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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
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September 30, 2024

Dr. Brian King, Ph.D.
Director
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. King:

Thank you for appearing before the Subcommittee on Health on Tuesday, September 10, 2024, to testify at the hearing entitled "Evaluating the FDA Human Foods and Tobacco Programs."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, November 1, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

1. Manufacturers are known to advertise and sell their illicit e-vapor products on youth-focused social media platforms. TikTok has been identified as a platform where users market and sell illicit e-vapor products to youth, and it is also owned and managed by a Chinese entity. These companies target underage youth and advertise that sales are made without completing age-and identity-verification at ordering or delivery. This is a direct violation of the PACT Act.

    a. What surveillance, if any, of vapor or nicotine pouch sales is the Food and Drug Administration (FDA) conducting on TikTok and other social media platforms, either alone or in conjunction with the Federal Trade Commission (FTC) and the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF)?

    b. Will you commit to bringing enforcement actions, in conjunction with your federal partners, against any manufacturers, distributors, or retailers found to be marketing or selling illicit e-vapor or pouch products to youth through such social media platforms?

2. Dr. King, you mentioned at the hearing on September 10 that premarket tobacco product application (PMTAs) with device access restriction technology will be reviewed on a case-by-case basis, and you clarified that the FDA has not adopted a de facto flavor ban for e-vapor products. Has the FDA issued any guidance on the types of device access restrictions – in terms of the features and functionality that would be required to prevent youth access – to support the authorization of non-tobacco and non-menthol flavored e-vapor products ("flavored e-vapor products")?

    a. If so, please provide us with a copy of that guidance.

    b. If not, please briefly describe the device access restrictions that would be required to support authorization of flavored e-vapor products.

    c. Please explain how, if the FDA issues marketing granted orders for flavored e-vapor products with device access restrictions, you expect adult tobacco consumers to migrate to those products while thousands of illicit flavored products without device access restrictions remain widely available in the marketplace?

3. According to data I have received, vaping products that the FDA has authorized only make up around 11 percent of the market. The rest of the market is made up of some actors attempting to comply with the Tobacco Control Act, but with applications stuck at the FDA, and some that are clearly illicit and making no attempt to follow the law. States have taken action to try to provide clarity to retailers about what products fall into those two groups, and Louisiana, in particular, has seen a reduction in truly illicit vaping

products. You have 1100 full time equivalents (FTEs). What is stopping you from directing a team to publish a list of manufacturers **that have publicly announced** that they have submitted PMTAs, and the products they have publicly announced, so retailers, convenience stores, and others can keep the truly illicit off the shelf?

4. Dr. King, the Committee understands that the term "telework" refers to a work flexibility arrangement that allows an employee to work from an approved alternative worksite other than the employee's official duty location for an approved number of days each pay period.

    a. Within each office under the Center for Tobacco Products (CTP), what percentage of employees telework?

    b. What is the range of approved telework days for each work period?

    c. What is the most typical number of approved telework days for each work period?

    d. How is the specified number of days enforced?

    e. Within the Center for Tobacco Products, what percentage of employees are fully remote?

    f. Can you provide a summary of actions you are taking to increase the frequency and quality of interactions with interested stakeholders?

The Honorable Brett Guthrie

1. In the hearing, you repeatedly contended that the CTP needs additional resources to clear the application backlog and move closer to the 180-day statutory timeline for application review. I would like to better understand how you are currently utilizing resources.

    a. What percentage of collected user fees are currently devoted to review for applications that have been filed?

        i. Can you provide that figure for Fiscal Year 2020, Fiscal Year 2021, Fiscal Year 2022, and Fiscal Year 2023 as well?

    b. How are those resources divided amongst Queue 1, Queue 2 and Queue 3, specifically for applications that have been accepted but have not yet received a filing determination, and for applications that have been filed but not yet received a marketing determination?

    c. Whether an application is accepted or receives a Refuse-to-Accept determination seems largely a matter of whether a form has been completed and submitted properly. Given that the forms in question are electronic, is there not a technological solution that the CTP could employ to streamline this phase,

allowing you to delegate more resources to the Office of Science for substantive scientific review of long-pending applications?

