

OPERATIONAL EVALUATION OF CERTAIN COMPONENTS OF FDA'S TOBACCO PROGRAM

December 2022



December 19, 2022

Dear Commissioner Califf,

The Center for Tobacco Products (CTP), the youngest of the Food and Drug Administration's Centers, is confronting enormous challenges from rapidly changing product development, high workload, evolving science, and litigation risk; it is at a pivotal place in its evolution. We proudly submit recommendations to strengthen the regulatory processes and operations of FDA's tobacco program to better position it to face the future.

Our evaluation and resulting recommendations focused on four program areas: regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. We did not address specific tobacco policy issues, which fall outside the scope of this review.

The recommendations contained in this report are the result of intensive effort to obtain input from governmental and non-governmental stakeholders, and we appreciate the honest and candid input we received. Our goal was to offer practical and constructive advice based on our own experience in regulatory strategy and process management, while recognizing the challenges and opportunities inherent in public health regulation.

The dedication and energy so many have already put into building the Agency's tobacco program well-positioned CTP to consider and implement our suggestions to improve the program's effectiveness. We share a deep belief in the ability of FDA to fulfill its regulatory responsibilities and protect the public from tobacco-related disease and death.

We appreciate the support of the Reagan-Udall Foundation's Board leadership, staff, and writers. We hope you find these recommendations useful as the Agency's tobacco program grows into the future.

Sincerely,

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Executive Summary

In little more than a decade, FDA has developed a regulatory structure for implementing the Tobacco Control Act to promote public health by reducing the harms associated with tobacco use. FDA created a new Center (the Center for Tobacco Products, CTP) now staffed by more than 1,100 hard-working civil servants dedicated to and focused on positively impacting public health.¹ CTP's efforts have had a measurable impact on advancing the Agency's mission to reduce death and disease from tobacco, as demonstrated by quantifiable achievements. This report evaluates the implementation of this program, taking measure of the successes as well as the shortcomings of these efforts and makes recommendations on how FDA can continue to meet its ambitious objective of reducing tobacco-related disease and death.

Applying new regulations to a large, existing industry is difficult, and CTP's task has been made even more difficult because of the sheer volume of product applications, changes in Agency leadership, and near constant litigation it has encountered. At the same time, CTP has also struggled to function as a regulator in part due to some of its own policy choices. For example, the breadth and timelines in the deeming regulation and the scope of the product review regulations have been difficult for both stakeholders and CTP to apply in practice.

Stakeholders observed a lack of consistent implementation of what they understood to be CTP's policies, particularly with respect to harm reduction from tobacco use. From the stakeholders' perspective, policy shifts with broad impact on the industry occurred without notice. The Center has faced significant challenges in clearing its policies through the career and political infrastructure. It took years to establish requirements and standards governing application reviews, frustrating industry and creating problems for the Center itself when it received deficient applications. Issues in application reviews resulted in litigation necessitating re-review of some applications. The current environment reflects an unintended shift from what was structured by law as a *pre-market* authorization framework to the reality of a *post-market* regulatory environment, which is much more difficult to deal with given that there are few incentives for industry to come into compliance and many incentives for industry to delay the process.

The work of standing up the tobacco program has come with a measurable cost to the Center. Having navigated an unprecedented number of application reviews, current staff are fatigued. Two of the Center's disparate constituents – public health advocates and the regulated industry – are frustrated and regularly turn to litigation to address their concerns with the Center. Defending against lawsuits has siphoned Agency resources from planned activity. The litigation resulted in court-imposed deadlines that upended the Center's plans for managing its workload. CTP's implementation of its program also has been affected by changes in leadership and Administrations. In its first thirteen years, CTP has operated under seven different Commissioners in three different Administrations, and recently welcomed its third Center Director.

The Agency has sought outside expertise in the form of this review to provide advice on how the Center can improve its operations and position itself for greater success in the future. In the 60 days allotted,

¹ FDA's recent regulatory actions on tobacco products. U.S. Food and Drug Administration. <https://content.govdelivery.com/accounts/USFDA/bulletins/32cefb5#:~:text=CTP%20is%20comprised%20of%20a,to%20tirelessly%20achieve%20this%20mission.> Accessed December 16, 2022.

the Independent Expert Panel (Panel) has conducted a high-level review of CTP's operations, analyzing input from Agency staff, stakeholders and the public, and providing observations and recommendations.

The review and recommendations are meant to assist the Agency in making changes to better carry out its regulatory responsibilities; to strengthen its relationships with stakeholders; and to fulfill the Center's vision "to make tobacco-related disease and death part of America's past, not America's future, and, by doing so, ensure a healthier life for every family."² The Panel has identified fundamental issues that the Center needs to address and has offered cross-cutting as well as program-specific recommendations to help CTP operate more effectively. The key points from the report can be summarized as follows:

- The Panel observes that CTP has been forced to operate primarily in a reactive mode, moving from one challenge to the next, mainly provoked by the outside forces discussed above. The Center should transition to becoming a more proactive and strategic program. With more substantial engagement with stakeholders and the public, CTP should take the time now to think strategically about where it is today and where it needs to go in the next several years.
- Although CTP has a critical mission to protect the public health from tobacco-related disease and death and is regulating products that have no inherent benefit and huge societal costs, it is a government regulatory program with a duty to run efficiently, fairly, and transparently. This responsibility to function as an effective product regulator should be captured in the Center's mission, vision, and goals and carried out to the best of the Center's ability.
- The Panel recognizes that to improve the effectiveness of its application review, the Center should make process improvements and identify and address the policy and scientific questions that underpin its regulatory framework.
- CTP needs to work with other entities on strategies to clear the market of illegal tobacco products more rapidly and provide more transparency to the public on its efforts to do so. This work is challenging but essential as CTP adopts a more strategic approach. While there is much the Center can do on its own, the Panel notes that enforcement of the premarket requirements in the tobacco laws, particularly to help prevent youth use of tobacco products, requires the involvement and support of agencies other than FDA. We encourage the Agency to elevate this issue and pursue a more comprehensive approach that leverages the resources of other agencies with a declared role in tobacco control.

Overall, the Panel is confident that many of the concerns raised in this report can be addressed by CTP's talented and dedicated staff, with the support of FDA leadership.

² Center for Tobacco Products. About the Center for Tobacco Products (CTP). U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp>. Accessed December 16, 2022.

I. Introduction

On July 19, 2022, the U.S. Food and Drug Administration Commissioner Robert Califf requested that the Reagan-Udall Foundation³ convene an Independent Expert Panel (Panel) to conduct an evaluation of the FDA Center for Tobacco Products (CTP) with the aim of addressing immediate issues and providing recommendations to position the Center for greater success in the future. This report focuses on operational issues; it does not address tobacco policy. While requested at the same time as the human foods program evaluation, this tobacco evaluation differs from the foods program evaluation in scope (the tobacco review focuses primarily on a single Center) and in range of activity (addressing only certain components of CTP's work).⁴

In requesting this review, Dr. Califf acknowledged, "We have made important progress and reached regulatory decisions on a broad array of millions of products. But even greater challenges lie ahead as we determine how the agency will navigate complex policy issues and determine enforcement activities for an increasing number of novel products that could potentially have significant consequences for public health."⁵ The Commissioner requested a complete evaluation within 60 business days.

The Panel (Panel)⁶ convened to evaluate⁷ and provide recommendations to FDA in four primary areas: regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. This report first provides background about the public health impact, history, current structure, and accomplishments of the tobacco program. Next, the report describes what the Panel heard from governmental and non-governmental stakeholders. The report then presents the Panel's own observations and recommendations, with explanatory discussion. The Panel makes both cross-cutting recommendations that apply to the four areas of its review and program-specific observations and recommendations in each. The review and recommendations are meant to help the Agency make changes to better carry out its regulatory responsibilities; to strengthen its relationships with stakeholders; and to fulfill the Center's vision "to make tobacco-related disease and death part of America's past, not America's future, and, by doing so, ensure a healthier life for every family."⁸

³ The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance the mission of the Agency.

⁴ Operational Evaluation of FDA's Human Foods Program. Operational Evaluation of FDA's Human Foods Program.

[https://reaganudall.org/sites/default/files/2022-](https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf)

[12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf](https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf). Published December 6, 2022. Accessed December 16, 2022.

⁵ FDA Conducting Evaluation of Key Agency Activities to Strengthen Operations presented in Appendix A.

⁶ Panel Members presented in Appendix B.

⁷ Evaluation methodology presented in Appendix C.

⁸ Center for Tobacco Products. About the Center for Tobacco Products (CTP). U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp>. Accessed December 16, 2022.

II. Background

Tobacco and Public Health

Tobacco is the leading preventable cause of death in the U.S. with cigarette smoking accounting for more than 480,000 deaths annually, according to the Centers for Disease Control and Prevention (CDC).⁹ Despite efforts to curb tobacco use, the smoking epidemic continues to contribute to “an enormous, avoidable public health catastrophe.”¹⁰

CDC data show that 12.5%¹¹ of adults in the U. S., about 30.8 million people, currently smoke cigarettes and more than 16 million Americans live with a smoking-related disease.¹² Tobacco product use primarily starts and is established during adolescence.¹³ If current rates of use continues, CDC data has shown that 5.6 million of today’s Americans younger than 18 will die early from a smoking-related illness.¹⁴ Each day in the U.S., about 1,600 youth smoke their first cigarette.¹⁵ However, since 2014, e-cigarettes have been the most commonly used tobacco product among youth. CDC reports that in 2022, 2.55 million U.S. middle and high school students reported using e-cigarettes in the past 30 days.¹⁶

Brief History of FDA’s Tobacco Program

(See Figure 1: Timeline of Select Tobacco Regulation Activities)

Tobacco’s public health impact was recognized in the first Surgeon General’s Report on “Smoking and Health” issued in 1964.¹⁷ Early FDA efforts in the 1990s to assert jurisdiction over tobacco products were unsuccessful as a result of litigation, but in 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act, TCA). The TCA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to give FDA authority to regulate the manufacture, distribution, and marketing of tobacco products, and directed the creation of a new Center for Tobacco Products (CTP) reporting to the Commissioner of Food and Drugs¹⁸ to implement the law and for “related matters assigned by the Commissioner.”¹⁹

⁹ Tobacco-related mortality. Centers for Disease Control and Prevention.

https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm#:~:text=Cigarettes%20and%20Death,-. Published April 28, 2020. Accessed December 16, 2022.

