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February 3, 2023

Dr. Robert Califf, M.D.
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD. 20993

Re: Reagan-Udall Foundation Report

Submitted by e-mail

Dear Dr. Califf:

On behalf of the Campaign for Tobacco-Free Kids (Tobacco-Free Kids), I write to provide our perspective on the recommendations, and supporting discussion, in the Reagan-Udall Foundation's *Operational Evaluation of Certain Components of FDA's Tobacco Program* (the Report),[1] issued in December. While we support some of the Report's recommendations as important to the efficient achievement of FDA's mission to prevent the disease and death caused by tobacco products, other portions of the Report reflect an industry perspective that would undermine that mission.

Clearing the Market of Illegal Products

One of the Report's most valuable contributions is its recognition of the urgency of addressing the reality that "millions of [e-cigarette] products have entered the market without pre-market authorization and remain on the market today, and new products continue to enter the market without the required authorization." Report at 22. Indeed, given the few marketing orders thus far granted for e-cigarette products, only a handful of e-cigarettes on the market are being sold in compliance with the law. Because many of these illegal products are flavored disposable products that are particularly appealing to young people, the ready availability of these products has significant and adverse public health consequences.

In particular, the Report notes that companies with illegal products on the market have "every incentive" to delay FDA action. Report at 22. The Report further notes that "[b]ecause companies have seen that FDA is not taking action for those products for which an application is pending, some companies have continued to market their products, in some cases reportedly submitting deficient applications or filing frivolous appeals to further delay enforcement

[1] https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_Dec.%202022.pdf.

actions." Report at 22. Thus, as we discussed in our written comments to the Reagan-Udall Independent Expert Panel,[2] it is of the greatest importance that FDA act expeditiously to decide all pending Premarket Tobacco Product Applications (PMTAs) and to bring enforcement actions sufficient to send a clear message to industry that all products on the market without marketing orders are subject to enforcement, regardless of whether they have pending PMTAs. It is imperative that FDA ensure that the statutory directive of *premarket* review be enforced, allowing no product to remain on the market, or enter the market, without a marketing order.

The Report makes several concrete recommendations that should be adopted to clear the market of these illegal products:

- Prominently post and maintain a list of legally marketed products to facilitate voluntary compliance and discourage the sale of illegal products by manufacturers, distributors, wholesalers and retailers. As the Report points out, although the Center for Tobacco Products (CTP) has lists of marketing granted orders and marketing denial orders on its website, "it does not clearly convey what those lists mean with regard to the lawful marketing of the products." Report at 25. The list of legally marketed products must be communicated to manufacturers, distributors and retailers with a message making it clear that no other products can be legally sold. It is critical for all tobacco product sellers to understand which products are legal and which are not.

- Bring high-profile actions against wholesalers and distributors who are handling illegally marketed products. Such actions will strengthen the message that any seller dealing in products not on the list of legal products will incur the risk of enforcement action. We agree with the Report's observation that "this action could help clear the downstream distribution pathways of illegal products and deter those who might bring new products to the market without marketing authorization." Report at 24. FDA should assess whether targeting wholesalers and distributors could prove more practical and productive than focusing enforcement resources on the many manufacturers and retailers currently selling illegal products.

- Streamline the process leading to enforcement actions filed by the Department of Justice (DOJ). The current failure to enforce the premarket review mandate must be a priority for DOJ as well as FDA. However, the Report describes the current enforcement process as "cumbersome," with time-consuming steps within both FDA and DOJ. Report at 22. The Report describes the process of then imposing civil money penalties as equally "cumbersome," with a "high bar" to bring cases and a DOJ reluctance to bring "cases and risk adversely affecting the tobacco program or other FDA programs or authorities if the actions fail the legal test." Report at 23. Although the Report recommends considering whether statutory changes are needed to streamline the enforcement process, FDA, working with DOJ, first should determine whether such streamlining could be achieved without going through the highly uncertain legislative process.

The Report also recommends formation of an "interagency task force to make enforcement of the tobacco laws a government-wide priority…." Report at 23. The Report

[2] Letter from Matt Myers to Susan Winckler, Nov. 7, 2022, at 7 (Myers letter), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2022_11_07_CTFK_Reagan-Udall-written-comments.pdf.

suggests that this task force include FDA, HHS, DOJ (including the Bureau of Alcohol, Tobacco and Firearms), the Department of Homeland Security (including Customs and Border Protection) and the Department of the Treasury (including the Alcohol and Tobacco Tax and Trade Bureau). Although we believe the Biden Administration must prioritize tobacco product enforcement at the highest levels of government, including FDA, HHS and DOJ, it is not clear that a "task force" consisting of such a broad swath of federal agencies is the most effective way forward. At the present time, the focus should be on enforcing the requirement that all new tobacco products, including e-cigarettes, have a marketing order to remain on the market, or enter the market. This specific enforcement objective calls for focused attention from FDA, HHS and the relevant enforcement authorities at DOJ, but the Administration should guard against creating new bureaucratic entities or processes that could increase, not decrease, the complexity of bringing effective enforcement actions against products that lack marketing authorization.