2. Director King, during an April 11, 2024, hearing at the House Oversight Committee, Commissioner Califf was asked about the lengthy authorization process at the Center for Tobacco Products (CTP) and how the CTP is not meeting the statutorily defined 180-day decision deadline. Commissioner Califf responded, "We want to meet the timelines like we do in all the other products, and we're going to do that as fast as we can. You make a good point there." Since April, nearly six months ago, what specifically has the CTP done to improve the efficiency of the premarket tobacco product application (PMTA) decision making process?

    a. Please provide a detailed, specific response, including how you are utilizing internal and external feedback, data analysis, performance goals and metrics, and change management to make these improvements, as well as a detailed timeline for implementation of the necessary changes.

3. To date, the FDA and Department of Justice (DOJ) have not filed a single lawsuit, sought a single injunction, or sought a single forfeiture application against any Chinese based manufacturer of illicit e-vapor products, against any foreign or domestic manufacturer of illicit disposable e-vapor products, or against any of the largest volume domestic distributors of illicit disposable e-vapor products.

    a. Have you have filed any lawsuit, sought any injunction, or sought any forfeitures against any Chinese based manufacturer of illicit e-vapor products? If yes, please list the manufacturer name and the enforcement action taken.

    b. Have you have filed any lawsuit, sought any injunction, or sought any forfeitures against any foreign or domestic manufacturer of illicit disposable e-vapor products, the ones that are thrown away after use and not refilled with liquid or a new pod or cartridge? If yes, please list the manufacturer name and the enforcement action taken.

    c. Have you filed any lawsuit, sought any injunction, or sought any forfeitures against any of the top 10 largest volume domestic distributors of illicit disposable e-vapor products? If yes, please list the domestic distributor name and the enforcement action taken.

4. You frequently cite the number of warning letters, civil money penalties, and injunctions the FDA has taken as enforcement success metrics. At the hearing on September 10, you said: "We take a comprehensive approach to regulation and that's across the supply chain. And that includes retailers and includes importers, distributors, and also manufacturers, we have taken action across that supply chain. And we've also taken escalated action in more recent years."

a. Please quantify the impact of the actions you have taken the illicit market in the U.S., year to date. What was the total illicit market volume in 2023 and what is it today?

b. Please provide detailed descriptions of the follow-up actions you have taken after the warning letters were sent, the civil monetary penalties assessed, and injunctions issued.

    i. Were the warning letters heeded?

    ii. Were the civil monetary penalties paid?

    iii. Were the injunctions obeyed?

c. Please provide the rates of recidivism by violators, and any other data the CTP has that demonstrates the actual impact of its enforcement actions.

d. Please provide a detailed description of the steps you intend to take to focus your enforcement efforts at the beginning of the supply chain, not the end, for illicit vapor products.

5. We have reviewed the CTP's Advisory and Enforcement Actions website and found that all 8 injunctions and all 70 civil money penalties that the CTP's website says were issued to "manufacturers" were actually issued to individual vape shops (online or brick and mortar) that only qualify as manufacturers because they mix and bottle their own e-liquids. I am more interested in the CTP focusing on manufacturers who make products by the hundreds of thousands that then get distributed to stores all over our country, not just their own store(s).

    a. If you disagree with this characterization, please identify and list all enforcement actions (as opposed to advisory actions such as warning letters) that the CTP has issued to: (a) manufacturers of illicit disposable e-vapor products; and (b) distributors of illicit disposable e-vapor products.

    b. Why is the CTP choosing to enforce against the smallest market actors rather than the largest manufacturers, importers, and distributors most responsible for illicit markets?

    c. Why is the CTP choosing to enforce against e-liquid manufacturers rather than the largest manufacturers of illicit disposable products, which dominate the U.S. market today?

    d. Why do you continue insisting that the CTP takes a "comprehensive" approach to enforcement "across the supply" chain when the facts simply do not support that statement and in truth your past enforcement actions have only focused on the sellers at the end of the supply chain or on stores that technically count at "manufacturers" in name only?