¹⁰ Office of the Surgeon General. Health consequences of smoking, surgeon general fact sheet. HHS.gov.

<https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/consequences-smoking-factsheet/index.html>. Published March 12, 2021. Accessed December 16, 2022.

¹¹ Tobacco product use among adults - United States, 2020. Centers for Disease Control and Prevention.

https://www.cdc.gov/mmwr/volumes/71/wr/mm7111a1.htm?s_cid=mm7111a1_w#T1_down. Published March 17, 2022. Accessed December 16, 2022.

¹² Health effects. Centers for Disease Control and Prevention.

https://www.cdc.gov/tobacco/basic_information/health_effects/index.htm#:~:text=Smoking%20leads%20to%20disease%20and,a%20serious%20smoking%20related%20illness. Published April 28, 2020. Accessed December 16, 2022.

¹³ Youth and tobacco use. Centers for Disease Control and Prevention.

https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm#:~:text=In%202022%2C%20about%204%20of,u se%20of%20a%20tobacco%20product.&text=in%202021%2C%20about%2011%20of,ever%20tried%20a%20tobacco%20product. Published November 10, 2022. Accessed December 16, 2022.

¹⁴ Id.

¹⁵ Fast facts and fact sheets. Centers for Disease Control and Prevention.

https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm. Published August 22, 2022. Accessed December 16, 2022.

¹⁶ More than 2.5 million youth reported e-cigarette use in 2022. Centers for Disease Control and

Prevention. <https://www.cdc.gov/media/releases/2022/p1007-e-cigarette-use.html>. Published October 6, 2022. Accessed December 16, 2022.

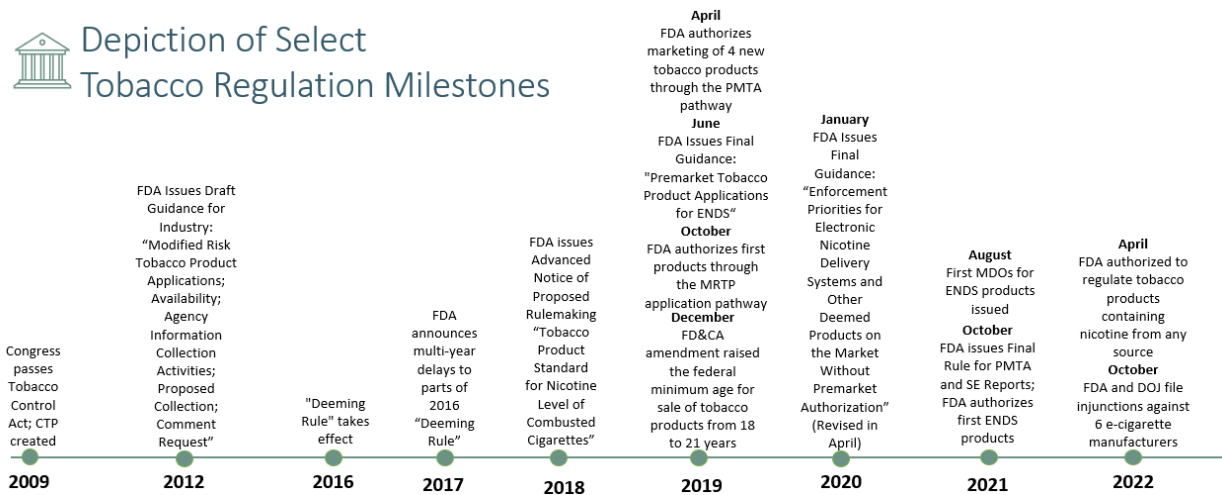
¹⁷ History of the surgeon general’s reports on smoking and health. Centers for Disease Control and Prevention.

<https://www.cdc.gov/tobacco/sgr/history/index.htm>. Published October 19, 2021. Accessed December 16, 2022.

¹⁸ FDCA section 901(e). 21 U.S.C. 387a(e).

¹⁹ Id.

Figure 1: Select Tobacco Regulation Milestones



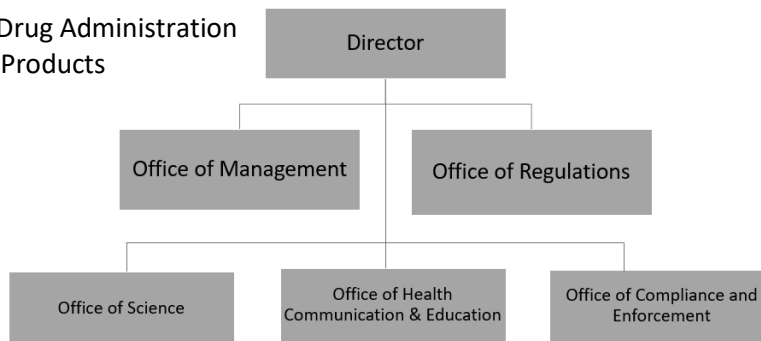
CTP’s stated mission is “to protect Americans from tobacco-related disease and death by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.”²⁰ CTP describes its work as developing policy, issuing regulations, conducting research, educating Americans on tobacco products, and making decisions on whether new tobacco products and products with modified risk claims can be marketed – including the review and evaluation of applications and claims before the new products are allowed on the market.²¹

CTP’s stated goals include:²²

- Preventing people from starting to use tobacco products;
- Encouraging tobacco users to quit; and
- Reducing the harm caused by tobacco use.

Figure 2 shows the structure of CTP.

Figure 2: Food and Drug Administration Center for Tobacco Products



²⁰ Center for Tobacco Products. About the Center for Tobacco Products (CTP). U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp#:~:text=for%20every%20family,-,Our%20Mission,poses%20to%20themselves%20and%20others>. Accessed December 16, 2022.

²¹ Center for Tobacco Products. About the Center for Tobacco Products (CTP). U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp#:~:text=for%20every%20family,-,Our%20Mission,poses%20to%20themselves%20and%20others>. Accessed December 16, 2022.

²² Center for Tobacco Products. About the Center for Tobacco Products (CTP). U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp#our%20mission>. Accessed December 16, 2022.

To legally market a new tobacco product (Figure 3), manufacturers must submit an application to FDA and receive a marketing authorization from the agency.

Figure 3: Tobacco Products Regulated by the FDA^{23,24,25}



2009 TCA regulated products: cigarettes, smokeless tobacco, cigarette tobacco, roll-your-own tobacco (circled)
2016 Additional deemed products: ENDS²⁶, cigars, pipe tobacco, gels, waterpipe tobacco
2022 Products containing nicotine from any source

Figure 4 (below) depicts the types of applications reviewed by CTP and decisions that could result from its reviews. Importantly, section 910 of the Federal Food Drug and Cosmetic Act requires premarket review of new tobacco products, which the Act defines as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. FDA regulations establishing the requirements for PMTAs specify that a PMTA is required for every individual tobacco product, which CTP has interpreted to mean each individual flavor or flavor combination of a product and certain other properties that uniquely identify the products.²⁷ Although the regulations permit manufacturers to bundle or group submissions, the preamble to the regulations says that when FDA receives a premarket submission that covers multiple new tobacco products, it intends to consider the information on each individual product as a separate individual PMTA.²⁸ This helps explain the high number of applications cited throughout this report.

²³ 2023 Budget Justification, note 4, supra.

²⁴ Center for Tobacco Products. FDA's "Deeming" regulation. U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products>. Accessed December 16, 2022.

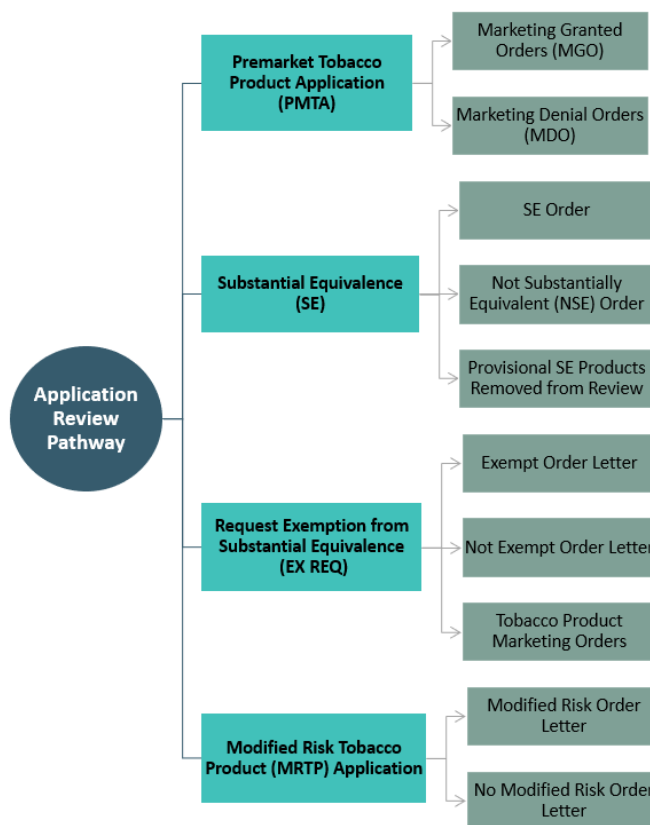
²⁵ The Federal Register. Deeming tobacco products to be subject to the federal food, drug, and cosmetic act, as amended by the family smoking prevention and tobacco control act; restrictions on the sale and distribution of tobacco products and required warning statements for tobacco products. 81 FR 28973 (May 10, 2016). <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>. Accessed December 16, 2022.

