November 12, 2024

The Honorable Richard J. Durbin
Chair
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chair Durbin:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the June 12, 2024, hearing before the Senate Committee on the Judiciary entitled "Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes." This letter is a response for the record to questions posed by the committee.

Sincerely,

Erin O'Quinn
Associate Commissioner for
Legislative Affairs

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Questions for the Record
Senate Judiciary Committee
United States Senate
"Combatting the Youth Vaping Epidemic by Enhancing Enforcement
Against Illegal E-Cigarettes"
June 12, 2024

Questions for Brian King, PhD, MPH
Director, Center for Tobacco Products
U.S. Food and Drug Administration

Senator Dick Durbin

1. **Under the 2009 *Family Smoking Prevention and Tobacco Control Act* (TCA), no tobacco product is permitted to enter the market unless its manufacturer first proves to the Food and Drug Administration (FDA) that it is "appropriate for the protection of public health." FDA is tasked with enforcing the TCA and regulating the tobacco industry, including e-cigarettes.**
   a. **What is FDA's approach to conducting inspections of retailers, distributors, and manufacturers to investigate potential illegal distribution or sale of unauthorized e-cigarettes and who conducts such inspections?**

   The Food and Drug Administration (FDA or the Agency) monitors for illegal tobacco products across the supply chain, which includes manufacturers, distributors, retailers, and importers, and takes action when violations are observed, based on the individual circumstances of the case. FDA's enforcement strategy is risk- and resource-based. Recognizing that the Agency is unable to take enforcement action against every single illegally marketed tobacco product – and that FDA needs to make the best use of its resources – the Agency makes compliance and enforcement decisions according to the specific facts in each case, taking into account its enforcement priorities, which includes a focus on products with prominent youth use and/or appeal. FDA also prioritizes follow-up inspections, investigations, and surveillance activities for firms that have received prior advisory or enforcement action for a violation.

   FDA regularly inspects registered establishments that manufacture, prepare, compound, or process tobacco products to determine compliance with existing laws and regulations. FDA also conducts inspections at vape shops where regulated tobacco products are manufactured, prepared, compounded, or processed within the premises using commissioned inspectors who are under contract to the Agency. During these inspections, inspectors verify that the products manufactured, prepared, compounded or processed at the establishment comply with the premarket authorization requirements. The Federal Food, Drug & Cosmetic Act (FD&C Act) requires FDA to conduct biennial inspections for each tobacco product establishment registered with FDA. In addition, as part of the premarket review process, FDA may conduct an inspection of the manufacturing facilities where the new tobacco product would be manufactured.

FDA has conducted inspections and investigations of distributors, taking action when violations are observed. FDA has issued approximately a dozen warning letters to distributors of tobacco products and conducted, in coordination with the U.S. Department of Justice (DOJ) and the U.S. Marshals Service, a seizure of unauthorized e-cigarette products valued at more than $700,000 at a distribution warehouse in California.

FDA contracts with states, U.S. territories, American Indian tribes, and third-party entities to conduct tobacco compliance check inspections of retail establishments. FDA-commissioned inspectors conduct these compliance check inspections for the Agency. FDA has an inventory of over 300,000 tobacco retailers that it inspects, which includes those selling e-cigarette products. FDA directs its contractors to conduct specific follow-up compliance check inspections at retail establishments where previous violations have been observed.

There are two types of compliance check inspections. First, during Undercover Buy Inspections, the retailer is unaware an inspection is taking place and a trained underage person, working with an FDA-commissioned inspector, attempts to purchase regulated tobacco products to determine compliance with identification check and minimum age of sale requirements. Second, during an Advertising and Labeling Inspection, FDA-commissioned inspectors present the retailer with a Notice of Inspection and announce their presence. The inspectors determine compliance with other requirements in effect, including for example, premarket authorization requirements. The program requirements of these contracts are consistent across states. Contracts include the approximate number of inspections each state/territory will conduct. Contractors base their proposal on a variety of factors, including historical inspection data and budgetary and personnel considerations. These contracts also include requirements that compliance check inspections are performed at a variety of different locations (e.g., urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout the state.

FDA also conducts online surveillance investigations of websites that market and sell tobacco products in the United States and verify that they comply with the premarket application requirements, among other requirements.

If FDA observes violations during these activities, the Agency may conduct further inspection and/or investigation and/or take a compliance or enforcement action as appropriate. Every action requires an individual investigation through which the Agency collects and reviews supporting evidence.

FDA will continue to take action across the entire supply chain against unauthorized tobacco products and against those manufacturing, distributing, importing, or selling unauthorized e-cigarette products – especially those most appealing to youth.

b. Please provide a breakdown of the number of personnel conducting these inspections related to unauthorized e-cigarettes on FDA's behalf between FDA employees, third-party contractors, and state partnerships, and the resources dedicated to each such entity by FDA, as applicable.

FDA conducts both tobacco retailer inspections, which include identifying unauthorized tobacco products along with underage sales, as well as tobacco manufacturer inspections, which include biennial inspections of registered tobacco manufacturers. These inspections cover all types of violations under the FD&C Act and associated regulations, including the manufacture, distribution, and sale of unauthorized e-cigarettes. FDA typically conducts hundreds of inspections of manufacturers per year and has conducted several coordinated compliance and enforcement efforts related to unauthorized e-cigarettes with our state partners at retail establishments over the last two years.

Currently, FDA is utilizing approximately 600 commissioned inspectors in jurisdictions under contract with FDA across the country to conduct inspections of tobacco retail establishments, some of whom have worked on the coordinated enforcement efforts related to unauthorized e-cigarettes. Most of the inspectors that conduct inspections are part-time and the exact number at any given period of time varies. The number of inspectors and whether they are full-time or part-time, varies from state-to-state. These inspectors are most often employees of a state, local, or territorial government and are commissioned by FDA. Most inspectors spend part of their time working for the Agency that employs them and part of their time doing the contracted work for FDA's tobacco retail inspection program.

In Fiscal Year (FY) 2023, FDA utilized 16 full-time inspectors and 22 part-time inspectors to conduct inspections at manufacturing establishments, including vape shops. As of June 2024, FDA utilized 19 full-time inspectors and 16 part-time inspectors.

c. Please provide a breakdown of the number of inspections related to unauthorized e-cigarettes between retailers, distributors, and manufacturers that took place since September 9, 2021.

Since September 9, 2021, FDA has conducted over 1700 manufacturer inspections at vape shops. FDA has conducted an additional 940 inspections of manufacturers and distributors that sell various types of regulated tobacco products. A component of these inspections includes verifying compliance with the premarket authorization requirements.

Most of FDA's inspections of manufacturers, distributors, and retailers cover all provisions of the law and regulations applicable to regulated tobacco products, so we cannot parse out those inspections that only apply to unauthorized e-cigarette products.

It is also important to note that FDA conducted inspections of manufacturers, distributors and online retailers related to unauthorized e-cigarettes and issued warning letters prior to September 9, 2021.

In 2023 and 2024, FDA's Center for Tobacco Products (CTP) conducted directed retail inspection efforts focused on unauthorized tobacco products and these efforts continue. To date, CTP has conducted over 1,300 retail inspections to check for unauthorized tobacco products.

d. Please identify what additional resources FDA projects may be necessary to adequately monitor the e-cigarette market and ensure compliance with federal law.

As set forth by Congress in the Family Smoking Prevention and Tobacco Control Act (TCA), FDA's tobacco program is entirely funded through user fees paid by the tobacco industry. While FDA regulates all tobacco products, including e-cigarettes, it only has the authority to assess and collect user fees from products that fall within the six classes specified in section 919 of the FD&C Act. FDA receives zero dollars from manufacturers of e-cigarettes that could be used to support review of the applications that have been received for nearly 27 million e-cigarette products or to address those that are on the market illegally, even though e-cigarettes are the products most used by youth.