e. What message do you think the FDA's enforcement priorities are sending to illicit Chinese manufacturers – by directing enforcement actions only against small U.S. vape shops – and day after day, year after year, letting the Chinese manufacturers run amok in the U.S.?

f. On June 10, 2024, the FDA published a press release announcing the establishment of the multi-agency task force committed to "bring all available criminal and civil tools to bear against the illegal distribution, and sale of e-cigarettes, vapes, and other electronic nicotine delivery system (ENDS)." Please explain in detail how the FDA, DOJ, and the multi-agency task force plan to establish penalties of sufficient severity to disincentivize ongoing violations by the largest manufacturers and distributors of illicit flavored disposable e-vapor products.

g. Do you agree that: (1) Chinese manufacturers are engaged in interstate commerce in the U.S. – so these companies are subject to the jurisdiction of the FDA and the federal courts?; and (2) the FDA and DOJ have all of the statutory authority they need to secure injunctions, import seizures, and civil money penalties against these Chinese manufacturers? Yes or no.

    i. Please explain in detail how, if the FDA, DOJ, and the task force members do not believe they can effectively impose penalties against Chinese manufacturers, the multi-agency task force will prevent the importation of illicit Chinese e-vapor products?

    ii. Please explain whether the FDA, DOJ, and the task force members intend to investigate directors, officers, executives, affiliates, and subsidiaries of the largest Chinese manufacturers who reside in or are domiciled in the U.S.?

h. This Committee has seen correspondence to the FDA from various sources telling you exactly who the largest manufacturers are, where they are located, and what illegal products they are bringing into the U.S. You know who the 20 largest manufacturers of illicit disposable e-vapor products are, where they are located, and who their major U.S. based distributors are (including 10 of the largest distributors). Please explain whether this assertion is correct or incorrect, and whether the FDA, DOJ, and the multi-agency task force intend to bring enforcement actions against these 30 large companies illegally operating in the U.S. market.

6. The Committee understands that Premarket Tobacco Application review suffers long delays and significant uncertainty even in the face of a congressionally mandated review period. These delays impart economic harm to companies, harm to consumers due to diminished reduced harm product choice and harm to innovation due to the disincentive to investment. Please provide the Committee an assessment of the remaining September

2020 Deemed Product PMTA review and an assessment of when the Center will complete such a review including:

a. For products that were originally Deemed Tobacco products with PMTAs due in September 2020, how many PMTAs remain either in scientific review or have not yet entered scientific review?

    i. What is the Center's projected timeline for completion of these PMTAs?

    ii. Please provide any data or metrics related to still-pending PMTAs including but not limited to memoranda, reports, briefings and electronic correspondence.

b. Industry states that applicants do not know the current status of their still-pending applications. What information do you provide to applicants as to the status of their PMTAs?

    i. Please provide any information in the CTP's possession in relation still-pending PMTA status as well as any plans or concepts to share such information with the public or applicants including but not limited to memoranda, reports, briefings and electronic correspondence.

c. What prevents the CTP from providing such PMTA status information to applicants?

    i. Please provide any information in the CTP's possession in relation to this issue including but not limited to memoranda, reports, briefings and electronic correspondence.

d. What dialogue, other than Deficiency Letters, has the Center engaged in with companies that received marketing orders?

    i. If the Center has engaged in such dialogue, the Committee would like further information including dates and records of any meetings, calls, or correspondence.

e. Will the Center commit to engaging in dialogue with applicants to assist in successful applications for reduced harm products such as nicotine pouch products?

    i. If not, why not? Please provide a rationale for your answer.

7. In the 2022 Consolidated Appropriations Act Congress gave the CTP authority to regulate synthetic nicotine products along with strict deadlines for premarket review – PMTAs were due to the FDA in May 2022. We understand that many of these applications have proceeded through acceptance review but have not progressed further. How many synthetic nicotine product PMTAs are still pending?

i. Please provide any information in the CTP's possession in relation to still-pending synthetic nicotine PMTAs including but not limited to memoranda, reports, briefings and electronic correspondence.

b. When will the CTP complete filing review for the synthetic nicotine product PMTAs?

i. Please provide any information in the CTP's possession in relation to the filing review of still-pending synthetic nicotine PMTAs including but not limited to memoranda, reports, briefings and electronic correspondence.

c. When will the CTP complete scientific review of the synthetic nicotine product PMTAs?

i. Please provide any information in the CTP's possession in relation to scientific review of still-pending synthetic nicotine PMTAs including but not limited to memoranda, reports, briefings and electronic correspondence.