²⁶ ENDS products: e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, electronic pipes

²⁷ 21 CFR 1114.7(c)(3).

²⁸ See 21 CFR 1114, 86 FR 55300, 55317 (October 5, 2021).

Figure 4: Application Review Pathways



CTP explains on its website that tobacco is the only consumer product regulated by FDA that causes disease, disability, and death when used as intended.²⁹ CTP notes that Congress created a new regulatory standard in the TCA – one that is geared to reducing the public health threat that tobacco use poses to all Americans, not just individual users. Under the FDCA as amended by the TCA, FDA may authorize the marketing of a tobacco product if it finds that “the marketing of a tobacco product...is appropriate for the protection of public health.”³⁰ FDA’s website states:

Instead of using the usual FDA standard of approving “safe and effective” products, FDA regulates tobacco products based on a public health standard that considers the risks and benefits of the tobacco product on the population as a whole. Our ability to enact science-based regulation has the true potential to reduce the death and disease toll from tobacco products. Our public health regulatory agenda focuses strongly on protecting young people, as well as reducing the dangers of those products, and encouraging current users to quit.³¹

Since its creation in 2009, CTP has accomplished a great deal. Between 2009 and 2022, CTP published 16 proposed rules, 16 final rules, 35 draft guidances, and 50 final Level 1 guidances.³² During this same time

²⁹ Center for Tobacco Products. Implementing the tobacco control act. U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/implementing-tobacco-control-act-through-policy-rulemaking-and-guidance>. Accessed December 16, 2022.

³⁰ Sections 910(c)(2) and (c)(4) of the FDCA.

³¹ Id.

³² Published regulations and Guidances as of 9-1-22. <https://www.fda.gov/media/88873/download>. Accessed December 16, 2022.

frame, the Center acted on 96% of approximately 9.1 million PMTAs, SE, and EX REQ applications³³ and issued over 340 MDOs for more than 1.2 million tobacco products,³⁴ with approximately 329,000 PMTAs still pending.³⁵ From 2009 to 2021, FDA personnel and commissioned inspectors working under contract with FDA in the states, territories, and tribes conducted 1.3 million retail inspections mostly to enforce the requirements against sale of tobacco products to minors. The Agency conducted more than 1,500 inspections of tobacco manufacturers and more than 4,000 vape shop inspections. In the same time period, FDA issued more than 140,000 warning letters, and assessed numerous civil monetary penalties (CMPs). FDA reports collecting more than \$17 million as of result of CMPs issued to tobacco retailers for repeated violations (largely the illegal sale of tobacco products to minors).³⁶ CTP developed and delivered seven educational campaigns that have reached millions of consumers. The Center is staffed by more than 1,100 dedicated career employees who are focused on and committed to protecting public health.³⁷

³³ Center for Tobacco Products. PMTA acceptance phase metrics data as of: September 30, 2022 - fda.gov. Tobacco Product Applications: Metrics & Reporting. <https://www.fda.gov/media/163295/download>. Accessed December 16, 2022.

³⁴ Department of Health and Human Services Fiscal Year 2023 Food and Drug Administration Justification of Estimates for Appropriations Committees (2023 Budget Justification). p. 28. <https://www.fda.gov/media/157192/download>. Accessed December 16, 2022.

³⁵ Center for Tobacco Products. PMTA acceptance phase metrics data as of: September 30, 2022 - fda.gov. Tobacco Product Applications: Metrics & Reporting. <https://www.fda.gov/media/163295/download>. Accessed December 16, 2022.

³⁶ All CMP payments collected are deposited in the U.S. Treasury as miscellaneous receipts, not allocated to CTP or FDA.

³⁷ Id.

III. Stakeholder Input

While acknowledging the extensive work by FDA and CTP, internal and external stakeholders expressed concerns about a lack of clarity, transparency, and communication regarding CTP's priorities and its decision-making processes, particularly regarding important public policy decisions associated with applying the Appropriate for the Protection of the Public Health (APPH) standard in the TCA. These concerns affected all four of the program areas within the scope of the Panel's review (i.e., regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders). Many stakeholders expressed concern about the lack of clear, consistent, and transparent policies. For example, in 2017, the Agency announced its intention to apply a harm reduction strategy designed to move tobacco product consumers down the continuum of risk from using combustible tobacco products to noncombustible products.^{38,39} However, stakeholders observed the Agency's more recent marketing authorization decisions appear to reflect a policy shift—specifically a reluctance to authorize any Electronic Nicotine Delivery Systems (ENDS) other than those that are tobacco-flavored. If such a policy shift occurred, the Agency did not specifically announce it in a regulation or guidance, leaving stakeholders to glean it from documents posted on FDA's website such as a Technical Project Lead (TPL) Review of PMTAs, MDOs posted in abbreviated form, or from heavily redacted documents provided in response to Freedom of Information Act (FOIA) requests.

This lack of clarity, transparency, and communication extends to questions about how the Agency intends to balance individual risk/benefit against population risk/benefit while carrying out its public health mission; how the Agency will weigh concerns about youth uptake of nicotine products against the harm-reduction potential of noncombustible tobacco products, how the Agency views the science that must inform these decisions (e.g., what does the science say about the likelihood that adults who use ENDS are going to completely quit smoking combustible tobacco products and the likelihood that youth who use ENDS will acquire a lifelong addiction to nicotine or go on to use combustible tobacco products), how the Agency views its role with respect to supporting product innovation in the non-combustible space; and how the Agency intends to proceed in the face of incomplete data and uncertainty as the science continues to evolve and new products become available. The American public will benefit from clear communication about the Center's approach to these issues — and the evolution of those approaches.

The Panel also heard from both internal and external stakeholders about the challenges CTP faces in addressing these fundamental policy questions while dealing with a nearly overwhelming workload of applications. Stakeholders expressed concerns about the Center's ability to manage its workload and operate proactively rather than reacting to internal and external deadlines and pressures such as the extensive litigation and court established deadlines that it has experienced. CTP itself identified two significant challenges to its ability to execute its mission: (1) inability to collect user fees from e-cigarette manufacturers; and (2) the application volume after the court-imposed application deadline of September 9, 2020. Specifically, PMTA pathway applications increased from a total of 432 received

³⁸ Office of the Commissioner. FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>. Accessed December 16, 2022.

³⁹ Gottlieb S. Comprehensive approach to nicotine and tobacco. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017>. Accessed December 16, 2022.

through October 31, 2019 to 8,014,608 received in FY20 (October 2019-September 2020).^{40,41} From October 2020 through July 2022, CTP received an additional 1,059,353 PMTAs, including approximately 940,000 non-tobacco nicotine PMTAs.⁴²

Regarding the application process, stakeholders observed that the current application review process is extremely cumbersome and time-consuming, characterizing the submission requirements as vague and frequently changing, which may adversely affect manufacturers' ability to innovate and meet submission deadlines. Stakeholders felt that the Agency's submission requirements favor large, established companies and prevent, or at least dissuade, small, newer companies from pursuing marketing authorization. Some complained about the unpredictability of the reviews, noting inconsistent handling of applications and changes in FDA's position (e.g., MDOs issued and then withdrawn).

Many expressed significant concern and frustration about the lack of action against illegal products that remain on the market after CTP has made an application decision (e.g., issued a refuse to file letter or an MDO), as well as new products that have entered the market without undergoing premarket review (e.g., disposable ENDS, non-tobacco nicotine products). This lack of action, they asserted, undermines the integrity of the application process and causes confusion regarding the actual legal status of certain products.

Some stakeholders said that "The Real Cost" and other CTP-implemented education campaigns show promise in combatting the initiation of youth/young adult smoking, but the educational focus was not without criticism. Some stakeholders question if the messages geared toward preventing youth from beginning to use tobacco products have, in fact, limited the number of adult users of combustible tobacco products who moved to a potentially less-harmful product.

⁴⁰ Office of the Commissioner. 2021 budget summary. U.S. Food and Drug Administration. <https://www.fda.gov/about-fda/budgets/2021-budget-summary>. Accessed December 16, 2022.

⁴¹ Center for Tobacco Products. PMTA acceptance phase metrics data as of September 30, 2022 - fda.gov. Tobacco Product Applications: Metrics & Reporting. <https://www.fda.gov/media/163295/download>. Accessed December 16, 2022.

⁴² Id.

Recommendations

After hearing from stakeholders and synthesizing the information it obtained, the Panel provides the following observations and recommendations.

IV. Cross-Cutting Recommendations

Observations

Although CTP has a vision and mission statement, the Center’s current goals and priorities are unclear in communication and practice. The Panel was unable to identify a current comprehensive plan that clearly articulates CTP’s priorities, direction for the future, and its near-term and longer-term goals and objectives. Fundamental policy and scientific issues remain unanswered that the Center must address.

