforcement & Training* (last updated Apr. 5, 2022), <https://www.fda.gov/tobacco-products/compliance-enforcement-training>.

³² 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>.

³³ *Id.*

³⁴ 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).

³⁵ *Id.* at 6.

³⁶ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>

products, for example, that have pending applications and discloses this information, it would send a strong message of accountability to the manufacturers, distributors, and retailers of similarly-situated products.

B. FDA Should Fulfill Its Statutory Obligations to Implement a Track and Trace System

To support its enforcement efforts and to satisfy its obligation under Section 920(b) of the TCA, FDA should implement a national track and trace system. Such a system would allow FDA to monitor the manufacture and flow of tobacco products through the entire supply chain, an action that would enhance FDA's enforcement efforts against non-compliant products and also reduce tobacco products' evasion of federal excise taxes.

Section 920(b) of the TCA, titled "Regulations Concerning Recordkeeping for Tracking and Tracing," unequivocally mandates that the Secretary of the Department of Health and Human Services "shall promulgate" recordkeeping regulations.³⁷ In promulgating the mandated regulations, subsection 2 of 920(b) requires the Secretary to consider "the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products."³⁸ Finally, the TCA provides that the "Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system."³⁹

Thus, Section 920 calls for the FDA to establish a track and trace system and envisions at least two central components of that system: (1) comprehensive recordkeeping at every level of distribution, and (2) unique identifying codes applied to each tobacco product. As detailed in a 2013 Citizen Petition submitted by Tobacco-Free Kids, the New York City Department of Health & Mental Hygiene, and several other public health and advocacy organizations requesting the establishment of a track and trace system,⁴⁰ under such a system, every participant in the legal market for tobacco products – from manufacturer to wholesaler to retailer – would be accountable for every product produced, received, maintained and transferred, and law enforcement would be better positioned to identify where in the distribution chain a product was diverted into the illegal market. In Section 920, Congress, in clear and strong terms, required the FDA to ensure such accountability. The required use of unique identifying codes also would assist distributors, retailers, and consumers in determining whether products are compliant with the law.

Finally, the track and trace system established pursuant to the statute must be fully independent of industry influence or control, and the data generated by such a system must remain within the control of the federal government, accessible by state and local authorities. Major tobacco companies have developed their own surveillance systems and frequently suggest

³⁷ 21 U.S.C. § 387t(b)(1).

³⁸ *Id.* § 387t(b)(2).

³⁹ *Id.* § 387t(b)(3).

⁴⁰ [https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2013-03-6%20Track%20&%20Trace%20Citizen%20Petition%20\(Partners\).pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2013-03-6%20Track%20&%20Trace%20Citizen%20Petition%20(Partners).pdf).

that governmental systems incorporate elements of such systems or rely on industry data and expertise to run them. However, such suggestions must be rejected, as industry surveillance systems are inadequate and function to serve the economic interest of companies rather than to enhance the effectiveness of public health regulation.⁴¹

III. Regulations and Guidance Process

A. FDA Should Make More Extensive Use of Its Rulemaking Authority to Issue Product Standards to Enhance Public Health

With respect to the Regulations and Guidance Process, the most salient FDA deficiency has been the agency's reluctance to use its rulemaking authority to issue products standards. The authority to impose products standards under Section 907 of the TCA to make tobacco products less hazardous, addictive and appealing is perhaps the most far-reaching authority FDA has to protect the public from tobacco-related disease and mortality. Yet, in its thirteen years of existence, CTP has yet to issue a final rule creating a product standard. The proposed rules prohibiting menthol as a characterizing flavor in cigarettes and prohibiting all flavors in cigars, both with enormous potential to save lives, will hopefully bring this record of inaction to an end.

Although there may be multiple reasons for CTP's reluctance to issue product standard regulations, it is likely that a major factor is the combination of the tobacco industry's propensity to file legal actions challenging agency tobacco decisions, along with the agency's failure to recognize the great deference its scientific decisions are likely to receive from courts. The fear of industry litigation seems to permeate almost every level of agency effort related to tobacco product regulation and is a substantial barrier impeding FDA's capacity to achieve its public health mission.

It is clear, however, that Congress intended FDA to have maximum discretion to impose product standards without a requirement of scientific certainty. Section 912 of the TCA expressly subjects regulations establishing product standards to the lenient standard for judicial review under the Administrative Procedure Act, which empowers courts to set aside agency actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."⁴² In other analogous regulatory contexts, courts have interpreted this judicial review standard to allow broad agency discretion to act even in the face of scientific uncertainty and imperfect data.⁴³ Thus, FDA should not be reluctant to use its authority to issue product standards and other regulations because it fears industry legal challenges.