The Honorable Michael Burgess, M.D.

1. Dr. King, at the hearing you stated that enforcement against illicit-vapor products is the Tobacco Center's number one priority. That is why the interagency taskforce was established in June of this year. I was surprised, however, when you told me that you were not personally sitting on the task force. I was also surprised that you did not know who was leading the inter-agency coordination work for the Tobacco Center and that you could not provide me with their name and contact information.

    a. Who is the FDA's lead for the interagency taskforce to combat illicit e-vapor products? Please provide their name, rank and contact information so that I may call them.

    b. How many FTEs does the FDA have dedicated to the taskforce work?

    c. How many FTEs does the CTP have dedicated to the taskforce work?

2. On June 10, 2024, the FDA and DOJ announced the creation of a multi-agency task force to bring the collective resources of the federal government to bear against those who supply illicit e-vapor products. We believe the task force has the potential to be a turning point in addressing the illicit e-vapor crisis and we are looking forward to its success. But, to ensure the desired effect, the task force must operate effectively to allow a fully coordinated federal enforcement response to illicit e-vapor products and must use all available tools as promised in the press release announcing its creation. Please answer the following questions.

a. In at least two critical ways of assessing success, the task force has not made any progress in the 3 months since its establishment was announced. It has not filed any civil (injunctions or forfeitures) or criminal actions against the leading U.S. distributors or top volume illegal foreign manufacturers since its creation. I see no evidence of discernable changes to the availability of illicit products in the supply chain or on store shelves in the U.S. - sales volumes continue to increase. Do you agree that creating a task force on paper is not worth anything until it takes real enforcement actions (like lawsuits and product seizures and maximum fines and penalties) against the largest illegal manufacturers and distributors in the marketplace and those actions impact the supply chain of illicit products making those products harder to find and buy in the U.S. market?

b. Will the task force commit to frequent public reporting on its progress so that it is held accountable? Will you agree to providing quarterly progress reports to this Committee? We don't want to wait for annual reporting.

c. Has the FDA, DOJ, and the other agencies that joined the task force executed a formal memorandum of understanding (MOU) or other governance document that:

    i. Defines lines of authority and responsibility?

    ii. Clarifies processes for coordination, cooperation, and resource allocation?

    iii. Prevents duplication of effort?

    iv. If so, please provide us with a copy of the MOU.

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

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

3. The 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. If not, please explain why not.

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 the 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?

The Honorable Robert E. Latta

1. Since the FDA now has regulatory authority over synthetic nicotine, do you believe that authority includes nicotine analogs?

    a. Does the FDA need any additional authorities from Congress to address the growing number of products with nicotine analogs?

2. We know very little about the current composition or exact formal membership of the multi-agency task force. Have Customs and Border Protection (CBP) and Homeland Security Investigations (HSI) formally joined the task force?

    a. If yes, who at each agency is formally leading the work and responsible for taskforce coordination and outputs?

b. If no, will the FDA and DOJ commit to ensuring that CBP and HSI formally join the task force within the next 30 days and provide written confirmation to this Committee once it has?

c. Do you agree with FDA Commissioner Dr. Robert Califf that import prevention and enforcement is 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 and HSI be valued and active members taking lead roles in preventing the importation of illicit products?

The Honorable H. Morgan Griffith

1. The FDA has only issued the standard civil money penalty (CMP) of up to $20,678 for "single violations" against retailers for illicit e-vapor products. But the FDA has authority to issue significantly larger CMP under the Tobacco Control Act.

    a. Has the FDA issued any enhanced CMPs to any manufacturers, importers, or distributors that violate the premarket authorization requirement by supplying illicit e-vapor products.

    b. What are the circumstances for receiving an enhanced penalty?

    c. To date, what amount in CMPs has the FDA actually collected from the CMPs already assessed for the sale, distribution, or manufacture of illicit e-vapor products?