In 2017 FDA announced a “comprehensive regulatory plan” to shift the trajectory of tobacco-related disease and death by placing nicotine, and the issue of addiction, at the center of the agency’s tobacco regulation efforts.⁴³ CTP then proceeded to issue a series of Advanced Notices of Proposed Rulemaking and Proposed Rules to Implement the Plan, but later stated that the dramatic increase in youth use of e-cigarettes caused the Agency to reevaluate certain parts of the plan.⁴⁴

Today, it is difficult for stakeholders to determine which parts of the plan the Agency is still pursuing and the status of any planned action items, making it challenging to measure the Center’s progress toward achieving its public health goals. As FDA’s plans and approaches to tobacco regulation changed, such changes were not always announced and communicated clearly to external stakeholders or even to staff. The Center faces unique challenges in the extreme external pressure and litigation risk it faces from stakeholders, but it needs to become more proactive if it is to overcome those challenges and move the program forward.

The lack of clarity about CTP’s direction, its priorities, and its near-term and longer-term goals and objectives, hinders CTP’s ability to effectively carry out its mission, establish efficient programs to accomplish its goals and objectives, and set appropriate metrics to assess outcomes. Lack of clarity about staff roles and responsibilities in fulfilling their mission can be detrimental to the quality of CTP work products and staff morale.⁴⁵ The Panel heard an overarching concern about the lack of broad public and stakeholder input into the Center’s regulatory, scientific, and enforcement priorities and policies.

CTP has access to tools that could facilitate their work. For example, the TCA directed FDA to create the Tobacco Products Scientific Advisory Committee (TPSAC or Advisory Committee).⁴⁶ The Committee’s

⁴³ Office of the Commissioner. FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death> . Accessed December 16, 2022.

⁴⁴ Office of the Commissioner. Statement from FDA commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use>. Accessed December 16, 2022.

⁴⁵ Comments came through the online stakeholder portal which was open to gather public input from October 21 to November 7, 2022.

⁴⁶ Office of the Commissioner. Charter of the Tobacco Products Scientific Advisory Committee. U.S. Food and Drug Administration. <https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/charter-tobacco-products-scientific-advisory-committee>. Accessed December 16, 2022.

charter indicates that it will meet approximately four times a year.⁴⁷ However, CTP has not convened the Advisory Committee since 2020, and prior to 2020, it met primarily to discharge its legally mandated role, making recommendations on Modified Risk Tobacco Product (MRTP) applications. As it did in its early years, CTP could use the Advisory Committee more extensively to obtain external expertise and insight, and to increase transparency on regulatory issues and the Center's approach and current thinking.

Recommendations

1. To address today's challenges and position itself for the future, CTP must pivot from a reactive mode to a proactive mode. CTP must invest the time, now, with staff and public input, to create and implement a Strategic Plan that identifies the Center's strategic objectives and plots an operational roadmap of the steps CTP will take over the next five years to achieve those objectives.

The Strategic Plan should:

- a. Make clear that the Center's principal focus is functioning as a product regulator.
 - b. Identify key policy issues that need to be addressed, provide a plan for addressing them, and establish priorities for action.
 - c. Characterize the critical scientific questions that must be answered for effective operation of the tobacco program and define the specific research needed to resolve them, including who is best positioned to conduct the necessary research.
 - d. Acknowledge where gaps in the data exist in making policy judgments (such as the Center's harm reduction posture); explain how the Agency intends to regulate products, including taking enforcement actions, in the short-term and in the long-term as more data emerges.
 - e. Increase review program efficiency, effectiveness, and transparency by establishing critical business processes that are clearly communicated to Agency staff and stakeholders.
 - f. Set key metrics and performance indicators to assess CTP's progress toward meeting the strategic objectives.
 - g. Be made publicly available, in detail, and considered a living document reflecting Agency priorities for tobacco regulation, providing a roadmap that is revised and matures with the program.
2. CTP should 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.

⁴⁷ Office of the Commissioner of the. Charter of the Tobacco Products Scientific Advisory Committee. U.S. Food and Drug Administration. <https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/charter-tobacco-products-scientific-advisory-committee>. Accessed December 16, 2022.

3. FDA should secure the agile hiring authorities and salary flexibility of the 21st Century Cures Act for the tobacco program to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate around tobacco. FDA should also work with the Office of Personnel Management to develop solutions to facilitate hiring professionals that match the program's needs.
4. The Agency should continue to pursue securing user fees from each sector regulated by the Center, including, for example, Electronic Nicotine Delivery Systems.

Discussion

CTP is perceived as being reactive and overwhelmed, versus proactive and strategic. A clear declaration of current strategic objectives and specific priorities can enable the Center to pivot into the effective product regulator role envisioned by the TCA. Developing and implementing a Strategic Plan that incorporates goals and timelines will help the Center manage potential shifts in priorities that occur both within and across Administrations.

The Panel strongly recommends that the Center invest the time – now – in examining the current program and thinking strategically about where it is deficient, where it needs to be in the future, and how best to get to that future. Crafting a Strategic Plan, and including staff and the public in the process, will allow both internal and external stakeholders to see the vision for the Center, provide input into its development, and understand where it fits into the overall regulatory objectives.

The plan must identify the key policy issues that need to be addressed for the effective operation of the Center and to explain how FDA is interpreting the APPH standard. It would be useful to gather, in one place, the key policy issues that the Center perceives have already been resolved and those that are still outstanding, and to document where to find resolutions of the issues. For example, the Strategic Plan should note which existing regulations or guidance documents resolve certain policy issues embodied in the application of the APPH standard and what regulations and guidance documents are under development or planned for the future. The plan should be transparent about CTP's priorities for resolving outstanding policy issues. The goal should be to establish the overriding principles that will be embodied in regulations or guidance that can be applied by CTP staff in product reviews and compliance actions.

The Panel has observed that some issues before CTP are fundamental policy questions that must be informed by science but are not, themselves, scientific issues. Rather, they are policy issues with profound societal impacts. One such question that scientific analysis alone will not resolve is how to weigh the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible tobacco products against the potential public health harms that youth who use ENDS will acquire a lifelong addiction to nicotine or proceed to use combustible tobacco products. At times, a lack of clarity about the distinction between, and the intersection between, policy and science has created controversy within CTP and may lead to a perception that the Center's scientific integrity is being challenged when, in fact, policy decisions that transcended the science are being made.

During the strategic planning process, the distinction between policy and scientific issues should be explored, the decisionmaker with the responsibility for each type of decision should be identified, and staff roles and responsibilities in contributing to issue resolutions should be clarified.

After identifying the scientific issues that underpin the fundamental policy questions, the plan should articulate methods for resolving those issues leveraging available public and private resources. The Plan should acknowledge gaps in available data and areas of uncertainty and describe how the Agency intends to proceed with application reviews and prioritize enforcement actions in the near- and the long- term as more data become available. The Agency should also clarify places where it intends to financially support studies to answer critical scientific questions and where applicants or other organizations will be expected to conduct studies and generate data.

Following the identification, documentation, and prioritization of the policy and scientific issues, CTP should examine its business processes to determine necessary changes to align with the Center's strategic objectives and to modernize to improve efficiency. The improved business processes should be documented and routinely communicated to FDA staff and stakeholders. Key metrics and performance indicators to evaluate CTP's progress towards achieving the strategic objectives should be established, documented, and used for ongoing assessment.

An effort that engages staff at all levels in the process of developing a Strategic Plan is time-consuming but necessary. Developing the plan should result in a more efficient Center and contribute positively to the staff's ability to achieve their goals.

In addition to the Strategic Plan, CTP would benefit from more routine use of the TPSAC and should seek its input into the development of policies, regulations and guidance documents, application reviews, and scientific decisions. This practice would provide useful external insight and transparency for these activities. The Panel suggests that the Center use the Advisory Committee for input, for example, on major PMTA decisions. Use of the TPSAC generates expert feedback on the issues at hand, provides the opportunity to publicly address relevant issues, and gives an additional level of transparency for CTP decision making. Upon expanding the use of the Advisory Committee, CTP should ensure it appoints members with relevant expertise.

Finally, given the Center's deep concerns about resources, it should carefully evaluate how its budget and staffing align with the Strategic Plan. For example, meeting many of the Center's enforcement goals are exasperated by the sheer number of pending applications. The path to resolving many of the Center's current challenges starts with establishing the scientific and policy framework to make clear and timely product decisions that withstand judicial scrutiny. Additional resources should be sought, particularly to provide some parity among the tobacco sectors assessed user fees for the Center's work; in the meantime reprioritization of existing resources will likely be needed. Delivering on the Strategic Plan will require sufficient qualified staff, hiring agility, and the salary flexibility such as that provided to other portions of the Agency under the 21st Century Cures Act.

V. Program-Specific Recommendations

A. Regulations & Guidance

Observations

Since passage of the TCA, CTP has issued numerous advance notices of proposed rulemaking, proposed rules, final rules, and guidance documents. Yet the Panel heard from stakeholders that certain foundational requirements are still lacking. A primary concern was the lack of clarity regarding how the Agency is applying the APPH standard. Stakeholders also highlighted the need for more specific guidance on the factors CTP weighs while evaluating applications.

Additional regulations and guidance are needed to provide direction to industry about FDA's current expectations and future plans. Specifically, stakeholders requested regulations to provide more clarity regarding modified risk tobacco products and, separately, standards for the maximum yields of specific toxicants; regulations regarding testing, reporting and possible disclosure of tobacco product constituents, ingredients, and additives; and regulation of nicotine levels in combustible tobacco products. Stakeholders also emphasized a need for additional guidance on the science needed to support product applications.