An additional $114.2 million in user fees (adjusted for inflation) would allow FDA to significantly bolster our enforcement efforts. Currently, FDA has had to spend a significant portion of the user fees it collects annually from the existing six product classes to regulate products outside of those classes, especially e-cigarettes.

The additional $114.2 million in user fees would help by increasing inspections, investigations, and surveillance capacity by about 25 percent, which includes activities related to manufacturing (including vape shops), imports, retail and online inspections, investigations and surveillance, and hiring additional staff to support these compliance and enforcement activities.

2. FDA currently conducts inspections of retailers to verify compliance with restrictions on the sale of tobacco products to minors. Do these inspections also include inspections for potential illegal distribution or sale of unauthorized e-cigarettes?

Yes. FDA's tobacco retailer inspections cover the marketing, sale, and distribution of tobacco products at retail locations. Inspections check for compliance with retail provisions, including the premarket authorization requirements, underage access restrictions and other requirements. Additionally, FDA's online tobacco surveillance program includes retailer website reviews to check for compliance with premarket authorization requirements.[1]

3. During the hearing, you testified that, "many recipients of warning letters correct the violative conduct."

a. Please provide the number of manufacturers, distributors, and retailers, respectively, that: 1) have been issued warning letters regarding the sale or distribution of unauthorized e-cigarettes since September 9, 2021, and 2) have come into compliance with federal law after receiving a warning letter.

As of June 12, 2024, FDA has issued more than 670 warning letters to tobacco manufacturers and distributors for the manufacturing, distribution, and/or sale of unauthorized new tobacco products. FDA has also issued over 550 warning letters to retailers for selling unauthorized tobacco products. The warning letters describe the violation(s) and give firms the opportunity

[1] https://www.fda.gov/tobacco-products/compliance-enforcement-training/retail-sales-tobacco-products#Online%20Retail%20Investigations

to take corrective action. FDA follows up on warning letters, generally prioritizing follow-up inspections, investigations, and surveillance activities for firms that, for example, provide an inadequate response or fail to respond to a warning letter.

If firms do not respond or provide an inadequate response and continued violations are observed, the Agency may collect evidence and take escalated actions such as seeking civil money penalties (CMPs) or working with federal partners on judicial actions such as injunctions and seizures. In addition, FDA may refuse entry of imported tobacco products into the United States if such products are not in compliance with the law. FDA generally keeps its cases open until the Agency receives an adequate response or confirms compliance through additional inspections, or online investigations, consistent with Office of Regulatory Affairs (ORA) procedure. This may take time to confirm; for example, a firm may come into compliance with respect to the product cited in the warning letter, but the marketing of other unauthorized products may be later identified. If violations continue to be observed, we may pursue enforcement action.

Through June 12, 2024, FDA has filed CMP complaints against 58 manufacturers and 140 retailers for continued violations of the premarket authorization requirements. Approximately half of these CMP actions have been closed, while approximately half of the CMP actions remain ongoing. In addition to civil money penalties, DOJ, on behalf of FDA, has filed eight complaints for injunctions against manufacturers for continued premarket authorization violations. In addition, FDA has coordinated with its federal partners to seize unauthorized tobacco products. In April 2024, FDA in coordination with DOJ announced that the U.S. Marshals Service seized unauthorized ENDS products in a warehouse in California valued at more than $700,000 and in 2023, FDA participated in a joint operation with Customs and Border Patrol (CBP) CBP at Los Angeles airport that resulted in the administrative seizure of more than $18 million worth of illegal e-cigarettes, including Elf Bar.

b. What is the average time between issuance of a warning letter and a re-inspection by FDA to verify compliance?

The time it takes between issuance of a warning letter and re-inspection by FDA to verify compliance depends on a number of case-specific factors. Firms that receive a warning letter have 15 working days to respond to the Agency with the steps they will take to address the violation(s) cited in the warning letter and to prevent future violations. FDA's follow-up activities generally begin as soon as FDA receives the firm's response or after the response deadline elapses for firms that do not respond. FDA prioritizes follow-up inspections, investigations, and surveillance activities for firms that for example, fail to respond to a warning letter, provide an inadequate response, or if we have information that they continue to manufacture, distribute, or sell unauthorized products. Currently, warning letter follow-up inspections and/or investigations have been conducted within a few months, however, factors that are case specific including logistics can cause longer timeframes for follow-up.

FDA's follow-up actions may take some time. These actions may involve numerous communications with firms to address their responses and confirm appropriate corrective actions, conduct online surveillance, and inspect brick-and-mortar establishments (e.g., manufacturing facilities/vape shops), among other things. In addition, coordination may be needed both among different parts of FDA and with other entities outside FDA including federal or state agencies.

In order to help increase inspections, investigations, and surveillance capacity by about 25 percent, including timely follow-up on warning letters, the Agency has requested an additional $114.2 million in user fees. These additional resources would also be used for activities related to inspections and re-inspections of manufacturers (including vape shops), importers, retailers, and online firms; related investigations and surveillance efforts; and hiring additional staff to support these compliance and enforcement activities.

c. Why have only a small fraction of firms receiving a warning letter for the sale or distribution of unauthorized e-cigarettes received a close-out letter?

FDA generally keeps its cases related to these firms open until the Agency receives an adequate response and confirms compliance as described in the answer to the previous question. Compliance cases remain open when the Agency is continuing to monitor them or when the Agency is working on further enforcement activity to maximize the impact of its action.

4. The sale or distribution of an unauthorized e-cigarette is a per se violation of the *Tobacco Control Act*. During the hearing, you testified that, "Typically, upon finding a violation and gathering the necessary evidence, FDA first issues a warning letter to achieve voluntary compliance … and give firms the opportunity to take corrective action. FDA follows up on warning letters, prioritizing follow-up inspections, investigations, and surveillance activities for firms that are most likely to continue to violate the law…."

a. If FDA verifies that a firm receiving a warning letter has not come into compliance with federal law, what must FDA do before issuing a civil monetary penalty (CMP)?

FDA's compliance and enforcement work is a multi-step process that ensures each action is supported by a strong evidentiary record and legally supportable. Firms that receive a warning letter have 15 working days to respond to the Agency. FDA's follow-up activities generally begin when FDA receives the firm's response or after the response deadline elapses for firms that do not respond. FDA generally prioritizes follow-up inspections, investigations, and surveillance activities for firms that, for example, fail to respond to a warning letter; provide an inadequate response; we have information that they continue to manufacture, distribute, or sell unauthorized products; or as part of other public health impact considerations.

FDA's follow-up actions may take some time; these actions may involve numerous communications with firms to address their responses and corrective action plans, online

surveillance, inspections of brick-and-mortar establishments (e.g., manufacturing facilities/vape shops), and other investigations. In addition, FDA may coordinate with other federal or state agencies. If FDA observes violations during inspections and/or investigations, the Agency may issue a compliance action or take or coordinate enforcement action as appropriate. These enforcement actions may include a CMP, injunction or seizure. CMPs are initiated by CTP filing a Complaint and serving the Complaint upon the respondent (the tobacco retailer, tobacco manufacturer, or other appropriate person). We note that CMPs are filed with the Civil Remedies Division of the Departmental Appeals Board of the U.S. Department of Health and Human Services, and injunctions and seizures must be coordinated and filed through DOJ.

b. Must a noncompliant firm first receive a CMP prior to being referred to DOJ for a potential injunction?

No. FDA generally issues a warning letter for initial violations, and such warning letters note that further violations could lead to enforcement action, including injunction or seizure actions. A noncompliant firm does not need to receive a CMP prior to being referred to DOJ for initiation of judicial enforcement action, such as an injunction or seizure, under the FD&C Act.