2. In recent testimony to the Senate Judiciary Committee, you stated that the FDA expects to publish draft guidance later this year describing a new approach to issuing enhanced CMPs. Why is the publication of updated guidance needed to begin issuing enhanced CMPs?

3. As part of the Deeming Regulation in 2016, the FDA announced that, for certain e-cigarettes and smokeless tobacco products (such as pouches) currently on the market at that time, that those products would be subject to "enforcement discretion." This meant that manufacturers could continue to sell products in the U.S. after August 2016 while simultaneously pursuing PMTA authorization. So, there are good actors that followed the law who had products on the market as of August 2016, with applications submitted to the FDA by the September 2020 court-imposed deadline, that are still awaiting a final decision by your FDA. Meanwhile, Chinese manufacturers who are dumping tens of thousands of illegal, flavored disposable products into our country without any enforcement. What is preventing the FDA from clearly articulating to the public which products fall into the group of those manufactured by good actors still awaiting FDA review?

4. One idea that has been floated to me would be to tie the amount of user fee dollars the CTP receives to performance thresholds. How would you feel about that?

    a. If Congress were to pass a bill to require that, can you please explain what the positives and negatives would be?

5. The CTP's website states that its mission is "To protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone." It seems clear that promoting and supporting strategies that enable everyone to live a healthier life necessarily includes harm reduction. Do you believe harm reduction is a part of that mission?

    a. If so, how do you define harm reduction?

    b. What role does harm reduction play – specifically in the lives of adult smokers who do not quit smoking?

6. According to the CTP database, since 2009, the CTP has authorized over 2,400 combustible cigarette products but only 54 novel smoke-free products. But combustible cigarettes are the deadliest form of tobacco, and smoke-free products present a less harmful choice for the 9 out of 10 adult smokers who do not quit smoking. So why would the CTP utilize its resources to authorize so many harmful products and not act on reduced harm products?

The Honorable Larry Bucshon, M.D.

1. The FDA's website states, "CTP's responsibilities under the law include setting performance standards," yet it is devoid of any meaningful metrics indicating the performance of the center. Why doesn't the CTP follow the practice of most other centers in the FDA, which maintain robust performance metrics and goals, supported by data, to evaluate the effectiveness of their performance?

    a. Leaders of these other centers have stated publicly that performance metrics and goals are responsible for the success of their center, and the Reagan-Udall Foundation clearly concluded that the CTP should follow this proven model. Wouldn't such a model help the CTP make proactive and reactive changes to its procedures and policies?

    b. What measures and data are you using to judge the performance of the center?

2. It is well known that reviews of premarket tobacco product applications (PMTAs) are failing to adhere to the congressionally mandated 180 days. What percentage of the CTP's budget is dedicated to completing PMTAs?

    a. Similarly, how many of the CTP's 1100 employees are contributing to product reviews or authorization decisions?

    b. How many FTEs work in each of the Center's four key focus areas listed on your homepage – Enforcement & Compliance; Public Education Campaigns; Policy, Rulemaking & Guidance; and Research?

3. During your testimony at the September 10, 2024, Committee on Energy and Commerce hearing, you noted that your office is seeking an additional $114 million in funding. Of that amount, you said that 25 percent of the resources would be used for application review. When a lawmaker responded that your office could instead "streamline the process," you replied, "Yes, or both. And we're working on that." In detail, how specifically is your office working to streamline the process?

4. H.R. 9425 proposes charging tobacco user fees based on gross sales of various manufacturers including vapor product manufacturers. This is problematic because the majority of the e-vapor marketplace is illicit, and we know that manufacturer and importers are not properly declaring their products at customs. Illicit Chinese manufacturers are highly unlikely to truthfully respond to requests from the FDA for sales data. How would you implement a system that is fair for the compliant U.S.-based manufacturers and that accurately assesses current sales of all vapor products (those in the legal and illegal supply chains)?

    a. How would you plan to collect user fees from foreign manufacturers that are not currently registered with the FDA, do not currently have applications for products pending with the FDA, and do not properly declare their imports with customs?

    b. Why should we have confidence that the CTP will enforce against illicit e-vapor manufacturers for the non-payment of user fees when you have not taken any enforcement against such entities for the manufacture of misbranded and adulterated e-vapor products?