The Panel recognizes that developing regulations and product standards is time-consuming and resource-intensive, but the long-term benefits are significant. Legally binding parameters described in regulation establish basic principles that can be used in product application reviews and enforcement actions. This structure generates efficiency, eliminating the need for case-by-case adjudications of some issues. Guidance documents can take less time to develop than regulations and can be used to convey FDA's expectations for matters where a binding regulation may not be needed or where the Agency's thinking is evolving and is not yet ripe for inclusion in a binding regulation. Guidance is more readily changed when the science, or needs of FDA, or the regulated community, change.

The current CTP process for developing and issuing regulations and guidance is insufficiently informed at the outset about the needs of CTP staff and various stakeholders. CTP could strengthen the quality and usefulness of its policy development function by gathering more input from staff and the public at the front end of the process.

Recommendations

5. CTP should evaluate and redesign the current policy development program to create a more effective approach to achieving the regulatory review and enforcement goals that the Center establishes.

The policy development program should:

- a. Collaboratively develop, publish, and maintain a comprehensive policy agenda listing foundational and other regulations and guidances needed to implement the Tobacco Control Act, including timeframes for development.

- b. Create an elevated CTP Office of Policy, incorporating the current Office of Regulations functions, with broader responsibility and authority to provide strategic policy leadership and direction across all Center functions.
- c. Use regulations strategically to prescribe categorical principles and standards to reduce the need for case-by-case determinations in application reviews and compliance and enforcement matters.
- d. Review and expand the use of existing guidance to provide clarity, predictability, and transparency concerning scientific standards for application review, and update the guidance as the science and CTP's application of that science evolves.

Discussion

The Panel heard from numerous stakeholders that additional transparency is needed in the regulations and guidance priorities and development processes. A publicly available policy agenda provides stakeholders with a view of what policies are under development and where the documents are in the development process. When updated regularly, a comprehensive policy agenda would provide helpful visibility into CTP's policy priorities and how it uses policy to implement its Strategic Plan. CTP should provide the opportunity for public input into the development of the agenda in accordance with FDA's Good Guidance Practice (GGP) regulations,⁴⁸ and stakeholders should be encouraged to submit draft guidance to the Agency for consideration.

In developing the policy agenda, CTP should prioritize, based on a strong administrative record, key principles that will guide application review and enforcement determinations, and that could eliminate the need for detailed submissions and reviews, or case-by-case enforcement adjudications. CTP has been the subject of numerous lawsuits over the past ten years which have challenged the Center's policies and adversely affected its ability to plan and prioritize issues and operate proactively. After resolving any resulting litigation, CTP will have a sound foundation for rejecting applications that do not meet the criteria established in the regulations and removing illegally marketed products from the market.

The offices within CTP should each identify top policy needs that could be addressed through regulations and guidance. Currently CTP uses the Office of Regulation to support some of these processes but establishing a cross-center policy-focused office would improve accountability and help — proactively — drive policies.

B. Application Review Process

Observations

The Panel heard from multiple stakeholders that the application review process, in general, requires a new approach. Although some processes are perceived as working well, such as SE pathways, other processes such as PMTAs are generally perceived as ineffective and problematic. Concerns included lack of adequate guidance and transparency regarding CTP expectations, lack of clarity regarding review standards, an unsustainable process of requiring a complete PMTA filing for each product when

⁴⁸ 21 CFR 10.115(f)(3).

thousands of product variations exist, and a more burdensome process for products that stakeholders assert pose less individual risk (e.g., ENDS), than traditional tobacco products. As noted previously, the unpredictability of the review process because of perceived inconsistent handling of applications and MDOs issued and then withdrawn undermines confidence in the process. The Panel did not receive significant feedback concerning the SE or EX REQ pathways.

In 2016, CTP deemed a large number of previously unregulated products to be tobacco products. The “deeming” regulation included compliance dates for certain provisions including staggered timelines for the premarket review requirements.⁴⁹ Although FDA was at first reluctant to prescribe expectations for reviewing those newly regulated products without first gaining experience and building a scientific evidence base, CTP issued guidance documents and was in the process of developing regulations for submission requirements. However, 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. The result has been an inefficient review process where CTP has been largely reactive, responding to a deluge of applications, rather than proactive and directing the content, and flow, of submissions.

Industry stakeholders requested more frequent, more specific, and more interactive communications with FDA prior to and during an application review. This is a typical request from applicants across FDA product categories and requires extensive personnel resources.

Recommendations

6. CTP should develop a more clear and predictable framework for high-quality PMTA and MRTTP application submission and reviews by:
 - a. Prioritizing timely development and completion of policies and scientific standards necessary for high quality submissions.
 - b. Simplifying, standardizing, documenting, and publicly disseminating review procedures.
 - c. Further developing operations management capabilities.
 - d. Clarifying supervisory roles and responsibilities for ensuring review quality and developing a process for the review team to timely identify novel or complex scientific issues that merit senior management attention or consultation with specialized subject matter experts.
 - e. Providing 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.
7. Consider clarifying in formal policy the Center’s plans for triaging its substantive reviews to conserve resources when there are certain critical sections of the application that can be indicative of whether all sections of the application merit review.

⁴⁹ 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 FR 28973 (May 10, 2016). <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>. Accessed December 16, 2022.

Discussion

The Panel recommends that CTP accelerate, intensify, and expand its efforts to establish regulatory policies and scientific standards for application review. While CTP has issued some foundational regulations and guidances, many gaps remain. The comprehensive policy agenda should set forth the roadmap of issues for CTP to clarify, in priority order. CTP must do a better job of explaining how and why it weighs the evidence, explicitly quantifying the trade-offs it is willing to accept, and distinguishing policy judgments from scientific information and determinations.

As in all FDA regulated product categories (e.g., drugs, devices), industry applicants bear the burden of developing an approvable submission. Applicants, however, will struggle to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations. A lack of clarity results in extraneous work on both sides--for applicants and for the Agency. CTP has a responsibility to clearly identify application requirements, if for no other reason than to reduce the burden on the Agency itself and improve efficiency. At this stage of the Center's development, while policies and standards are being clarified, the Panel observes that clarifying regulatory policies and scientific standards would increase review program efficiency and effectiveness more than a higher rate of individual communications with applicants. To the extent that CTP intends to review certain critical sections of an application first, and if deficient, not proceed to other sections, such a policy should be reflected in a public guidance that explains to applicants how CTP will triage its substantive reviews. Such an approach could help CTP review applications more quickly and efficiently.

Applicants would benefit from a greater understanding of CTP's application review decisions. While CTP releases summaries of MGOs, including additional detail about the product attributes or data that supported the decision would be helpful to stakeholders. The Panel recognizes that CTP is limited in what can be disclosed about MDOs and therefore recommends that, although it will take resources, CTP prepare non-product specific summaries of reasons for issuing MDOs, and post them at regular intervals, to increase review program transparency.

Although CTP has issued general standards and expectations for PMTA submissions through regulations and guidance, CTP should consider further clarifying in guidance the specific data expectations for categories of products (e.g., types of cigars, disposable ENDS, non-tobacco flavored ENDS, non-tobacco nicotine-based products). CTP should also 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. For example, FDA's Center for Devices and Radiologic Health (CDRH) has a process by which it 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 (i.e., the 510(k) pathway). Recognizing CTP authorities are different, CTP should consider whether it could adopt a similar process by which a new product, such as tobacco-flavored ENDS, may secure an MGO, and then serve as a model product submission or be used to establish review expectations for similar products, much like the predicate approach that exists for the tobacco product SE pathway. CTP should consider what it can do under existing authorities to streamline the review and submission process for significant numbers of applications in this way, where there is scientific evidence to support such an approach. This may be particularly useful when the risk profile and product attributes of a certain type of product are well-understood, and only limited additional data would be needed for authorization. Subsequent products could then proceed through a less-burdensome submission pathway and CTP could better manage its workload.

As CTP considers process mapping and process improvement for application review, FDA operations experts or external consultants could help CTP leadership identify, vet, and plan to operationalize needed business process improvements. In addition, the Center would benefit from recurring review of these processes. In other FDA Centers, reauthorization of user fee programs (e.g., Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA)) every five years provides a regular opportunity for those Centers to assess and improve their application development and review business processes. Recognizing that tobacco products and authorities are different, CTP should establish its own schedule and practice to prioritize similar periodic assessments to monitor and improve performance.

Further, CTP should continue to grow its operations management capabilities. Such development may include workload-, project-, quality-, and change-management capabilities. These “back-office” functions are important for operational efficiency and effectiveness and CTP staff professional quality of life, burnout avoidance, and talent retention. FDA employees described the past several years of the review program as full of ad hoc troubleshooting, as well as abrupt shifts in direction. Operations management capabilities can help CTP promote stability, order, productivity, and a tone of calm professionalism for CTP’s hard-working and dedicated review staff.

In addition to the application framework, CTP should clarify its internal policies and procedures for supervisors to ensure review quality. For example, CTP should clarify:

- The purpose and scope of secondary and tertiary reviews;
- When (ideally early in the review process) and how the review team should identify novel or complex scientific decisions that merit senior leadership engagement; and
- When (again, early in the review process) and how the review team should identify novel or complex scientific decisions that merit consultation with specialized subject matter experts inside or outside of the Agency.

The Panel suggests CTP conduct a public meeting or other broad stakeholder engagement activity to solicit feedback concerning the PMTA process. Such a meeting will increase transparency, give stakeholders an opportunity to be heard, and provide CTP with some potentially helpful suggestions. Such feedback could help the Center develop its revised application framework, and finalize and implement the framework.