It also is important to understand the genesis of the situation faced by FDA, in which the agency was flooded with PMTAs filed for millions of e-cigarette products by a date certain, creating a huge backlog of applications with little prospect of timely action by the agency. This situation is the result of a "perfect storm" of ill-advised FDA policy decisions[3] and delays, with industry conduct designed to exploit those decisions and delays to the benefit of the industry and to the detriment of public health. To summarize,[4] the key factors included:

(1) FDA's delay in issuing a proposed deeming rule, which allowed the e-cigarette market to explode in an unregulated environment and made FDA review of these products under the deeming rule "postmarket" instead of premarket;

(2) barely one year after the deeming rule became final, an FDA Guidance issued in August, 2017 which purported to suspend operation of premarket review as to e-cigarettes that were on the market as of the effective date of the deeming rule, a Guidance later held illegal by a federal court;[5]

(3) a deluge of PMTAs for more than 6.5 million e-cigarette products, far in excess of the number anticipated by FDA and including applications which did not represent serious efforts to marshal the evidence necessary to meet the statutory public health standard;

(4) lengthy delays in FDA decision-making on PMTAs, particularly those menthol and other flavored products constituting the most significant threats to young people, allowing these products to remain on the market for an extended period without the required marketing orders;

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[3] We agree with the Report's observation that it is important to distinguish between scientific issues and policy issues that are informed by science, but are not themselves scientific issues. *See* Report at 15. However, the Report fails to identify the policy choices made by FDA that were misguided and contributed to the breakdown of the premarket review of e-cigarettes. An obvious example is the decision in 2017 to suspend the premarket review process as applied to e-cigarettes for years into the future, as discussed *infra.*

[4] A more detailed discussion of these factors is included in the Myers letter, at 3-5.

[5] The Report advocates development of a Strategic Plan for tobacco regulation to move FDA "from a reactive mode to a proactive mode," citing the 2017 "comprehensive regulatory plan," as an example. Report, at 13-14. However, the Report ignores the fact that the 2017 plan featured the suspension of premarket review for e-cigarettes, which was found by a federal court to be both illegal and a key factor contributing substantially to the youth e-cigarette epidemic. *See Am. Acad. of Pediatrics 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). This experience teaches that any Strategic Plan must be consistent with the TCA, constitute sound policy, and be flexible enough to adapt to changing circumstances.

(5) an apparent policy decision by FDA to take no enforcement action against products with pending PMTAs, regardless of their risk to young people; and

(6) the industry's marketing of products with nicotine not derived from tobacco (synthetic nicotine) in a concerted effort to evade FDA regulation under the Family Smoking Prevention and Tobacco Control Act (TCA), forcing Congressional action to close this loophole, and FDA's failure to enforce premarket review as to synthetic nicotine products in accord with Congressional action.

Unfortunately, the Report does not recognize the significance of these factors and instead attributes the problem of unreviewed PMTAs largely to the litigation brought by public health groups, finding that "a litigation deadline for application submission compromised CTP's ability to set its own review pace and the Center was unable to issue PMTA regulations describing the requirements for submissions in advance of the deadline for application submission." Report at 19. The Report's analysis fails to recognize that the statutory requirement of premarket review is not dependent on the prior issuance of "regulations describing the requirements for submissions." Thus, a federal court vacated as illegal the 2017 FDA Guidance which purported to suspend premarket review for an indefinite period.[6] The court found that the Guidance was "a decision to hold in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers that the agency itself acknowledges are alarming, for five or more years . . . all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law."[7] In the ruling setting a new application deadline, the court found that "the industry contends disingenuously that it cannot complete its applications without further formal guidance," finding "a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so," producing "a shockingly low rate of filings."[8] The fact is that companies had ample information about the kinds of evidence that would satisfy the public health standard from various FDA Guidances (including a Draft Guidance issued with the final deeming rule in 2016),[9] workshops discussing technical issues, proposed regulations, and the provisions of the TCA itself. The Report ignores the findings of the federal court, as well as the reality that, if the court had not set new deadlines to govern the premarket review process, the result would be far more e-cigarette products on the market for a longer time period without the marketing orders required by the TCA.

Greater Transparency in the Premarket Review Process

The Report recommends greater transparency in FDA tobacco decision-making generally, including "[p]roviding more details in public summaries of Marketing Granted Orders, and providing summaries at regular intervals of deidentified reasons why Marketing Denial Orders were issued to provide applicants more insight into CTP's regulatory decision-making process." Report at 19. We agree with the objective of greater transparency concerning FDA's decisions, both to grant marketing orders and to deny them. It should be recognized that FDA's failure to provide the public more information about its decisions on PMTAs is at the behest of

[6] *Am. Acad. of Pediatrics*, 379 F.Supp.3d at 498.

[7] *Id.* at 493.