5. To date, the CMPs issued by FDA—primarily to retailers, not manufacturers—have been for approximately $20,000 each. The law permits FDA to bring actions involving multiple violations in a single proceeding, resulting in CMPs of up to $1.2 million. However, FDA has not done so to date. Why has the agency not issued higher CMPs as permitted under federal law?

Section 303(f)(9) of the FD&C Act provides that CMP amounts may not exceed certain limits and requires a number of factors to be considered in determining the penalty under those limits. The 140 recent CMPs issued to retailers and 58 issued to manufacturers for amounts exceeding $19,000 are the first actions CTP has taken under section 303(f)(9) of the FD&C Act; the penalty amounts are permissible under that provision. CTP is actively working on guidance to provide further clarity about CMPs, including how CTP intends to count violations and when it may bring enhanced civil money penalties.

6. During the hearing, you testified that "FDA prioritizes compliance and enforcement actions against products that appeal to youth." But, to my knowledge, FDA has not taken enforcement action against the <u>manufacturers</u> of several unauthorized e-cigarettes that are among those with the largest market shares or reported on federal health surveys to be most popular with youth, including JUUL and Elf Bar.

a. When FDA identifies a retailer selling an unauthorized e-cigarette, does FDA also send a warning letter to the e-cigarette's manufacturer? If not, why not?

For FDA to be able to send a warning letter to a manufacturer following an inspection of a retailer, we would need to collect sufficient evidence to identify the manufacturer of that specific violative product and demonstrate that a specific manufacturer is currently manufacturing that product and distributing it into interstate commerce. Some firms

manufacture products with the same brand name, so seeing a certain product in a retail establishment may not provide information about the specific manufacturer of that specific product on the shelf. We investigate fully to make these determinations, and FDA may use multiple methods of inspection or investigation to take action against a firm.

b. Why hasn't FDA taken enforcement action against the manufacturers of these products?

According to the results of the 2023 National Youth Tobacco Survey, e-cigarettes remained the most commonly used tobacco product among youth, with disposable e-cigarettes being the most popular type. Elf Bar, a disposable product, was the most commonly used brand by current youth e-cigarette users (56.7 percent) and has been the focus of targeted FDA compliance and enforcement actions for several months. For example, in April 2024, FDA announced the issuance of complaints for CMPs for against 20 brick and mortar retailers and two online retailers for the sale of unauthorized e-cigarettes, including Elf Bar. Our enforcement actions work, and we frequently see changes in market share after major enforcement actions. Most recently, many unauthorized brands popular with youth that have been noted subjects of FDA enforcement, including Puff, Hyde, and Esco, are no longer among those with the highest market share in the United States.

Recognizing that the Agency is unable to take enforcement action against every single illegally marketed tobacco product – and that FDA needs to make the best use of its resources – the Agency will continue to make compliance and enforcement decisions according to its enforcement priorities, which includes a focus on products with prominent youth appeal. FDA conducts surveillance of youth use of tobacco products, including through the most timely and scientifically rigorous methods available, and is able to monitor and address products across the marketplace.

All e-cigarette products, including those made by JUUL, are required by law to have FDA authorization to be legally marketed. The Agency's continued review does not constitute authorization to market, sell, or ship JUUL products.

7. FDA has stated that, "For unauthorized tobacco products, the pendency of an application does not create any sort of a safe harbor to sell that product."

a. Please list each enforcement action FDA has taken against manufacturers of unauthorized e-cigarettes with pending PMTAs, including—as permissible—a notation of whether such PMTA was timely filed pursuant to court orders or statutory deadlines (for tobacco-derived nicotine products and synthetic nicotine products).

For the vast majority of unauthorized tobacco products, the pendency of an application does not create a safe harbor to sell that product. We can issue, and have issued, warning letters for products for which an application has been submitted and is pending review. FDA's enforcement strategy is risk- and resource-based. Recognizing that the Agency is unable to take compliance and enforcement action against every single illegally marketed tobacco product—and that FDA needs to make the best use of its resources—the Agency will

continue to make enforcement decisions according to its enforcement priorities, which includes a focus on products with prominent youth use and/or appeal.

b. Have FDA officials ever represented to retailers, distributors, manufacturers, or their representatives, that the agency is not prioritizing enforcement against unauthorized e-cigarettes with pending PMTAs?

FDA has not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization. The Agency has been clear that a new tobacco product must have FDA authorization before it can be legally marketed, and generally, products without authorization are at risk of enforcement action. As of June 12, 2024, FDA had authorized 23 tobacco-flavored e-cigarette products and devices. FDA provides a publicly available list of e-cigarette products and devices with marketing granted orders (MGOs) so that retailers, consumers, and others may know which products may be legally marketed.[2] FDA has also published a downloadable one-page list of those e-cigarette products and devices.[3]

FDA has publicized this information numerous ways including an explicit statement on the Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products webpage.[4] As mentioned above for the vast majority of unauthorized e-cigarettes on the market today, the pendency of an application does not create a legal safe harbor to sell that product.

There are a few tobacco products for which the webpage describes the specific instances in which FDA does not intend to pursue enforcement. For example, there are a few tobacco products that have received a marketing denial order (MDO) that are under further Agency review and for which FDA has stated the Agency does not intend to pursue enforcement action during the pendency of the re-review. In addition, in a very limited number of instances, some courts have granted stays of MDOs pending judicial review in order to maintain the status quo, or FDA has administratively stayed MDOs. In those particular instances, FDA does not intend to take enforcement action.

The decision whether to take enforcement action will be made on a case-by-case basis, taking into account youth use and/or appeal and other factors. Before taking any such action, the Agency intends to follow its usual compliance and enforcement practices and will generally issue a warning letter before initiating enforcement action (such as civil money penalties, seizure, or injunction) and afford the recipient an opportunity to respond or take corrective action (although there is no legal requirement that FDA send a warning letter before the Agency can initiate an enforcement action).

[2] https://www.accessdata.fda.gov/scripts/searchtobacco/
[3] https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JULY2024.pdf
[4] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#Enforcement%20Priorities

Senator Tom Tillis

1. **Director King, you have said that there is "no question" that "e-cigarettes have lower risk than combustible cigarettes" and that "the vaping epidemic is over." This is positive news, but it begs the question then: what is the FDA doing – and the Center for Tobacco Products (CTP), in particular –to inform adult smokers that these less harmful options are available and why is the Center not operating within its statutory deadlines to make decisions on product applications – products that present the potential for less risk than combustible cigarettes?**

CTP has publicly acknowledged the continuum of risk for tobacco products for many years, including most recently in a perspective piece intended for healthcare providers in the journal Nature Medicine.[5]

The available science indicates that e-cigarettes, as a general product class, have lower levels of risk compared to combustible cigarettes. However, it is important to note that there is variability across this product class, including with regard to ingredients and risk. Accordingly, premarket product review plays an integral role in FDA's efforts to regulate these products. As set forth in the law, FDA must evaluate a premarket tobacco product application (PMTA) to determine whether the applicant has shown that authorizing the marketing of the new tobacco product would be "appropriate for the protection of the public health."[6] The law is clear that a new tobacco product must have FDA authorization before it can be legally marketed. Applicants must submit enough information to meet the necessary public health standard, and the review process is necessary to ensure scientific integrity of the marketing decision.

FDA continues to make significant progress on the review of PMTAs. To date, FDA has received PMTAs for nearly 27 million e-cigarette products. The volume of tobacco applications received is exponentially greater than submission volume for other FDA regulated products. To date, FDA has resolved more than 26 million of these applications. The application process is ongoing, and the Agency continues to receive applications. FDA continues to gain review experience and implement new efficiencies to reduce application review times. Furthermore, the quality and rigor of applications received is improving. As the Agency continues to review this unprecedented number of applications, the Agency is working diligently to reduce application review times down to the 180-day statutory timeframe.