C. Compliance & Enforcement

Observations

The TCA established a regulatory scheme for tobacco products that generally requires pre-market authorization for “new tobacco products.” The TCA defines “a new tobacco product” as any tobacco product that was not commercially marketed in the U.S. as of February 15, 2007, or that was modified and commercially marketed after that date.⁵⁰ Between January 2021 and September 9, 2022, FDA issued nearly 300 warning letters to firms for failure to submit a timely premarket application. Collectively, those firms have more than 17 million e-cigarette products listed with the Agency.⁵¹ FDA recently

⁵⁰ FDCA section 910(a).

⁵¹ FDA News Release, FDA, DOJ Seek Permanent Injunctions Against Six E-cigarette Manufacturers, October 18, 2022, https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers?utm_medium=email&utm_source=govdelivery last accessed December 16, 2022.

initiated its first injunction proceedings to enforce the premarket review requirements for new tobacco products.⁵²

Despite these efforts and the known public health risks associated with these products, in particular, the risks of e-cigarette use by children and teens for a variety of reasons, millions of 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. Most contributing stakeholders, including nonprofit advocacy groups, some industry representatives, and CTP staff, expressed great frustration concerning this situation and urged action to remedy it and re-establish tobacco product regulation as a pre-market program.

The Panel understands there are numerous factors that contribute to the magnitude of this problem. Nonprofit advocacy groups stated that tobacco products are different from medical products that FDA reviews and clears. The groups observed that it is unusual for a medical product company to defy FDA and stay on the market, but such practice is routine in tobacco regulation. While the Agency has on its website a list of products for which MGOs have been issued, numerous stakeholders observed that the list of products that can be *legally* marketed is not widely disseminated. The absence of a clear list limits the proactive measures available to wholesalers, distributors, and retailers who might want to limit their liability for selling illegally marketed products.

In addition, once a product is on the market illegally, a company marketing the product has every incentive to delay FDA action that would stop its sale. FDA has stated that “all new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA’s discretion...”⁵³ The Agency has also announced that it is prioritizing enforcement against ENDS products, for example, that are illegally marketed in the U.S. and not the subject of a pending premarket application.⁵⁴ Because 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 action. Some companies have engaged in other techniques to evade enforcement. The Panel heard that numerous companies have, for example, changed their company name after receiving a warning letter and continue to operate and sell illegal products.

CTP, consistent with the rest of the Agency and most other administrative agencies, cannot independently bring enforcement actions in court. The U.S. Department of Justice (DOJ) is charged with bringing injunction or seizure cases on behalf of FDA. The Panel heard from staff and stakeholders that the current process of bringing enforcement actions is cumbersome, and ultimate decisions on whether to take enforcement action rest with DOJ rather than FDA. FDA and DOJ normally consider injunctions only after a series of inspections identify serious violations of the TCA and after the subject of the inspection has received one or more warning letters seeking voluntary compliance. To file a complaint for injunction in federal court, FDA’s Office of the Chief Counsel must work up the case describing the evidence to support the TCA violations and drafting a complaint and pleadings, and then send the case to DOJ. DOJ must assess the evidence to determine whether it is sufficient to support enforcement action. If it decides to pursue a case, DOJ must obtain internal clearance to send a “sign-or-sue” letter to

⁵² Id.

⁵³ Perspective, note 5(?) supra.

⁵⁴ Id. Department of Health and Human Services - Food and Drug Administration. Department of Health and Human Services Fiscal Year 2023 Food and Drug Administration Justification of Estimates for Appropriations Committees. <https://www.fda.gov/media/157192/download>. Accessed December 16, 2022.

the proposed defendants advising them of the proposed case and offering them an opportunity to sign a proposed Consent Decree. If agreement on a consent decree cannot be reached, the case must be filed and litigated in court, requiring substantial FDA and DOJ resources over many months.

Actions to seize and remove from the market adulterated or misbranded tobacco products also require FDA and DOJ resources and court action, and FDA's tobacco cases must compete for DOJ resources with other issues that require DOJ attention. The Agency has authority to impose civil money penalties for violations of the TCA, but again, the procedures for imposing the penalties are cumbersome, creating a high bar for the Agency in bringing cases, and the penalties prescribed in the Act may be insufficiently low to deter illegal conduct. Furthermore, the Panel observed that the tobacco program faces a high litigation risk for its enforcement actions, and DOJ may be reluctant to bring cases that risk adversely affecting the tobacco program or other FDA programs or authorities if the actions fail the legal challenge.

The Panel also recognizes that bringing case-by-case enforcement actions against thousands of firms illegally marketing millions of products is impractical. But failure to take timely enforcement action jeopardizes public health and undermines FDA's credibility and effectiveness in tobacco product regulation. The Agency has not been transparent regarding the reasons it has failed to clear the market of illegal products, or even whether its policy preference is to do so, contributing to stakeholder frustration and, in some situations, additional litigation.

Finally, it is unclear how the Center's Office of Compliance and Enforcement programs align with what was described as CTP's biggest enforcement concern: illegal products on the market. The Office of Compliance and Enforcement has a range of functions, from addressing advertising and promotion to directing inspections of manufacturers. But it is unclear where within the Center responsibility lies for establishing and implementing overall compliance policy, and how the Office of Compliance priorities flow from larger strategic goals of the Center.

Recommendations

8. FDA should seek higher-level Administration involvement to establish an interagency task force to make enforcement of the tobacco laws a government-wide priority, particularly to address the marketing of illegal products and the risks of youth use.
9. The Agency should consider whether statutory changes to provide streamlined processes for tobacco enforcement, including increased consequences for TCA violations, should be pursued.
10. In addition to pursuing formal enforcement through DOJ, FDA should explore alternative approaches to achieving compliance.
11. CTP should enhance its use of public communications to provide greater transparency about the Agency's approach to compliance and enforcement, including prominently posting and maintaining a list of legally marketed products to facilitate voluntary compliance and discourage the sale of illegal products by manufacturers, distributors, wholesalers, and retailers.
12. The Center should ensure that the workplan and goals for the Office of Compliance reflect any new priorities that the Center adopts as a result of its evaluation of additional enforcement approaches.

Discussion

FDA cannot change the current tobacco enforcement paradigm on its own. If enforcement of tobacco laws is considered a priority for the Agency and the Administration, particularly given the disproportionate public health impact of illegally marketed tobacco products on youth, significant resources must be devoted to establishing enforcement processes that are more effective in clearing the market of illegal products. FDA should ask the Administration to create an inter-agency task force to examine the current tobacco compliance and enforcement program with a goal of streamlining the program to promptly clear the market of illegal products and coordinating future efforts to police the market. The task force could include FDA, HHS, DOJ (including the Bureau of Alcohol, Tobacco, Firearms, and Explosives, the Department of Homeland Security (DHS) (Customs and Border Protection), and the Department of the Treasury (the Alcohol and Tobacco Tax and Trade Bureau). States could also be invited to participate. The task force should consider federal legislative options that would streamline the processes for tobacco enforcement and increase the consequences for violations of the Act, which would have the effect of deterring future misconduct.

In the absence of an Administration-created task force, FDA should reach out to its federal partners, including those mentioned above, to coordinate actions on tobacco enforcement. Together with DOJ and other agencies that can be engaged, FDA can establish a formal set of tobacco-related enforcement goals, priorities, and operating procedures. One obvious component of this that FDA and DOJ may be already implementing is prioritizing certain actions that can be taken as a group, with the intent to send a message encouraging voluntary compliance to those marketing categories of products illegally. For example, FDA's recent warning letters issued to five companies marketing ENDS products packaged to look like toys, food, or cartoon characters that are likely to promote use by youth⁵⁵ are a positive step, but FDA and its federal partners should do more. The Agency should also consider bringing high profile actions against wholesalers and distributors who are handling illegally marketed products; 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.

Recognizing that it will not be possible to immediately clear the market of illegal products, CTP should be explicit about its adoption of and basis for a risk-based enforcement strategy. The strategy should explain how it categorizes various types of products on the risk spectrum that are not mentioned in current guidance. For example, FDA's enforcement priorities with regard to non-tobacco nicotine products and disposable ENDS should be communicated. The Panel has observed that States are taking steps to address the health risks from tobacco products. To the extent that FDA's policy and enforcement priorities overlap with those of a state, it may be possible to partner with that state to conserve resources and more efficiently achieve mutual goals.

In addition to improving the process for formal enforcement action, FDA should explore alternative approaches to achieving compliance that do not require formal enforcement action through DOJ. CTP also should look at other innovative strategies that it could use to encourage compliance and simplify enforcement actions. The Center should consider whether it could promulgate targeted regulations that identify the technical safety or scientific standards that marketed products would need to meet and clearly outline the elements of a violation. Such regulations could streamline enforcement action against those that do not comply.

⁵⁵ Office of the Commissioner. FDA warns firms for selling illegal e-cigarettes that look like toys, food, and cartoon characters. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-warns-firms-selling-illegal-e-cigarettes-look-toys-food-and-cartoon-characters>. Accessed December 16, 2022.

As noted previously, reviewing currently pending applications and issuing MGOs and MDOs is the first step in clarifying which products are legally marketed and which are not -- paving the way for enforcement action to remove illegal products from the market. While the Panel recommends that these reviews continue – and, be accelerated, if possible, - that effort should not prevent FDA and other federal partners from pursuing other compliance and enforcement strategies in the meantime.

