

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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March 28, 2023

The Honorable Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

The Committee on Oversight and Accountability is conducting oversight of the Food and Drug Administration's (FDA) regulation of tobacco and nicotine products through its Center for Tobacco Products (CTP). A recent evaluation of CTP by the Reagan-Udall Foundation (RUF) found that CTP has not clearly set out the most basic elements of its tobacco and nicotine regulatory programs.¹ This has resulted in confusion, inefficiency, litigation, and suspicions of political interference. CTP has fostered uncertainty in the marketplace and has allowed unsafe and unregulated products to proliferate. Therefore, we seek documents and information regarding CTP's activities to enable transparency and to ensure the CTP is performing required functions.

The 2009 enactment of the Family Smoking Prevention and Tobacco Control Act (TCA) coincided with the emergence of electronic nicotine delivery system (ENDS) products.² When FDA exerted jurisdiction over these products in its 2016 "deeming" rule, it sought time to develop the necessary criteria to regulate them by delaying the application timeline.³ However, a 2019 court order negated this plan and required FDA to rule by September 9, 2021, on Premarket Tobacco Product Applications (PMTAs) submitted by September 9, 2020.⁴ The result was over eight million PMTAs being filed.⁵ The FDA failed to meet the court-mandated timeline and is still completing the process of reviewing PMTAs.⁶ This overwhelming number of applications has only exacerbated the existing lack of clearly defined decision-making criteria. As a result,

¹ Reagan-Udall Foundation, *Report: Operational Evaluation of Certain Components of FDA's Tobacco Program* (Dec. 2022).

² *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. 28973 (May 10, 2016) (codified at 21 C.F.R. pt. 1100, 1140, 1143).

³ See FDA Notice, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability*, 82 Fed. Reg. 37459; Gray Robinson, Anna W. Wiand, *FDA's Deeming Rule Extends the Agency's Authority over Tobacco Products* (May 16, 2016).

⁴ *American Academy of Pediatrics, et al., v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019) (Dkt. No. 127 at 12, Dkt. No. 182 at 1).

⁵ Thomas A. Briant, *Where the FDA Is at With PMTAs*, CSP DAILY NEWS (Sep. 16, 2022).

⁶ Hannah Hammond, *FDA Pushes Back Deadline to Review PMTAs*, CSP DAILY NEWS (Feb. 7, 2023).

more than 30 companies filed legal actions over FDA denials.⁷ Some applicants contend FDA's decisions were arbitrary and capricious because of the FDA's "failure to promulgate rules governing the [PMTA] process, or otherwise to announce ascertainable standards."⁸

The December 2022 RUF evaluation describes CTP, charged with regulating the manufacture, distribution, and marketing of tobacco products,⁹ as "reactive and overwhelmed."¹⁰ CTP offers PMTAs as a pathway for manufacturers of tobacco products to provide American consumers access to products "appropriate for the protection of public health."¹¹ Yet CTP appears to be unable to perform its basic functions and ensure that Americans have access to products that have the potential to lower the rate of smoking-related disease and death.¹² As the RUF evaluation lays out, despite issuing 16 proposed rules, 16 final rules, 35 draft guidances, and 50 final Level 1 guidances since the enactment of the TCA in 2009, "fundamental policy and scientific issues remain unanswered."¹³ In addition, a lack of clarity and transparency pervades almost every aspect of CTP's operations. The scientific data required to support approving either PMTAs or modified risk tobacco product applications (MRTPs), the rationale behind application denials, and policy goals and objectives is opaque and unclear. Indeed, stakeholders described having to guess what CTP's policies might be since they were not clearly expressed through regulation or guidance.¹⁴ This lack of transparency by CTP results in substantial market uncertainty, proliferation of unregulated products, and enforcement failures.

We have deep concerns that CTP's decisions have been influenced by political concerns rather than scientific evidence. Comments from FDA staff to RUF, which are no longer available on its website, reflect such concerns. For example, one commenter said, "[i]n cases where reviews are finished and scientific decisions are made, they are also overruled by political agendas and pushed to change decisions."¹⁵ Another stated, "scientific disagreement is frowned upon, if not entirely suppressed,"¹⁶ while a third said leadership was "...unsupportive of a reviewer's fundamental duty to provide an unbiased review using the best available science."¹⁷ FDA must clearly identify and publicize what scientific criteria are necessary for a product, to include ENDS and smokeless products, to be authorized through the PMTA pathway and—where appropriate—the subsequent MRTP pathway.