In addition to product review, opportunities also exist to educate adult smokers about the relative risks of tobacco products, including e-cigarettes, using evidence-based approaches. In fact, FDA's CTP Strategic Plan objective 4.3 outlines work to "educate adults who smoke about the relative risks of tobacco products."[7] FDA is actively working to build the evidence base on this issue. For example, FDA initiated formative research to inform potential messaging related to

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[5] https://www.nature.com/articles/s41591-024-02926-7.epdf?sharing_token=ETQ3Pkp1wxvSB6hBvIyqZNRgN0jAjWel9jnR3ZoTv0P4kOyNQzfYBPc4k1kVmBUHXSGdi4r5jGtJqGGrr2LUvq3nc1uYYe1eGRY0HFzWsxpAw6VEKuUwyrU2rIEA9i8NcEPSgCHB5M3tluE1e-5ujJePkexBpPqkbXuBzuDUWi4%3D

[6] Section 910(c)(4) of the FD&C Act.

[7] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctp-strategic-plan

misperceptions about nicotine and the continuum of risk among adult smokers.[8] The National Institutes of Health (NIH), in coordination with FDA, published a Notice of Funding Opportunity inviting applicants for a single Research Project Cooperative Agreement that will utilize health communication research to better understand the impact that messaging about the continuum of risk for tobacco products may have on various segments of the population, including both the intended audience (i.e. adult smokers) and unintended audiences (e.g., youth). This messaging work must be balanced with FDA's continued work to prevent youth tobacco product initiation, including through "The Real Cost" public education campaigns, and with efforts to encourage first line use of FDA-approved cessation therapies.[9]

In addition to continuing to build the scientific evidence base on best approaches to message on this issue, the Agency is concurrently working to educate the public – specifically adult smokers – based on the scientific evidence presently available. For example, earlier this year, FDA posted a new website focused on the relative risks of tobacco products.[10]

2. Director King, in December 2022 the Regan Udall Foundation, at the direction of FDA Commissioner Califf, issued its final report on the Center for Tobacco Products mismanagement and disfunction.

The report offered a number of recommendations to improve authorization, enforcement, clarity and transparency at CTP. Among those recommendations, the Regan Udall Foundation specifically called on FDA 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."

Further, the Regan Udall Foundation specifically recommended that the Task Force include FDA, HHS, DOJ (including the ATF), DHS (including Customs and Border Protection), and the Department of the Treasury (the Alcohol and Tobacco Tax and Trade Bureau).

On Monday, just two days before the hearing, FDA and DOJ announced the creation of an interagency task force to curb distribution and sale of illegal e-cigarettes. This announcement comes more than two and half years after the Regan Udall report's recommendation and, notably, does not include U.S. Customs and Border Protection (CBP)

a) What took so long? and

b) Why was CBP excluded from the task force when we know that China is flooding the US with illicit e-cigarette and vapor products?

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[8] In August 2023, a Notice of Funding Opportunity was published by the National Institutes of Health, in coordination with CTP, for "Public Health Communication Messaging about the Continuum of Risk for Tobacco Products" available at https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-021.html.

[9] https://onlinelibrary.wiley.com/doi/full/10.1111/add.16296

[10] https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products

The Reagan-Udall Foundation evaluation included 15 recommendations, all of which CTP has been diligently working on since the Center issued its response to the external evaluation in 2023. The progress made to address these recommendations has been routinely, consistently, and transparently communicated to the public via a public facing website that is updated quarterly. As was noted at the time of the initial response to the evaluation, some recommendations may take longer than others to address, but the Center was committed to addressing them all.

FDA has a long history of actively engaging with other government agencies and organizations to enhance enforcement and compliance activities. For example, FDA works closely with the DOJ to inform its compliance and enforcement actions. DOJ also files and litigates judicial enforcement actions, such as injunctions and seizures, on behalf of the Agency. FDA coordinates with CBP on administrative seizures of unauthorized tobacco products being imported into the United States.

With regard to interagency engagement in response to the noted Reagan-Udall Foundation evaluation recommendation, FDA's ongoing work in this space has been included in the quarterly updates noted above. Specifically, Senior officials from the Department of Health and Human Services (HHS) Office of the General Counsel (including FDA Office of the Chief Counsel), FDA Office of the Commissioner, CTP, and DOJ met in July 2023 to continue ongoing discussions and close collaboration on issues related to enforcement. Additionally, meetings occurred with the Federal Trade Commission in February 2023 and January 2024, and ATF in May 2023. These meetings ultimately informed potential next steps, including the subsequent coordination of a formal interagency Task Force to optimize our collaborative process and broaden our approach. CBP was not excluded from the Task Force; the Agency is a member, as noted during the July 12, 2024, hearing testimony.

FDA is hopeful that this "all government" approach and collective Agency resources will help enhance compliance and enforcement actions across the tobacco product supply chain in the United States, including importation of unauthorized e-cigarettes. With regard to Chinese imports, there are both domestic firms that may use overseas manufacturers and import finished products or parts and firms that are foreign owned. Per Nielsen, unit sales data for the four-week period ending April 20, 2024, the top three brands—Vuse, JUUL, NJOY—accounted for nearly 85% of the e-cigarette market nationally. These U.S.-owned firms—some of which use foreign manufacturers for parts of their products—account for the vast majority of the U.S. e-cigarette market. In contrast, while imported illicit tobacco products are a concern, Chinese-owned firms account for less than 10 percent of e-cigarette sales nationally.

3. Why shouldn't CTP also have to achieve measurable metrics in return for its fees?

When Congress established the CTP under the TCA, it set out the tobacco user fee framework while also prohibiting FDA from using other funds for tobacco regulation activities. Other Centers at FDA are funded through a combination of budget authority (BA) and user fees. In order to collect user fees, the Centers have a baseline amount of BA that must be funded to "trigger" the collection of the fees. Since CTP is 100 percent funded by tobacco industry user fees, a reauthorization program would not be feasible because there is no baseline BA to ensure continuity of operations.

While CTP does not reauthorize its program every five years, CTP demonstrates accountability through other means. For example, CTP submits reports to Congress on annual spending, compliance and enforcement actions, and application review, among other items.

4. If CTP can't deliver on its statutory and court ordered deadlines today, why should it continue to receive funding at all, much less receive additional funding with no accountability?

CTP regulates an unprecedented marketplace, which is evidenced by the nearly 27 million applications the Agency has received for e-cigarette products alone. This volume is exponentially greater than all other regulated product classes under FDA's purview. CTP has worked diligently to review these applications, but the sheer volume submitted made review nearly impossible within the initially prescribed statutory review period. However, the Center has made considerable progress on this front, with the goal of getting through the bolus of applications as expeditiously as possible while also ensuring the scientific and legal defensibility of each review. The Center's goal is to ultimately clear the backlog and issue decisions within the prescribed 180-day statutory deadline.

CTP recognizes the importance of transparency and regularly reporting metrics for work completed across the Center, including application reviews. The Center submits reports to Congress on a variety of topics, including annual spending, compliance and enforcement activities, and product review, among other things.

As set forth by Congress in the TCA, FDA's tobacco program is entirely funded through user fees paid by the tobacco industry. CTP funding has not kept up with the growth in the tobacco market and workload. While FDA regulates all tobacco products, including e-cigarettes, it only has the authority to assess and collect user fees from products that fall within the six classes specified in section 919 of the FD&C Act. FDA receives zero dollars from manufacturers of e-cigarettes that could be used to support review of the applications that have been received for nearly 27 million e-cigarette products or to address those that are on the market illegally, despite the fact that e-cigarettes are the products most used by youth. Since FY 2019, FDA is authorized to collect a fixed amount of $712 million each fiscal year; however, this amount does not reflect all of the tobacco products marketed today, including ENDS products, and does not reflect the workload associated with these products or the marketplace. FDA has proposed to modernize the tobacco user fee framework to begin collecting an additional $114 million in FY 2025 from all tobacco products.