⁴¹ Ana B. Gilmore et al., *Tobacco industry's elaborate attempts to control a global track and trace system and fundamentally undermine the Illicit Trade Protocol* 28 TOBACCO CONTROL 127 (2019), <https://tobaccocontrol.bmj.com/content/28/2/127>; Hana Ross et al., *Why governments cannot afford Codentify to support their track and trace solutions*, 27 TOBACCO CONTROL 706 (2018), <https://tobaccocontrol.bmj.com/content/27/6/706>.

⁴² 21 U.S.C. §3871(a)(1)(A) and (b), incorporating by reference 5 U.S.C. §706(2)(A).

⁴³ See, e.g., *FCC v. Prometheus Radio Project*, 141 S.Ct. 1150, 1160 (2021) (agency acted lawfully when it "made a reasonable predictive judgment based on the evidence it had" despite that evidence being "[f]ar from" perfect.); *Indus. Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 656 (1980) (agency was "not required to support its findings . . . with anything approaching scientific certainty."); *Coalition for Responsible Regulation, Inc. v. Environmental Protection Agency*, 684 F.3d 102,120 (D.C. Cir. 2012) (per curiam) (courts "give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise." Given that the

B. FDA Should Avoid Undue Delay in Issuing Regulations

Even when CTP has been required to issue regulations by statute, or has indicated its intent to do so, its regulatory process has been encumbered by significant delays that have concrete and adverse public health consequences. Examples include:

- 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 2016.⁴⁴ 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. 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 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 2012⁴⁵ 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.⁴⁶ Pursuant to that court order, FDA issued a final rule on March 18, 2020.
- The proposed rule prohibiting menthol as a characterizing flavor in cigarettes. The TPSAC issued its menthol report recommending removal of menthol cigarettes from the market in 2011, which the industry then challenged. Their lawsuit garnered a lower court ruling barring use of the report by FDA, which was then later overturned. *R.J. Reynolds Tobacco Co. v. FDA*, 810 F. 3d 827 (D.C. Cir. 2016). The FDA issued its own menthol report in 2013 concluding, as TPSAC did, that menthol cigarettes likely "pose a public health risk above

Clean Air Act is "designed to protect the public health," "the existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding.").

⁴⁴ Final Rule, 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).

⁴⁵ *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).

⁴⁶ *Am. Acad. of Pediatrics v. FDA*, 330 F. Supp. 3d 657 (D. Mass. 2018). However, industry lawsuits against the rule have 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.).

that seen with nonmenthol cigarettes.”⁴⁷ Despite these conclusions, two advanced notices of proposed rulemakings in 2013 and 2018, and an FDA Commissioner’s pronounced intention to advance a notice of proposed rulemaking, 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.⁴⁸

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.

C. The FDA Should Move Expeditiously to Complete the Tobacco Product Standard Rulemaking Process for Menthol Cigarettes and Flavored Cigars and Should Issue Proposed and Final Rules Limiting the Nicotine in Cigarettes to Minimally or Non-Addictive Levels

The proposed rules on menthol cigarettes and flavored cigars were issued in May of this year and the comment period ended on August 2. Given the wealth of science unequivocally finding that flavored tobacco products attract kids and that removing menthol cigarettes from the marketplace will improve public health,⁴⁹ the completion of these rules should be a top priority for the agency.

Similarly, FDA should, by the end of 2023, follow through with its stated intention to issue the notice of proposed rulemaking regarding nicotine levels in combustible tobacco products.⁵⁰ Current evidence establishes the potentially historic lifesaving impact of reducing nicotine content in cigarettes to non-addictive or minimally addictive levels. In 2018, FDA estimated that approximately five million additional adults who smoke could quit smoking within one year of implementation, and by the year 2100, more than 33 million people – mostly youth and young adults – would have avoided becoming regular smokers.⁵¹ Smoking rates could

⁴⁷ FDA, PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2013), <https://www.fda.gov/media/86497/download>.

⁴⁸ See Compl. (Doc. No. 1) at 40, *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>.

⁴⁹ See Comments of Public Health Groups in Docket No. FDA-2021-N-1309, “Tobacco Product Standard for Characterizing Flavors in Cigars” (Aug. 2, 2022), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/Support_Prohibiting_Flavored_Cigars_8_2_2022.pdf; Comments of Public Health Groups in Docket No. FDA-2021-N_1349, “Tobacco Product Standard for Menthol in Cigarettes” (Aug. 2, 2022), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/Support_Prohibiting_Menthol_Cigarettes_8_2_2022.pdf.

⁵⁰ 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>.