The Panel strongly recommends that CTP use public communications to provide greater transparency about the Agency’s approach to compliance and enforcement, including prominently posting and disseminating a list of legally marketed products to facilitate voluntary compliance and discourage the sale of illegal products by manufacturers, distributors, wholesalers, and retailers. CTP should more clearly articulate that products that received MGOs can be legally marketed if the products are otherwise in compliance with the TCA, while products that have received MDOs cannot be legally marketed. Although CTP has lists on the website of MGOs and MDOs, it does not clearly convey what those lists mean with regard to the lawful marketing of the products. Recipients of those orders know what the actions mean, but it may not be obvious to wholesalers, distributors, or retailers that products that are either the subject of an MDO or products that lack an MGO are not legally marketed. In a separate place on its website, CTP states, “New tobacco products on the market without the required premarket authorization are marketed unlawfully and subject to enforcement action at FDA’s discretion”⁵⁶ but FDA’s failure to remove products from the market that lack the required authorization can be misinterpreted as authorizing lawful marketing.

CTP needs to articulate its position regarding whether products lacking the required marketing authorization should be removed from the market regardless of whether the Agency has taken action to remove them. CTP could describe its policy of seeking voluntary compliance by issuing a warning letter before initiating enforcement action, and explain that notwithstanding any FDA action or inaction, the products that lack a marketing authorization are not legally marketed and should not be sold.

Further, this message should be communicated more broadly than just on FDA’s website, and it should be repeated at regular intervals. A clear, public-facing message about legal and illegal products should be provided to all retailers, wholesalers, and distributors, as well as other federal, state, and local authorities. The message could also be incorporated into the Center’s overall messaging campaigns, including its regular news updates and on social media.

CTP’s Office of Compliance and Enforcement should be a full partner in the effort to reassess the compliance and enforcement program, and as part of that re-assessment, should review the work plan and goals for the Office to ensure those goals align with the latest compliance and enforcement strategies. The Office of Compliance and Enforcement should have increased input into the Center’s overall policy process to help establish policies that will make it easier to take enforcement actions.

⁵⁶ Center for Tobacco Products. Market and distribute a tobacco product. U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product>. Accessed December 16, 2022.

D. Communication with the Public and Other Stakeholders

Observations

Communication concerns permeate all program areas addressed by the evaluation. This section addresses communication as an independent function of the Center, including both the public health messaging and the use of communications tools to help the Center achieve its policy goals.

The mission of CTP is not only to protect Americans by regulating the manufacturing, distribution, and marketing of tobacco products but also by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.⁵⁷ The Center has a public education website containing three sections: Health Effects of Tobacco Use, Public Health Education Campaigns, and Youth and Tobacco.⁵⁸ CTP has set a priority to protect Americans from tobacco-related disease and death, and to provide information about tobacco products and the dangers they pose to the public. The Center has also indicated that educating people, especially young people, about the risks of using tobacco products, is a critical part of FDA's public health mission. These educational priorities include informing the public about CTP's regulatory actions, youth education about the risks of using e-cigarettes, and ongoing updates to its "The Real Cost" cigarette campaign.

Many stakeholders stated that additional truthful and accurate information to help adult consumers make informed decisions about the role of nicotine and the risks of combustible and smoke-free products is needed. In particular, some stakeholders were interested in CTP clarifying the role of vaping, beyond warning against youth use, and communicating more clearly about harm reduction and the relative risk of tobacco products.

Although this report addresses public communication in other sections the Panel observed that CTP could use its communications function more strategically to achieve its overall public health goals. For example, stakeholders were confused about CTP's policies and goals as they relate to tobacco harm reduction, pointing primarily to statements made at conferences rather than formal communication from the Agency. Stakeholders were also critical of CTP's lack of clear communication about its plans to address products marketed without the required PMTA. Finally, CTP could improve communication around the state of the science that informs its regulatory processes and decisions.

Recommendations

13. CTP should obtain public input during the development of the Strategic Plan and communicate with stakeholders and the public about the Center's strategic objectives as well as key messages, and metrics for measuring plan effectiveness.
14. The Center should solicit broad public input as it continues to develop its tobacco public education campaigns, which are critical to the public health mission.

⁵⁷ Center for Tobacco Products. Public Health Education. U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/public-health-education>. Accessed December 16, 2022.

⁵⁸ Center for Tobacco Products. Public Health Education. U.S. Food and Drug Administration. <https://www.fda.gov/tobacco-products/public-health-education>. Accessed December 16, 2022.

15. CTP should improve the overall transparency of the tobacco program, particularly with respect to the regulatory process and its scientific underpinnings.

Discussion

Views on CTP's public education campaigns varied by stakeholder perspective. CTP should adopt a process that allows stakeholders to provide input into the development and goals of these campaigns so that stakeholders will at least feel that their voices have been heard. The Center should also consider how to address the calls for communication about the relative risk of tobacco products. If CTP declines to include these messages in its campaign, it should explain the rationale for its decision. The Center should also consider ways to educate the public about how it designs and develops its campaigns and how education campaign effectiveness is assessed.

Beyond education, the Panel heard that, broadly, stakeholders sought more timely and clear information about Center processes, the state of the science, and regulatory decision-making. CTP should enhance its use of tools, like white papers, listening sessions, targeted workshops, and regular webinars to better communicate with the public and stakeholders about its priorities, decision-making, and policy and scientific views.

VI. Conclusion

The Independent Expert Panel is honored to have been selected for this important task and has worked diligently to review FDA's Tobacco Program with a focus on regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. CTP clearly benefits from a talented and hard-working staff that have dealt with numerous challenges. The Center plays an important role in preserving and protecting the health of U.S. citizens, and the Panel's goal is to provide recommendations that can help strengthen the Center's programs. We recognize that reexamining and making changes to the program while the program continues to operate will not be easy, but we believe that taking the time to do so now will have long-term benefits, enhancing the efficiency and effectiveness of the tobacco program and contributing to improved morale. We hope that in addition to pursuing increased transparency and enhancing its application review and enforcement operations, the Center will be able to secure additional resources, to carry out its mission more effectively.

APPENDIX A

FDA STATEMENT

FDA Conducting Evaluation of Key Agency Activities to Strengthen Operations

For Immediate Release:

July 19, 2022

Statement From:

Robert M. Califf, M.D., MACC
Commissioner of Food and Drugs - Food and Drug Administration

In February 2022, I rejoined the U.S. Food and Drug Administration as Commissioner of Food and Drugs, having served in the role five years earlier. Since my return, the agency has taken many significant actions that benefit the public health. Yet at the same time, the agency has confronted a series of challenges that have tested our regulatory frameworks and stressed the agency's operations, prompting me to take a closer look at how we do business.

As a result, for two of the agency's key programs, I have commissioned external agency experts to conduct a comprehensive evaluation for:

The agency's Human Foods Program, including the Office of Food Response and Policy (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), as well as relevant parts of the Office of Regulatory Affairs (ORA)

While America's food supply is safe, and our Foods program experts have significantly contributed to the availability of more nutritious food options for consumers, the program has been stressed by the increasing diversity and complexity of the nation's food systems and supply chain. Fundamental questions about the structure, function, funding, and leadership need to be addressed. The agency's inspectional activities related to the program also need to be evaluated, particularly in light of stresses related to the COVID-19 pandemic.

The Center for Tobacco Products (CTP)

Just over 13 years ago, Congress tasked the FDA with regulating tobacco products. In the ensuing years, we have made important progress and reached regulatory decisions on a broad array of millions of products. But even greater challenges lie ahead as we determine how the agency will navigate complex policy issues and determine enforcement activities for an increasing number of novel products that could potentially have significant consequences for public health. CTP will continue its important work during the evaluation, including review pending applications and take enforcement actions as needed.

I have discussed this evaluation with the relevant leadership of these Centers and offices, all of whom welcome the opportunity to work towards organizational excellence. Each of these areas

are full of hardworking and talented individuals who have dedicated their careers to working across a variety of scientific, policy, legal and administrative activities. FDA employees deserve the best support possible so they can fulfill their strong commitment to public health – and the American public that we serve.

The Reagan-Udall Foundation, an independent partner organization for the agency, will be working with an external group of experts on the evaluation. The Foundation will report its findings, including an initial assessment of the processes and procedures, resourcing, and organizational structure for the Foods program and CTP, to the agency within 60 business days of initiation. It may take some time to implement any recommended changes, but I am committed to addressing them and communicating them to the public in a timely manner. It is my belief that this effort will continue strengthening the FDA and better position the agency to deal with the many immediate public health issues we are facing, while preparing for the many scientific challenges and fascinating opportunities of the future.

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Inquiries

Media:

[FDA Office of Media Affairs](#)

301-796-4540

Consumer:

888-INFO-FDA

APPENDIX B

Panelist Biographies

Lauren Silvis, JD, (Chair), spent two years as Chief of Staff at FDA following her time as the Deputy Center Director for Policy in FDA's Center for Devices and Radiological Health. Recently, she served as Senior Advisor on COVID-19 Response for the U.S. Department of Health and Human Services.

Jane Axelrad, JD, spent 25 years at FDA as the Associate Director for Policy at FDA's Center for Drug Evaluation and Research. She stood up the Center's Office of Regulatory Policy, providing strategic policy advice to the Center Director and other senior staff. Before retiring from FDA, she was the Agency lead responsible for developing a comprehensive program for the oversight of the evolving drug compounding industry. Today she is Principal at Axelrad Solutions LLC.

Keith Flanagan, JD, stood up two new offices within FDA's Center for Drug Evaluation and Research: the Office of New Drug Policy and the Office of Generic Drug Policy. Previously, as Senior Health Counsel to the U.S. Senate Health, Education, Labor & Pensions (HELP) Committee, he co-authored numerous FDA reform laws. He is the owner of Flanagan Strategies, LLC.

Charlene Frizzera is President and Co-founder of CF Health Advisors following three decades at the Centers for Medicare and Medicaid Services, including roles as the Acting Administrator and Chief Operating Officer. She led the Agency's policy and operational aspects, including budget, information technology and systems, human resources, contracting, administration, and program integrity.