5. Why hasn't the agency leveraged the success of other Centers and indicated a willingness to work with Congress to pass legislation funding CTP through user fees with accountability measures?

CTP recognizes the importance of transparency and regularly reporting metrics for work completed across the Center, including application reviews. The Center will continue to update Congress on CTP's annual spending, compliance and enforcement activities, and product review,

among other things. Further, FDA has engaged with Congress regarding user fee legislation and is very willing to continue this engagement.

Marijuana Vapes

In my home state of North Carolina, the Eastern Band of Cherokee Indians and Qualla Enterprise LLC established an operation to produce, cultivate, and sell marijuana. This venture comes as our nation is already facing an unprecedented drug crisis that is harming our communities. Constituents and law enforcement officials have expressed concern on how State and Federal law can be upheld without clear guidance.

1. **On May 30, 2024, the U.S. Food and Drug Administration (FDA) announced it is seeking civil money penalties to online retailers and brick & mortar stores for unauthorized e-cigarettes/vapes. What type of inspections does FDA conduct for marijuana vapes like the ones sold by Eastern Band of Cherokee Indians and Qualla Enterprise LLC?**

2. **If you go on Eastern Band of Cherokee Indians and Qualla Enterprise LLC's website, *Great Smoky Cannabis Company*, you can now purchase one of over two dozen marijuana vapes. On these packages, there are no warning labels for children, no description on how the product was tested, and no indication on where the vape pens were manufactured. Can I get FDA's commitment to conduct an inspection to *Great Smoky Cannabis Company* marijuana vapes being sold on their website?**

3. **The vape pens being sold by the Eastern Band of Cherokee Indians and Qualla Enterprise LLC state that the THC levels range from 65%-79%. Do you agree that these levels of THC are safe?**

4. **In April, an Associate Judge for the Eastern Band Tribal Court, the Superintendent at Cherokee Central Schools, and tribal health leaders raised their concerns about the marijuana venture's impact on the behavioral health of youth. Do you agree that if a child uses one of the Easter Band's marijuana vape pens or consumes the snickerdoodle cookies—it could have a negative impact to their health?**

FDA shares many of your concerns about THC vapes and the impacts of THC on children and youth. FDA has sent over 100 warning letters to firms marketing cannabis-derived products, including some warning letters to firms marketing delta-8 THC foods, such as candies and snacks that are appealing to children. FDA will continue to act, within our authorities, against products that put the public at risk.

FDA's authority to regulate products, including conducting inspections of manufacturers, is limited to those products that fall within an FDA-regulated product category as defined in the FD&C Act. To the extent that some THC products, such as certain THC vapes, may not meet the definition of any FDA-regulated product, FDA's authority is limited. It is a company's responsibility to ensure all of its FDA-regulated products comply with the applicable laws and regulations administered by FDA.

Multi-Agency Taskforce

1. **Memorandum of understanding ("MOU") for multi-agency task force. Has FDA, DOJ, and the other agencies that joined the task force executed an MOU that (1) defines lines of authority and responsibility, (2) clarifies processes for coordination, cooperation, and resource allocation, and (3) prevents duplication of effort? If so, please provide us with a copy of the MOU.**

    a. **If not, why is there no MOU in circumstances where FDA has a policy of executing MOUs for agency collaborations and a long history of executing MOUs with agency partners?**

    b. **Given the complexity of the e-vapor crisis – involving multiple federal agencies and multiple federal statutes – will FDA and DOJ commit to finalizing an MOU, and providing a fully executed copy to this Committee, within the next thirty (30) days?**

2. **Objectives of the multi-agency task force. FDA and DOJ's announcement on June 10, 2024, clarified that the task force aims not only to bring more civil and criminal enforcement actions, but also to protect the public health by preventing the widespread availability of illegal e-vapor products.**

    a. **Has the task force established key performance indicators, performance metrics, or enforcement action goals to measure its success in preventing the sale and distribution of illicit e-vapor products? If so, please share those metrics with this Committee.**

    b. **Does the task force agree that, more so than the number of enforcement actions it initiates, the most meaningful measure of its success will be a reduction in the actual sale and distribution of illicit e-vapor products in the marketplace? If so, please describe how the task force intends to measure its impact.**

    c. **Does the task force accept that, to meaningfully impact an illicit e-vapor market of this scale and scope, it must bring enforcement actions involving the strongest tools against the largest actors? If so, please explain how the task force will focus its efforts and resources on issuing enhanced civil money penalties, import seizures, injunctions, forfeiture applications, and criminal prosecutions against the leading manufacturers and distributors of illicit products.**

    d. **Is the task force committed to reversing the approach adopted to date by FDA – in which its injunction applications and civil money penalties have been issued only to retailers – and instead pursue the largest manufacturers and distributors of illicit imported disposable products by market share? If so, please explain how the task force will identify the largest manufacturers and distributors of illicit imported disposable e-vapor products by market share.**

e. As many of the largest manufacturers of illicit e-vapor products are domiciled in China, and it is difficult to impose judicial orders and administrative penalties against Chinese companies, what strategies is the task force developing to hold such Chinese companies accountable? Please describe the disclosable parts of those strategies and explain how the task force will impose penalties against Chinese companies that bear the greatest responsibility for the relentless growth of the illicit e-vapor market.

f. Will the Task Force prioritize preventing the importation of illicit products or shutting the distribution down within the United States? Why is one approach better than the other?

3. Composition of the multi-agency task force. There is some confusion about whether Customs and Border Protection ("CBP") has joined the task force. FDA and DOJ's announcement about the task force did not list CBP among the agencies that have joined the task force. However, Deputy Assistant A-G Arun Rao testified as follows to this Committee: "The task force combines the expertise of multiple law enforcement partners, including ATF, the US Postal Inspection Service, the US Marshals Service, US Customs and Border Protection as well as the Federal Trade Commission."

a. Has CBP joined the task force? If CBP has not joined the task force:

i. The Committee has received reports that CBP field staff may be frustrated by a lack of timely information from FDA's Center for Tobacco Products ("CTP") regarding the admissibility or inadmissibility of shipments of e-vapor products. Has this frustration contributed in any way to CBP's decision not to join the task force, or at least its decision not to join the task force by June 10, 2024? If this was a contributing factor, please explain how the task force intends to remediate the apparently suboptimal working relationship between CBP and CTP field staff.

ii. Do you agree with FDA Commissioner Dr. Robert Califf that import prevention and enforcement is likely the most effective way to prevent the flow of illicit products into the U.S. from China, and it is therefore critically important that CBP join the multi-agency task force and take a leading role in preventing the importation of illicit products?

iii. Will FDA and DOJ commit to ensuring that CBP joins the task force within the next 30 days and provide written confirmation to this Committee once it has?

b. Has the Department of State or any other agencies responsible for national security joined the task force? If not:

i. Do FDA and DOJ understand, based on the report "The Global Illicit Trade in Tobacco: A Threat to National Security," that illicit tobacco markets are a national security threat?