⁵¹ Benjamin J. Apelberg et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, NEW ENGLAND J. MED. (Mar. 15, 2018), <https://www.nejm.org/doi/full/10.1056/NEJMSr1714617>; see also “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes,” Advance Notice of Proposed

drop to as low as 1.4 percent, resulting in more than 8 million fewer tobacco-caused deaths through the end of the century.⁵² The dimensions of this public health benefit make timely implementation of this policy a moral imperative.

IV. Communications With the Public and Other Stakeholders

A. FDA Should be More Transparent about the Bases for Its Decisions on Premarket Review

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 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 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.⁵³

B. In Its Public Education Campaigns, FDA Should Continue to Prioritize Communication About the Risks of Tobacco Products, Including to Discourage the Use of E-Cigarettes by Young People

According to FDA, beginning in 2020 it has prioritized public education efforts aimed at educating youth about the health harms and addictiveness of e-cigarettes.⁵⁴ 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 today,⁵⁵ this is an entirely reasonable judgment as to the agency's public education priorities.

Rulemaking, 83 Fed. Reg. 11,818, 11,820 (Mar. 16, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-03-16/pdf/2018-05345.pdf>.

⁵² *Id.* at 11,837.

⁵³ 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 (last updated Aug. 15, 2022).

⁵⁴ FDA, *Public Health Education Campaigns*, <https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns> (last visited Nov. 7, 2022).

⁵⁵ Cooper et al., *supra* note 15, at 1285.

In various comments to the Panel, industry representatives argued 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. 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,⁵⁶ FDA would be ill-advised to undertake broad-based public education campaigns designed to minimize the perceived dangers of nicotine in e-cigarettes. There is a substantial risk that such public education 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.

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 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.

WHAT DO YOU SEE AS THE STRENGTHS AND CHALLENGES OF THE FDA CENTER FOR TOBACCO PRODUCTS?

Strengths

- The broad authority to regulate tobacco products under the TCA. In the TCA, Congress gave FDA very broad authority to protect the public against the products, and predatory conduct, of the tobacco industry. This includes the authority to issue product standards

⁵⁶ 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>.

that can mitigate the health hazards, addictiveness and appeal of tobacco products, to be the gatekeeper to protect against new products and health claims used in the marketing of products that create health risks and to require prominent and graphic health warnings on cigarettes that more effectively inform the public about the harms caused by those products.

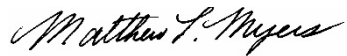
- Through user fees, the availability of significant resources to fund tobacco regulation and public education efforts. Total revenue generated by tobacco user fees is \$712,000,000 for FY2023. CTP employs over 1,100 staff. CTP has broad responsibilities and significant challenges regulating the tobacco market, but it has substantial resources to execute those responsibilities and meet those challenges.
- CTP's Tobacco Regulatory Science Program, a partnership with the National Institutes of Health, and particularly its Tobacco Centers of Regulatory Science (TCORS), made up of scientists with a broad range of expertise to generate research to inform the regulation of tobacco products.
- The general deference of courts to the scientific judgments of regulatory agencies, which is important in successfully defending final rules and administrative orders when challenged by the industry.

Challenges

- The importance of understanding the differences between the tobacco industry and the other industries regulated by FDA and the distinctions between the statutory scheme for regulating tobacco and that established for other products. The failure to consistently recognize these distinctions leads to resistance to new, different and bold approaches necessary to regulate a historically bad acting industry in a way that serves the public health.
- Inability to take effective regulatory action in a timely manner. Many of the deficiencies in FDA's tobacco regulatory work since enactment of the TCA can be traced to a failure to act quickly and decisively to prevent damage to the public health from industry conduct. Examples include (1) a five year delay in issuing the Deeming Rule to subject all tobacco products, including e-cigarettes, to FDA's regulatory jurisdiction; (2) delay in issuing proposed and final rules mandating graphic health warnings for cigarettes after the initial final rule was vacated by the courts; (3) over a decade delay between when TPSAC published its exhaustive report on the adverse public health impact of menthol cigarettes and when FDA issued a proposed rule banning menthol as a characterizing flavor in cigarettes; and (4) delays in issuing decisions on marketing applications for e-cigarettes, far after deadlines set by a federal court (for tobacco-derived products) and by Congress (for synthetic nicotine products).
- A reluctance to enforce the statutory requirement that all new tobacco products undergo premarket review prior to market introduction, and a reluctance to go beyond warning letters in enforcing this requirement.

- A regulated industry with enormous resources to expend on influencing the regulatory process in ways that frustrate the achievement of the objectives of the Tobacco Control Act.
- Fear of industry lawsuits, combined with a failure to appreciate the deference accorded regulatory agency scientific judgments, leading to a failure to take decisive action in a timely fashion.

Respectfully submitted,

A handwritten signature in cursive script that reads "Matthew L. Myers".

Matthew L. Myers
President