5. You do not have to wait on new user fee legislation to collect more money for enforcement. If you aggressively use the Civil Monetary Penalties Congress made available to you, more enforcement resources could be collected quickly. But to date, the FDA has only issued the lowest CMPs of up to $20,678 for "single violations" against individual retailers for illicit e-vapor products. the FDA has not issued any enhanced CMPs to any manufacturers, importers, or distributors that violate the premarket authorization requirement by supplying illicit e-vapor products. Manufacturers, importers, and distributors often have much deeper pockets than retailers, and likely view modest CMPs as a mere cost of doing business.

a. Why are you only using the lowest available CMP level available to you in the statute?

b. Why are you only issuing CMPs for single violations against individual retailers?

c. Why are you not issuing enhanced CMPs for intentional violations by manufacturers, wholesalers, distributors, etc.?

d. Do you agree CMPs could be used to generate more money – money you could then use to increase enforcement actions?

The Honorable Richard Hudson

1. I reiterated my concern at the hearing that you have addressed less than .0005 percent of the illegal market even after your warning letters, seizures of illegal vapes, and legal action. To continue my questioning – What concrete steps can you commit to take in the next 90 days to rid our country of $2.4 billion worth of illegal Chinese disposable vapes?

2. I am really concerned about the lack of enforcement that has led to these products being so accessible. Do you know how many distributors are selling unauthorized products?

    a. Is the FDA inspecting all of these distributors?

    b. Based off inspections, has the FDA found evidence of non-authorized products on the shelf?

    c. So what has the FDA done on these?

    d. Has the CTP ever issued a monetary penalty against these distributors?

        i. Do you have numbers on that?

    e. Of the over $723,000,000 in tobacco user fees obligated in 2023, what percent is spent on compliance and enforcement activities?

        i. How does the CTP determine if that level of spending is appropriate compared to other user fee spending?

3. In the 2009 Tobacco Control Act, Congress gave the CTP the ability to take 180 days to evaluate a PMTA, where appropriate, to authorize the product for market, and still request and analyze post-market data to remove a product if necessary. Yet applications have been pending for years, and you stated that the onus is on industry to provide the necessary evidence – while also stating some applicants submit millions of pages of evidence to review. It seems the CTP expects a level and degree of evidence that is not contained in the Tobacco Control Act, while ignoring the authorities, processes, and

deadlines that Congress specifically provided. Why isn't the CTP utilizing this post-marketing surveillance process to meet the congressionally mandated 180-day deadline?

4. An increasingly alarming problem facing America's public health is the flow of unregulated illicit nicotine pouch products coming into this country from China. Nicotine pouch products have become a more popular alternative for adult cigarette smokers looking for less harmful nicotine options. However, illicit products, most of which are coming from China, are avoiding the FDA regulation, confusing consumers, and retailers, and muddying the waters for manufacturers that are following the rules. While enforcement action has largely focused on e-cigarettes, the FDA has paid little attention to illicit Chinese nicotine pouches and enforcing the rules on those imported products, especially those products where the foreign manufacturer failed to even apply for the FDA authorization. What is the CTP doing to address the illicit market of Chinese vapes and pouches, which have flooded the market of U.S. consumers?

    a. What further steps can the CTP take to reduce the market for illicit Chinese vapes and pouches?

    b. Do you believe that the CTP allowing regulated, authorized vapes and pouches to enter the market would help crowd out the market for illicit vapes and pouches and allow for more targeted, effective enforcement measures?