ii. **Do FDA and DOJ understand that illicit tobacco markets operate globally and are major funding sources for international terrorist organizations, including Hamas?**

iii. **Do FDA and DOJ understand that illicit e-vapor products make billions of dollars for the Chinese Tobacco Monopoly and are a key funding source for the Chinese government?**

iv. **Will FDA and DOJ commit to ensuring that the Department of State joins the task force within the next 30 days and provide written confirmation to this Committee once it has?**

c. **In addition to federal agencies, state and local agencies are responsible for enforcement of state and local laws that implicate illicit e-vapor products. Does the task force intend to admit state or local law enforcement agencies to its membership or, otherwise, will the task force coordinate with state and local law enforcement, or the National Association of Attorneys General? Please describe how the task force will coordinate its investigations, enforcement decisions, and attorney engagements with state and local agencies.**

d. **In testimony before this Committee, Dr. Brian King said that the task force is "multi agency, and that takes time to make sure we get the right folks to the table, and we set the foundation for more programs." When does the task force expect to finalize its composition? Please explain the process by which agencies join the task force, when that process will be completed, and whether and to what extent the White House is involved in the process.**

4. **Operation of the multi-agency task force. Please answer the following questions about the task force:**

a. **What is the effective date and expiration date for the task force?**

b. **When did the task force first meet and how often does it meet?**

c. **Does the task force have a steering committee, and if so, who are its members?**

d. **Does the task force have liaison officers from each agency, and if so, who are the officers?**

e. **How are personnel, resources, and funds allocated to and within the task force?**

f. **How many staff from each agency, and in total, have been assigned to the task force?**

g. How will agency staff not assigned to the task force share information with the task force?

h. What procedures are in place for the sharing of non-public information within the task force?

i. What processes has the task force adopted to ensure efficiency and avoid bureaucracy?

j. How are decisions to bring enforcement actions made and how are disagreements resolved?

k. Will the task force issue detailed public reports on its progress? If so, how frequently? If not, will FDA and DOJ commit to providing written updates to this Committee at least quarterly?

l. How will the task force work with and learn from outside experts? What is the process for interested parties to share information?

Combined Response to Senator Tom Tillis' Questions 1-4 on the Multi-Agency Taskforce:

FDA has a long history of working closely with federal partners, such as DOJ and Customs and Border Protection (CBP). This collaboration has led to meaningful outcomes, such as the first injunctions against the sale of unlawful ENDS products in coordination with DOJ, and the first seizure of unauthorized e-cigarettes in coordination with DOJ and the U.S. Marshals Service. We have learned important lessons that have informed our commitment to strengthening interagency engagement. Addressing unauthorized e-cigarettes is a whole supply chain issue, and an "All-of-Government" approach is critical.

On June 10, 2024, DOJ and FDA announced the creation of a federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes. As of the date of the hearing, the task force is in the early stages of developing processes and procedures and identifying metrics for success. The purpose of the task force is to coordinate and streamline efforts to bring all available criminal and civil tools to bear against the illegal distribution and sale of e-cigarettes responsible for nicotine addiction among American youth.

In addition to FDA and DOJ, CBP is a member of the task force. Additional law enforcement partners include the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), the U.S. Marshals Service (USMS), the U.S. Postal Inspection Service (USPIS), and the Federal Trade Commission (FTC). Additional agencies may join the task force in the coming weeks and months.

The federal task force will focus on several topics, including investigating and prosecuting new criminal, civil, seizure and forfeiture actions under the Prevent All Cigarette Trafficking Act of 2009 (PACT Act); the FD&C Act, as amended by the TCA; and other authorities. Violations of these statutes can result in felony convictions and significant criminal fines and civil monetary

penalties. They can also result in seizures of unauthorized products, which can help to make illegal e-cigarettes less accessible, including to young people. Through their participation in the task force, USMS will help FDA and DOJ effectuate seizures of unauthorized e-cigarettes within the United States.

FDA is committed to providing updates, as appropriate, to Congress as the organization and work of the taskforce progresses.

FDA's understanding of the illicit e-vapor market

1. **What does FDA believe is the size of the illicit Chinese e-vapor market in the U.S. either in terms of total volume or percentage of all nicotine vapor products sold in the U.S.?**

2. **Does FDA have any data or other information to dispute the assertion that, since 2020, the number of illicit Chinese e-vapor products available in the U.S. market has grown by a rate of 1,500% and that so far there has been no substantial change in this growth trajectory?**

3. **As FDA, DOJ, and the multi-agency task force should focus on the most impactful enforcement actions, what surveys or other methods does CTP use to measure or monitor the prevalence of illicit tobacco products generally, and illicit e-vapor products in particular, in the U.S.?**

To understand the science and the changing market, FDA uses several tools and methods, including but not limited to: the National Youth Tobacco Survey, the Population Assessment of Tobacco and Health Study, data from poison control centers, reports to FDA's Potential Tobacco Violation Reporting System, FDA's own surveillance, inspections, and investigations, and outside data sources and research such as Nielsen. As part of the newly announced interagency task force on e-cigarette enforcement, FDA looks forward to continuing to work collaboratively with our federal partners and will benefit from the collective resources and expertise of the federal government.

Although unauthorized tobacco products from Chinese-owned manufacturers account for a minority of the market share of products sold in the U.S., they remain concerning. It is difficult to quantify the market share of unauthorized disposable ENDS products sold in the United States, including Chinese products, as many may be imported by firms that have mis-declared their entries. One source for market share data is the CDC Foundation, which publishes e-cigarette sales data from a private sector vendor on a quarterly basis.[11] Their most recent data on dollars sales of e-cigarettes indicate that the following are the top 10 e-cigarette products marketed in the United States through December 2023 (released April 2024):

1. Vuse
2. JUUL
3. Breeze Smoke
4. Elfbar

[11] https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth

5. NJOY
6. HQD
7. Lost Vape Orion
8. Juicy Bar
9. Loon Maxx
10. Mr. Fog

Senator Charles E. Grassley

1. **In October 2019, the FDA warned the public to stop using vaping products containing THC amid an outbreak of vaping-related illnesses, which can be deadly. However, these unauthorized products are still readily available in both retail locations as well as online. What is the FDA's position regarding the legality of THC vapor products, including THC derived from hemp, and what is the FDA's strategy for removing these unauthorized products from the market?**

FDA shares many of your concerns about THC vapes. FDA has sent over 100 warning letters to firms marketing cannabis-derived products. FDA will continue to act, within our authorities, against products that put the public at risk.

FDA's authority to regulate products, including conducting inspections of manufacturers, is limited to those products that fall within an FDA-regulated product category as defined in the FD&C Act. To the extent that some THC products, such as certain THC vapes, may not meet the definition of any FDA-regulated product, FDA's authority is limited. It is a company's responsibility to ensure all of its FDA-regulated products comply with the applicable laws and regulations administered by FDA.

2. **In May 2023, the FDA directed U.S. customs to seize incoming shipments of "Elf Bar," a popular unauthorized Chinese vape. As numerous outlets have reported, Elf Bar simply rebranded as "EBCreate" to avoid seizure. EBCreate offers unauthorized wholesale in the United States on its website. Why hasn't the FDA shut down EBCreate's website and other websites offering wholesale of unauthorized vapor products when doing so could keep these products off retail store shelves?**

FDA monitors the marketplace and is aware that manufacturers may change the name of their product to avoid detection. In general, a manufacturer name change does not prevent the Agency from taking action. For example, if a manufacturer changes the name of a product for which a marketing denial order (MDO) applies, that MDO also applies to the newly named product and all associated names will be included in the screening process (e.g., Elf Bar to EB Design). FDA has taken numerous actions related to these products, including partnering with Customs and Border Protection to administratively seize over $18 million dollars in unauthorized ENDS e-cigarette products, including Elf Bar products. FDA has also issued warning letters and filed CMPs against retailers for selling Elf Bar products, as well as their rebranded products, such as EB Design. For example, on May 1, 2024, FDA issued warning letters to 14 online retailers for selling unauthorized e-cigarette products, such as Elf Bar/EB Design. FDA's import alerts cover dozens of firms that manufacture unauthorized e-cigarette products including the various Elf brands. You may also be aware of another significant FDA seizure in coordination with DOJ and the U.S. Marshals Service to seize over $700,000 in unauthorized e-cigarette products in California, including Elf Bar and EB Design products.