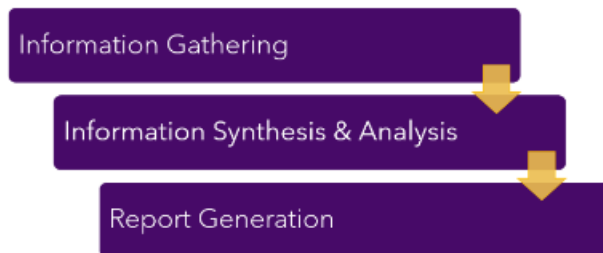
Alberto Gutierrez, PhD, a Partner at NDA Partners, a ProPharma Group Company, spent 25 years at FDA gaining expertise in preclinical and clinical testing, premarket notifications of devices, applications for approval, and post-marketing surveillance and compliance. He retired in 2017 as the Director of In Vitro Diagnostics and Radiological Health in the Center for Devices and Radiological Health.

APPENDIX C

FDA Evaluation Methodology

On July 19, 2022, FDA Commissioner Robert M. Califf charged the FDA Foundation to facilitate, via an Independent Expert Panel (Panel), an operational evaluation of FDA’s tobacco program. A Tobacco Program Panel was established and announced on September 21, 2022, comprised of former FDA leaders and regulatory strategists as well as process improvement specialists. Former FDA Chief of Staff Lauren Silvis, JD, was selected to lead the team of Jane Axelrad, JD, Keith Flanagan, JD, Charlene Frizzera, and Alberto Gutierrez, PhD.

The Panel carried out a three-phase evaluation process focused on regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders, spanning 60-business-days between September 21 and December 19, 2022. The evaluation process consisted of (1) Information Gathering; (2) Information Synthesis; and (3) Report Generation.



Information Gathering

The Panel gathered information, perspectives, and experiences from numerous sources, including 1-on-1 interviews, virtual stakeholder meetings, and an online Stakeholder Portal.

Stakeholder Portal: The Stakeholder Portal, which was announced via [press release](#), allowed stakeholders to share their insights about what is working in FDA’s tobacco program, the challenges it faces, and suggestions to improve program operations. The Stakeholder Portal remained open from noon ET on October 21, 2022, until 11:59 p.m. ET on November 7, 2022, and received 49 public comments in total. Commenters were asked to self-identify their stakeholder group from among the following options: Academia/Research, Consultant/Attorney, Consumer/Consumer Advocate, FDA Staff, Harm Reduction, Industry, Public Health, and Other. The comments were shared with and closely reviewed by the Panel. Commenters were provided the option to remain anonymous; the details of those who included their contact information were shared with the Panel along with their comment. The majority of the comments were published publicly during the time the portal was open, except those that identified individuals by name or by current government position; those were shared only with the Panel.

Stakeholder Meetings: The Panel heard from 33 stakeholders during three days of virtual meetings on October 21, October 24, and October 25, 2022. The meetings allowed stakeholders to share insights and interact directly with the Panel. Facilitated by a single moderator, each session included 5 to 6 panelists who were each granted up to 8 minutes of remarks followed by a question-and-answer period with the Panel. Topics included: regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. The meetings were open to the public at no cost and the audio was made available online via Zoom webcast.

1-on-1 Interviews: Nineteen current and former FDA staff were consulted for interviews and follow-up conversations with the Panel to complete the Information Gathering phase of the operational evaluation.

Information Synthesis & Analysis

Following the Information Gathering phase, the Panel compiled, reviewed, and synthesized the information it obtained. This process included a series of Panel work sessions. On the basis of the themes and patterns that emerged from conversations with stakeholders and their review of public comments, the Panel extracted key findings and began outlining recommendations for the report.

Report Generation

Building on the outline developed during the Information Synthesis phase, the Panel collaborated to determine their recommendations for the final report. The Panel worked to set forth multiple recommendations for consideration by the Commissioner that address the needs and gaps identified throughout the Information Gathering and Information Synthesis phases.

APPENDIX D

Tobacco Independent Expert Panel
Virtual Meeting

Stakeholder Comment Schedule

Session #1 – Application Process

October 21, 11am-2pm ET

11am	Introduction/Ground Rules
11:05am	Public Health Law Center, Desmond Jenson
11:13am	Vapor Technology Association, Tony Abboud
11:21am	American College of Preventive Medicine, Donna Grande, MGA
11:29am	American Vapor Manufacturers, Amanda Wheeler
11:37am	Q & A Session for above Stakeholders
11:57am	Short Break
12:05pm	Philip Morris International, Keagan Lenihan and JB Simko
12:13 pm	Taxpayers Protection Alliance, Martin Cullip
12:21pm	Coalition of Manufacturers of Smoking Alternatives, Brittani Cushman
12:29pm	Center for Tobacco Control Research & Education, UCSF, Lauren Lempert
12:37pm	Altria Client Services, Paige Magness
12:45	Q & A Session from Panel to remaining stakeholders

Session #2 – Regulation and Guidance Process

October 24, 1-4pm ET

- 1pm** Introduction to meeting/Introduction of IEP/Ground Rules
- 1:05pm** Reason Foundation, Michelle Minton
- 1:13pm** Cigar Association of America, Barry Schaevitz
- 1:21pm** University of Minnesota, Dorothy Hatsukami
- 1:29pm** JMS Scientific Engagement, Jim Solyst
- 1:37pm** Q & A Session for above Stakeholders
- 1:57pm** Break
- 2:03pm** NJOY, Jeffrey Weiss
- 2:11pm** Consumer Choice Center, Jeff Stier
- 2:19pm** American Heart Association, Susan K. Bishop
- 2:27pm** Smoke Free Alternatives Trade Association, Kimberly Hesse
- 2:35pm** Q & A Session for remaining Stakeholders from Panel
- 2:55pm** Break
- ~~**3:00pm** University of Louisville School of Medicine, American Heart Association Tobacco Regulation Center, Aruni Bhatnagar~~
- 3:08pm** Latham & Watkins/ITG Brands, Ben Haas
- 3:16pm** R Street Institute, Mazen Saleh, MSc
- 3:24pm** The Tobacco Company, Greg Zimmerman
- 3:32** Premium Cigar Association, Joshua Habursky
- 3:40** Q & A Session for remaining Stakeholders from Panel

Session #3

9-10:20am: Compliance and Enforcement

10:35am-noon: Public Education and Communication

October 25, 9am-12pm ET

9am	Introduction/Ground Rules
9:04am	Campaign for Tobacco Free Kids, Matthew Myers
9:12am	National Association of Convenience Stores (NACS), Lyle Beckwith
9:20am	American Academy of Pediatrics, James Baumberger, MPP
9:28am	National Tobacco Reform Initiative, Michael Cummings
9:36am	RAI Services Company (Reynolds American, Inc), John F. O'Brien
9:44am	American Lung Association, Erika Sward
9:52am	Q & A Session for above Stakeholders from Panel
10:15am	Break
10:35am	22nd Century Group, John Pritchard
10:43am	Cancer Action Network (American Cancer Society), Catherine (Katie) McMahon
10:51am	University of Louisville, Brad Rodu
10:59am	Consumer Advocates for Smoke-free Alternatives Association, Alex Clark
11:07am	Truth Initiative, Stacey Gagosian
11:15am	Americans for Tax Reform, Tim Andrews
11:22am	Harvard Medical School at Massachusetts General Hospital, Nancy A. Rigotti, MD
11:30am	Q & A Session for remaining Stakeholders from Panel
11:50am	Conclusion

APPENDIX E

Stakeholders

49 comments were received through the online Stakeholder Portal.

The following stakeholders provided input to the Independent Expert Panel outside of the Portal.

Individuals

Abboud, Tony	Gorji, Perham	Perdue, Paul
Andrews, Tim	Haas, J. Benneville (Ben)	Pritchard, John
Apelberg, Ben	Harbusky, Joshua	Rigotti, Nancy
Appleberry, Robin	Hatsukami, Dorothy	Roth, Lauren
Barth, Janelle	Hesse, Kimberly	Saleh, Mazen
Baumberger, James	Hull, Lynn	Schaevitz, Barry
Beckwith, Lyle	Jenson, Desmond	Simko, JB
Bishop, Susan	King, Brian	Simoneau, Ann
Bugin, Kevin	Koplow, Bret	Solyst, Jim
Cecil, Todd	Lempert, Lauren	Stein, Peter
Clark, Alex	Magness, Paige	Stier, Jeff
Crosby, Kathleen	McMahon, Catherine (Katie)	Sward, Erika
Cullip, Martin	Mednick, David	Vincente, Wendy
Cummings, Michael	Minton, Michelle	Warner, Ken
Cushman, Brittani	Mital, Michele	Weiss, Jeffrey
Dickinson, Liz	Murray, Kim "Skip"	Wheeler, Amanda
Faris, Owen	Myers, Matthew L.	Woodcock, Janet
Felberbaum, Michael	Nelson, May	Zeller, Mitch
Gagosian, Stacey	Nitzkin, Joel	Zimmerman, Greg
Grande, Donna	O'Brien, John F.	

Organizations

Altria Client Services
American Vapor Manufacturers Association
Americans for Tax Reform
Campaign for Tobacco Free Kids
Center for Tobacco Control Research & Education, UCSF
Coalition of Manufacturers of Smoking Alternatives (CMSA)
Juul Labs, Inc.
National Tobacco Reform Initiative
RAI Services Company (Reynolds American, Inc.)
Smoke Free Alternatives Trade Association
Taxpayers Protection Alliance
Truth Initiative



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