5. In your testimony, you repeatedly said there is "no safe harbor" for products that have timely filed applications but are still waiting on the FDA to decide on their application. You also said 500,000 applications remain pending. But you did not state how many of the 500,000 remaining applications were filed before the September 2020 deadline, how many were filed after that deadline, and how many of the applications are for synthetic nicotine products with applications filed in 2022 as required by Congress.

    a. How many were filed before the September 2020 deadline?

        i. Do you consider this number of applications "timely filed"?
        ii. How many product stock keeping units (SKUs) do those applications cover?

    b. How many synthetic product applications are in the 500,000 applications still pending?

    c. How many of those were filed before the 2022 filing deadline?

    d. How many product SKUs do those applications cover?

    e. In the case of nicotine pouches with timely filed applications (before the Sept. 2020 deadline), these products have now been waiting for authorization for over four years now—no nicotine pouch product has been granted a marketing order. Zyn and On!, two leading pouch brands manufactured in the USA by publicly-traded companies, will sell hundreds of millions of units in the U.S. market this

year. Would you say these products are prohibited for retailers to sell legally and that no nicotine pouch products should be being sold in the U.S. right now?

6. You stated in your testimony that there are zero applications currently awaiting your review as Director. Does this mean most of the backlog is at the Office of Science?

    a. When is the plan for the processing the remaining 500,000 e-vapor applications you stated are remaining to be decided on? Have you committed to any milestones or deadlines to clear this backlog?

    b. Is the FDA going to finish all e-vapor applications first and then move to nicotine pouch product applications as appears to be the case?

    c. Why has the FDA elected to forego any prioritization of nicotine pouches, when the market is rapidly growing? Including ones that applied earlier than many of the e-vapor products?

7. As you confirmed at the hearing on September 10, the FDA has not authorized a single PMTA for nicotine pouches. Although you did not confirm at the hearing when the first nicotine pouch PMTAs were filed, the CTP's own website confirms that hundreds of PMTAs for nicotine pouch products were indeed filed by September 9, 2020.

    So there has been no authorizations for pouch products despite the fact that most of the leading brands submitted the PMTAs over 4 years ago. Based on the 26 million products for which the FDA has received applications and the 34 marketing granted orders, a tobacco product really needs to be one in a million to be authorized by the FDA. This is not sustainable. The low authorization rate is a root cause of the illicit market; illicit manufacturers are filling the void created by the FDA's approach to PMTAs.

    During your tenure, only two product lines of smoke-free reduced risk nicotine products have been authorized (Vuse Alto tobacco-flavored SKUs and NJOY menthol-flavored SKUs). Products authorized during your predecessors tenure are largely lacking any of the innovation present in the illicit market products (innovation that may be meeting consumer demands but without the necessary regulatory oversight).

    Without a robust market in regulated, consumer-appealing, alternative smoke-free products, do you believe enforcement can ever work when consumer demand is so high? If so, please explain your plan for how that would work.

    a. Do you now recognize that the lack of authorized products is a direct cause of the massive illicit market?

        i. If so, what is your integrated and comprehensive plan to authorize more products into the regulated system and enforce against that those should not be in the market?

ii. If not, please explain how the lack of authorized products is not related to the enormous quantity of illicit products available on stores shelves in the U.S.

b. Why has the FDA taken an effectively prohibitionist approach to market authorizations for e-vapor products?

i. If you disagree that the FDA has taken a prohibitionist approach, please explain whether currently authorized e-vapor products are meeting adult consumer demand.

c. Does the FDA believe there is a connection between the growth of the illicit marketplace and the lack of a viable and legal pathway to market for e-vapor products?

d. FDA has authorized only two e-vapor product lines under your leadership, possibly because of pressure from Congress, but these do not come close to meeting adult consumer demand. Does the FDA have any intention of meeting adult consumer demand with authorized products?

i. If it does not intend to meet the demand with these products, does the FDA believe consumers will continue to source illicit products through unregulated and unlawful markets? What changes will the FDA adopt to meet this demand?

8. At the hearing on September 10, you spoke of the scientific standard for authorization as if it were an objective test that applicants either satisfy or fail to satisfy based on their PMTAs. If that's your position – completely ignoring the reality that the CTP must interpret and apply the standard to each application and undertake a balance exercise between the costs and benefits of the subject products to users and nonusers – there is a need for legislative reform. What legislative changes would you recommend so that more products receive authorization?