3. **Chinese companies are responsible for the majority of illicit disposable vaping products in the United States, yet these products are readily available. These companies often avoid seizure at U.S. ports of entry by changing their label names, and**

in some cases intentionally mislabel unauthorized vaping products as other goods to avoid inspection. What efforts is your agency taking to keep up with companies' efforts to avoid seizure at ports of entry so that U.S. customs authorities have accurate and updated information to seize unauthorized products?

The law is clear that a new tobacco product must have FDA authorization before it can be legally marketed, and generally, products without authorization are at risk of enforcement action. As of June 11, 2024, FDA had authorized 23 tobacco-flavored e-cigarette products and devices. Tobacco manufacturers, distributors, and retailers have a responsibility to comply with the law and should not be marketing, distributing, or selling products that have not received a marketing authorization. FDA has a comprehensive tobacco compliance and enforcement program, which monitors for violations of federal tobacco laws and regulations and takes enforcement action across the supply chain—including manufacturers, distributors, retailers, and importers.

Addressing illegal imported tobacco products is a high priority for FDA. Many of these products are being shipped from China to the United States, including some disposable e-cigarettes. Regarding Chinese imports, it's important to distinguish between domestic firms that may use overseas manufacturers and import finished products or parts and firms that are foreign owned. Per Nielsen, unit sales data for the four-week period ending April 20, 2024, the top three brands – Vuse, JUUL, NJOY – accounted for nearly 85 percent of the e-cigarette market nationally. These U.S.-owned firms – some of which use foreign manufacturers for parts of their products – account for the vast majority of the U.S. e-cigarette market. In contrast, Chinese-owned firms account for less than 10 percent of e-cigarette sales nationally

FDA is addressing this issue across the entire supply chain, including targeting manufacturers, importers, distributors and retailers, and taking escalating actions against those who continue to violate the law. FDA monitors the marketplace and is aware that manufacturers may change the name of their product to avoid detection. In general, a manufacturer name change does not prevent the Agency from taking appropriate action.

For those products that are properly declared, FDA works with CBP and the U.S. Postal Service at the International Mail Facilities to screen products at entry for compliance with applicable requirements. FDA's import entry dashboards, available on the Agency's website,[12] provide data related to properly declared import entries that are processed through FDA's screening systems. FDA's information technology systems help expedite the import review process by reviewing and validating entry information. CBP's Automated Commercial Environment (ACE) system communicates with FDA's electronic screening systems, such as the Import Entry Review and Operational and Administrative System for Import Support (OASIS). These systems work in combination with the Predictive Risk Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system to assist with screening imported products. PREDICT presents shipments for further review based on its analytical results.

FDA uses Import Alerts to inform FDA field staff, CBP, and the public that the Agency has enough evidence to allow for the detention without physical examination of products that appear to be in violation of FDA's laws and regulations, including many unauthorized e-cigarettes from

[12] https://datadashboard.fda.gov/ora/cd/impentry.htm

China.[13] FDA regularly updates the Import Alerts, including to account for changes in brand name (e.g., Elf Bar to EB Design). FDA has generally been refusing admission to products listed on these Import Alerts.

Many e-cigarette products offered for import are not properly declared. CBP has authority to administratively seize products that are smuggled or clandestinely imported. The agencies are collaborating to stop the flow of unauthorized e-cigarettes into the United States. These products are either destroyed or exported out of the country. For example, CBP is able to identify and can seize a misdeclared product under their authority, such as the 1.4 million units of unauthorized e-cigarettes products seized at Los Angeles airport last year.[14] All of the shipments originated in China. Approximately 250,000 imported tobacco products shipments are reviewed each year with 1,300 product lines (each line may include tens of thousands of products) being refused in FY 2024 so far.

[13] https://www.accessdata.fda.gov/cms_ia/industry_98.html
[14] https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes

Senator Amy Klobuchar

The FDA has already sorted through more than 25 million applications for the approval of mostly foreign-based e-cigarette products. In reviewing these applications, the FDA must determine whether the product is "appropriate for the protection of public health."

1. Can you tell me about the process of doing premarket reviews for vaping products and how it can be improved?

FDA reviews a PMTA to determine whether the application has sufficient evidence to show that marketing of a new tobacco product would be "appropriate for the protection of the public health" (APPH) – the standard legally required by the 2009 TCA.[15] FDA's evaluation of whether a PMTA contains evidence that the marketing of the product would be APPH takes into account the risks and benefits to the population as a whole, including youth, the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[16] FDA makes marketing authorization decisions on a case-by-case basis. As part of FDA's evaluation of these products, the Agency will issue a marketing granted order if it determines that the potential for the product to benefit adults who smoke outweighs the risk to youth. The review of these applications takes time to ensure that the final decisions are not only scientifically and legally defensible but also aligned with the authorities granted by Congress. It is the responsibility of the applicant to provide sufficiently robust scientific evidence to demonstrate that the necessary public health standard has been met. To date, several applicants have successfully met this standard, and we have seen an improvement in the quality of application submissions.

In the past three years, FDA has remained committed to helping manufacturers and importers understand how to prepare applications. For example, FDA published the final PMTA rule that sets forth content and format requirements for PMTAs and issued guidance related to the application process.[17] In addition, FDA developed technical resources for applicants submitting electronic applications,[18] and held multiple meetings and listening sessions with a variety of stakeholders to answer questions about the PMTA process, including a two-day public meeting on the PMTA process hosted on October 23 and 24, 2023.[19]

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[15] Pub.L. 111–31.

[16] Section 910(c)(4) of the FD&C Act

[17] *See* 86 FR 55300 (Oct.5, 2021), available at: https://www.federalregister.gov/documents/2021/10/05/2021-21011/premarket-tobacco-product-applications-and-recordkeeping-requirements#p-1357; Guidance for Industry: *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends (intending to assist applicants with the preparation of PMTAs for ENDS products, among other things).

[18] *See e.g.,* https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/preparing-and-submitting-premarket-tobacco-product-application (answering questions to and providing resources for preparing standard and supplemental PMTAs, and amendments, and submitting such documents electronically).

[19] https://www.fda.gov/tobacco-products/ctp-newsroom/premarket-applications-opportunities-stakeholder-engagement-public-meeting-10232023

FDA has also hired additional, dedicated personnel to enhance program management and implementation, including a PMTA coordinator and substantial equivalence (SE) coordinator. These new coordinator positions were established to work with Office of Science senior leadership and serve as staff who are dedicated to developing and refining program priorities, setting goals, and coordinating implementation across the office. Additional staffing resources have been focused on improving transparency, stakeholder engagement, and communications, including developing and implementing a plan to post scientific memos and reviewer guides, when appropriate.

FDA has taken steps to improve its transparency regarding decisions with regard to application reviews, including e-cigarette products that have received authorization by FDA to be marketed. This includes enhancements to FDA's Tobacco Products Marketing Orders webpage to make this important information easier to find and understand.[20] FDA also encourages retail organizations and trade groups to sign up for email updates from CTP, which provide the latest information on marketing granted orders (MGOs). Additionally, in March 2023, FDA launched the Searchable Tobacco Products Database,[21] a new user-friendly list of tobacco products that may be legally marketed in the United States. The database is designed to serve the public, especially retailers, by providing key information in a single location.