[8] *Am. Acad. of Pediatrics, et al. v. FDA*, 399 F.Supp.3d 479, 485 (D. Md. 2019), *appeal dismissed sub nom., In re Cigar Ass'n of Am.*, 812 F.App'x 128 (4th Cir. 2020).

[9] https://www.federalregister.gov/documents/2016/05/10/2016-10687/premarket-tobacco-product-applications-for-electronic-nicotine-delivery-systems-draft-guidance-for.

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.[10] The premarket review process should not be conducted in secret; nor should the judicial process.

Risks of "Streamlining" Premarket Review

The Report proposes that CTP "consider whether certain products would benefit from the creation of new pathways, established based on current scientifically-supportable standards, to illuminate a route forward for discrete categories of products, and seek statutory change if current authorities are not sufficient to support more streamlined reviews." Report at 20. With new e-cigarette products, and modifications of products, appearing all the time, FDA must be cautious about "streamlining" the review process. The Report analogizes to the process whereby the FDA's Center for Devices and Radiologic Health "can assess the safety and efficacy of novel medical devices and at the same time classify them according to the appropriate risk, resulting in a less-burdensome equivalence approach . . . ." *Id.*

However, for the reasons stated in the Myers letter (at 1-2) submitted to the Reagan-Udall Panel, the regulation of tobacco products is fundamentally different than the regulation of drugs, food and medical devices. For example, the purpose of premarket review under the TCA is to prevent the introduction into commerce of new tobacco products that are more hazardous, addictive and appealing than their predecessors, not to provide streamlined pathways to market for products (like drugs, food and medical devices) that may offer substantial public health benefits. Thus, any analogy to products like medical devices has limited utility for tobacco products.

In addition, there are serious issues concerning FDA's legal authority to make any substantial alterations or simplifications of the premarket review process that may affect the marketing order 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.[11]

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[10] 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. 22, 2022) (*Logic*). 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 (3d Cir. Jan. 27, 2023), Doc. No. 60.

[11] *See* Comments of American Academy of Pediatrics, 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. (Dec. 10, 2021), https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2021_12_10_IQOS-3-MRTPA-Comments.pdf.

Second, we see no reason for FDA to seek new legislative authority to "streamline" the PMTA process to provide easier pathways to market for tobacco products. 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.

The Appropriate Role of TPSAC

The Report recommends that CTP "increase its use of the Tobacco Products Scientific Advisory Committee (TPSAC) to obtain expert input on scientific issues and policy development, including regulations, guidance, and data needs for effective product regulation." Report at 14. We generally support an expanded role for TPSAC in FDA tobacco regulation. Although the Report recognizes TPSAC's statutorily mandated role in the evaluation of modified risk applications, it does not address FDA's marginalization of TPSAC in performing that role. In that regard, we refer you to the letter of six public health groups, including Tobacco-Free Kids, from October 19, 2020, which documents the increasingly insignificant role of TPSAC, even in performing its statutorily mandated role in the agency review of modified risk applications.[12]

The Report also specifically suggests that CTP use TPSAC for "input" on "major PMTA decisions." Report at 16. Although we believe this suggestion has merit as to tobacco products not yet on the market, it also creates a risk of causing additional delay as to the review of products already on the market which, as explained above, are in violation of the TCA and may be causing public health harm right now. Because FDA's highest priority as to new product review should be completing that review as quickly as possible, consistent with the statutory standard, we urge caution in using TPSAC as part of the product review of products already on the market.

Summary

We believe the Reagan-Udall Foundation Report is a valuable contribution to the public discourse on FDA and its performance as a regulator of tobacco products. Although we have misgivings about some aspects of the Report, we believe the following recommendations and suggestions should be implemented by FDA:

- As part of a prioritization of enforcement against new tobacco products on the market, or entering the market, without FDA authorization, a list of authorized products should be posted, with a message making it clear to the industry that no other products may be legally sold.

- High-profile legal actions should be brought against wholesalers and distributors handling illegally marketed products.

- The process leading to enforcement actions against unauthorized products should be streamlined within FDA and within DOJ.

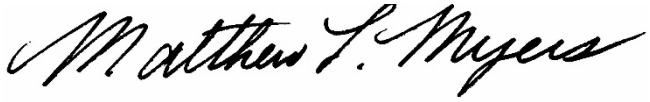
[12] https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2020_10_10_Letter-to-FDA-on-TPSAC-role-MRTP-proceedings.pdf.

- FDA should ensure greater transparency in the premarket review process, such that the public can understand the bases for marketing granted orders and marketing denial orders. That transparency should be extended to the judicial process, as appeals are pursued contesting FDA premarket review decision-making.

- The role of TPSAC should be expanded on scientific issues relevant to FDA regulatory decision-making, particularly in assuring fulfillment of its required statutory role in modified risk proceedings.

Thank you for your consideration of our views.

Sincerely,



Matthew L. Myers
President

CC: Dr. Brian King (by e-mail)