In conjunction, FDA must also clearly and accurately communicate information regarding the relative risk that products, to include ENDS and smokeless products, pose—and do not pose—to the adult nicotine product user population. Since 2005, the percentage of adult

⁷ Jim McDonald, *Vape Companies vs. FDA: Appeals and Legal Actions*, VAPING360 (Sept. 20, 2022).

⁸ *Gripum, LLC v. FDA*, No. 21-2840 (7th Cir. 2022).

⁹ Food and Drug Admin., *Section 106(a) Report to Congress: Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act* (July 6, 2022).

¹⁰ *Supra* n. 1, at 15.

¹¹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 910(c)(2), 910(c)(4).

¹² *Supra* n. 1, at 13.

¹³ *Id.*

¹⁴ *Id.* at 15.

¹⁵ *Comments in FDA Assessment Suggest Agency in Disarray*, TOBACCO REPORTER, (Oct. 31, 2022).

¹⁶ *Id.*

¹⁷ *Id.*

smokers in the United States has fallen from 20.9 percent to 12.5 percent.¹⁸ Nevertheless, there are still 30 million adult smokers in the United States, and nearly half a million Americans die from smoking related disease every year.¹⁹ This is a population that could benefit from accurate information and access to potentially safer FDA authorized products.

Finally, both the RUF evaluation and a recent HHS OIG report highlight severe deficiencies in FDA's enforcement capabilities.²⁰ If products are allowed to go to market or stay on the market without authorized applications, then the entire regulatory effort would appear to be pointless. The RUF evaluation reported FDA has not even provided a well-publicized list of authorized products for retailers to reference.²¹ Publishing a list of authorized and—if reflective of FDA enforcement discretion decisions—products with pending PMTAs, is an obvious step FDA can and should take immediately. We also urge FDA to devote the necessary resources to take those products most attractive to underage users off the market as quickly as possible.

To assist in the Committee's investigation into the FDA's regulation of tobacco and nicotine products through the CTP, please provide the following documents and communications as soon as possible but no later than, April 11, 2023:

1. All FDA staff comments submitted to the Reagan-Udall Foundation in conjunction with the Operational Evaluation of Certain Components of FDA's Tobacco Program;
2. All communications between the White House, Department of Health and Human Services, and FDA, to include any office within the CTP, regarding tobacco or nicotine related policy decisions and evaluation of any application approval or denial decisions;
3. All documents and communications between FDA and the Centers for Disease Control and Prevention regarding CTP policies, application decisions, educational campaigns, or communications;
4. All documents and communications between FDA and public health advocacy groups regarding CTP policies, application decisions, educational campaigns, or communications;
5. All documents that describe the specific analytic process FDA uses to apply the "appropriate for the protection of public health" standard; and
6. All documents and communications related to FDA's enforcement efforts to remove illegally marketed tobacco or nicotine products from retail locations.

¹⁸ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Monica E. Cornelius, et al., *Tobacco Product Use Among Adults — United States, 2020* (March 18, 2022).

¹⁹ Centers for Disease Control and Prevention, Smoking & Tobacco Use, *Tobacco-Related Mortality* (last visited Mar. 7, 2022).

²⁰ *Supra* n.1; U.S. Dep't of Health and Human Services, Office of Inspector General, *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement* (Dec. 2022) (OEI-01-20-00241).

²¹ *Supra* n. 1, at 25.

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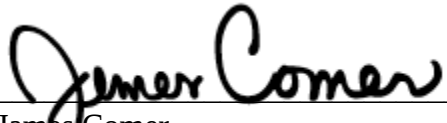
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Additionally, please make arrangements to schedule a briefing with Committee staff on this matter as soon as possible, but no later than April 4, 2023.

To schedule the briefing, arrange for the delivery of responsive documents or ask any related follow-up questions, please contact Committee on Oversight and Accountability Majority Staff at (202) 225-5074. Attached are instructions for producing the documents and information to the Committee.

The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. Thank you for your cooperation with this inquiry.

Sincerely,

A handwritten signature in black ink that reads "James Comer". The signature is written in a cursive style with a large, looping "J" and "C".

James Comer

Chairman

Committee on Oversight and Accountability

cc: The Honorable Jamie Raskin, Ranking Member
Committee on Oversight and Accountability