To date, FDA has received PMTAs for nearly 27 million e-cigarette products. This unprecedented volume of tobacco applications received is exponentially greater than submission volume for other FDA regulated products; for example, FDA medical product Centers receive thousands of applications a year. To date, FDA has resolved more than 26 million of these applications. As of the date of the hearing, FDA had authorized 23 tobacco-flavored e-cigarette products and devices. As the Agency continues to review more and more products, it remains committed to continued education and transparency.

2. How can Congress support the FDA to ensure that these products are not being sold to our kids?

FDA's continued compliance and enforcement efforts have occurred at the same time as encouraging recent declines in youth tobacco use. Specifically, the 2023 National Youth Tobacco Survey (NYTS) found there was an overall decline in current overall tobacco product use among middle- and high school students (16.5 percent to 12.6 percent) since 2022, which was largely driven by a decline in e-cigarette use. However, FDA's work is not done, and the Agency is committed to building upon this latest progress to meaningfully prevent and reduce youth tobacco product use.

FDA shares the goals and urgency of keeping all tobacco products out of the hands of youth and preventing the sale of unauthorized e-cigarettes. FDA has made important strides and conducted important work to protect the public health by regulating the manufacture, distribution, marketing and sale of tobacco products, including e-cigarettes. In the past two years alone, FDA has taken several first of its kind enforcement actions, including filing injunctions against e-cigarette manufacturers in coordination with the DOJ, filing CMP complaints against

[20] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders
[21] https://www.accessdata.fda.gov/scripts/searchtobacco/

manufacturers and retailers for manufacturing and selling tobacco products that lacked the required marketing authorization, and seizing approximately $700,000 in unauthorized e-cigarettes from a warehouse in California in conjunction with DOJ and the U.S. Marshals Service. However, given available resources, the Agency needs to prioritize actions.

FDA is actively looking at existing laws and regulations to identify opportunities for updates that could help address illegal manufacturing, marketing, and distribution of e-cigarettes. In general, FDA is looking at ways to better identify and hold accountable the responsible party in the United States, increase consequences for activities related to offering illegal products for import and strengthening our ability to refuse importation.

Importantly, FDA's ability to utilize any new authorities will also be dependent on resources and addressing this issue requires an "All Government" approach. With more resources and continued and collective engagement across agencies, FDA can increase compliance and enforcement actions across the supply chain.

FDA's tobacco program is entirely funded through user fees paid by the tobacco industry. While FDA regulates all tobacco products, including e-cigarettes, it only has the authority to assess and collect user fees from products that fall within the six classes specified in section 919 of the FD&C Act. FDA receives zero dollars from manufacturers of e-cigarettes that could be used to support review of the applications received for nearly 27 million e-cigarette products or to address those that are on the market illegally, even though it's these tobacco products that youth are using most. Since FY 2019 FDA is authorized to collect a fixed amount of $712 million each fiscal year. Under current law, this amount is not indexed to inflation. FDA has proposed in the budget request to modernize the tobacco user fee framework to begin collecting an additional $114 million in FY 2025 from all tobacco products.

Senator Richard Blumenthal

1. **Dr. King: FDA recently announced that it is rescinding its original marketing denial order (MDO) for JUUL products and returning the application to pending status. In that same statement, FDA said "all e-cigarette products, including those made by JUUL, are required by law to have FDA authorization to be legally marketed." Yet JUUL issued a statement that same day saying its products would remain on the market. Would you say that JUUL's continued marketing of its products is a violation of the law? If so, is FDA and its enforcement partners planning to take enforcement action against JUUL?**

FDA's administrative stay temporarily suspended the marketing denial orders (MDOs) issued in June 2022 to JUUL Labs, Inc. while the Agency conducted additional review. As of June 6, 2024, FDA rescinded the MDOs. Because the MDOs have been rescinded, the administrative stay suspending those MDOs has ended. Rescission of the marketing denial orders is not an authorization or a denial and does not indicate whether the applications are likely to be authorized or denied. Rescission of the marketing denial orders means the applications are pending substantive review by FDA. As stated in the recission letter, FDA needs additional information to conduct its toxicology analysis, and, in light of that, has given JUUL Labs, Inc., an opportunity to provide additional information responding to toxicology and any other deficiencies identified in their applications. The JUUL applications are still under review. FDA declines to provide additional comment on them before review is completed and a final decision is issued.

All e-cigarette products, including those made by JUUL, are required by law to have FDA authorization to be legally marketed. The Agency's continued review does not constitute authorization to market, sell, or ship JUUL products.

2. **Dr. King: You testified that FDA has received applications for more than one million non-tobacco nicotine products from more than 200 applicants. How many of those products are the subject of applications received by the May 14, 2022 deadline set by Congress in the Consolidated Appropriations Act of 2022? How many of those products for which applications were timely filed are the subject of applications that are still pending before FDA? Has FDA brought any enforcement actions against any products that are the subject of timely filed pending applications and remain on the market? If so, please identify these products. Of the non-tobacco nicotine products with applications filed after the May 14, 2022 deadline, how many of these products are the subject of applications still pending at FDA? Has FDA brought any enforcement actions against any of these products with pending applications filed after the deadline that are still on the market? If so, please identify these products.**

The nearly one million non-tobacco nicotine (NTN) applications referenced in the hearing are the products received by the May 14, 2022, deadline set by Congress in the Consolidated Appropriations Act of 2022. FDA has completed acceptance review of 100 percent of the NTN applications received by this May 2022 deadline. Of the nearly 1 million applications, approximately 926,000 did not meet the acceptance criteria and received a refuse-to-accept letter.

Approximately 9,500 applications were accepted and are currently pending review. PMTAs for NTN products are included in the PMTA totals for all nicotine sources in the FDA Tobacco Product Applications: Metrics & Reporting webpage.

FDA is working to complete review of the remaining NTN applications. To date, no NTN product has received premarket authorization. These reviews of NTN products are being conducted in tandem with the deemed tobacco product applications and are reviewed in the same manner. All PMTAs must meet the same statutory requirements.

Enforcing against unauthorized e-cigarette products, including unauthorized NTN products popular with youth, are among our highest enforcement priorities. New tobacco products without authorization are at risk of enforcement action. FDA has not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization, irrespective of whether those products contain tobacco derived or non-tobacco nicotine. The pendency of an application does not create a legal safe harbor to sell that product. We can issue, and have issued, warning letters for products for which an application has been submitted and is pending review.

As of June 10, 2024, FDA has issued more than 670 warning letters to manufacturers and distributors for the illegal manufacture, distribution, and/or sale of unauthorized new tobacco products, primarily e-cigarettes. About 150 of these were for NTN products. FDA also issued 57 complaints for civil money penalties (CMPs) seeing the maximum statutory amount of over $19,000 to manufacturers for the manufacture of tobacco products, including NTN products, that lacked the required marketing authorization. FDA issued more than 470 warning letters to retailers for the sale of unauthorized NTN e-cigarettes and issued 140 CMP complaints to retailers for selling unauthorized e-cigarettes, most of which were for the NTN products Elf Bar and Esco Bar, which are the two most commonly reported brands among current e-cigarette users according to the 2023 National Youth Tobacco Survey (NYTS).

In December 2023, FDA, in collaboration with U.S. Customs and Border Protection, announced the seizure of approximately 1.4 million units of unauthorized e-cigarette products, including brands such as Elf Bar. These actions were part of a three-day joint operation that resulted in the seizure of 41 shipments containing illegal e-cigarettes with a total value of more than $18 million. FDA also issued import alerts, including adding some e-cigarette products such as Elf Bar to an existing import alert, for unauthorized products subject to detention without physical examination at U.S. borders and ports and at International Mail Facilities.

In addition to the actions described above for marketing unauthorized products, FDA has issued more than 1,500 warning letters and over 310 CMP complaints to retailers for the sale of NTN products to underage purchasers.