9. As I mentioned at the hearing on September 10, the multi-agency task force should have clear enforcement objectives that it is aiming to complete within a clear timeline. We know nothing about the basic structure and operation of the multi-agency task force. At the Senate Judiciary hearing a few months ago where you testified, DOJ said this issue is the FDA's number one priority. Please provide detailed answers to the following questions:

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. Since you mentioned that you are not personally involved in the operation of the task force, who is the highest ranking individual from the FDA on the task force?

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

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

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

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

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

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

l. Will the task force issue detailed public reports on its progress? If so, how frequently?

    i. If not, will the FDA and DOJ commit to providing written updates to this Committee at least quarterly?

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

n. Who will be held accountable if this task force does nothing more to prevent the illicit market?

o. Who chairs the task force?

The Honorable Neal Dunn, M.D.

1. Dr. King, millions of products available are coming from our greatest adversary—China. These products are specifically designed to target children and teenagers, and illicit Chinese vapes make up a significant portion of the $7 billion e-cigarette market. Although illicit imports are coming from a finite number of known entities in China, huge quantities of illicit e-vapor products continue to make their way across our borders, onto store shelves and ecommerce sites, and into the hands of youth throughout the country. While most illicit e-vapor products are mis-declared to Customs and Border

Protection (CBP), some U.S. import brokers correctly declare them, and the FDA tracks entry decisions in its public OASIS database. The OASIS data shows that even when properly declared to CBP and the FDA as e-vapor products, the FDA is not stopping products from known illicit Chinese e-vapor manufacturers from entering the country.

An analysis of the nearly 10,000 declared e-vapor shipments from China in federal fiscal year 2024 to-date (October 1, 2023 to July 24, 2024) shows:

(a) the FDA automatically released 72 percent of all shipments into the U.S. and only refused 7.2 percent;
(b) More than 18 percent of all shipments were released even after further review by the FDA (1,824 shipments), 330 of which were physically inspected by the FDA; and,
(c) Shipments allowed entry from known Chinese illicit e-vapor manufacturers comprised nearly 40 percent of all shipments, and these manufacturers produce the largest illicit e-vapor brands, including the top brands reported by youth in the 2024 National Youth Tobacco Survey.

I would like to understand how the FDA, CBP, and the multi-agency task force intend to stop illicit imports from entering the U.S. market through ports of entry. Why is the FDA waving through declared e-vapor products from China, especially when they are primarily shipped by known Chinese illicit e-vapor manufacturers, and in circumstances where the FDA Commissioner Dr. Robert Califf acknowledged that import enforcement is likely the most effective way to prevent the flow of illegal e-vapor products from China?

2. Dr. King, the FDA has identified approximately 85 disposable e-vapor brands as misbranded and adulterated in warning letters. But the FDA has added only about 10 of those disposable brands to import alerts for detention without physical examination at ports of entry, including only 5 brands from the largest 20 manufacturers of flavored disposable products. Please explain whether the FDA, CBP, and the multi-agency task force intend to prioritize addition of all illicit e-vapor manufacturers and brands to import alerts (other than those that have marketing granted orders, timely filed premarket applications that remain pending, or judicial stays of marketing denial orders)?

3. Dr. King, for the overwhelming majority of e-vapor products, which are not subject to current import alerts, CBP requires clarity from the FDA on which e-vapor products are admissible and which are inadmissible. Please explain how the FDA provides such information to CBP, and whether the information is provided on a manufacturer-basis, brand-basis, or product-basis.

    a. How long does it take the FDA to provide this information to CBP after it is requested? What are the steps?

    b. Please explain, also, whether the multi-agency task force intends to ensure that actionable information is provided by the FDA to CBP field staff in a timelier manner so that illegal e-vapor products can be denied entry.

4. Dr. King, the December 2023 press release on the seizure of 1.4 million illegal e-cigarettes was the first public statement issued about large-scale import seizures of illegal e-cigarettes involving the FDA and CBP since June 2021, March 2021, and January 2021. This is important as it appears, from the FDA's press releases, that significant numbers of illicit e-vapor products are mis-declared in import documents. Please explain whether the FDA, CBP, and the multi-agency task intend to increase the frequency of such joint seizures going forward to detect a higher proportion of mis declared illicit e-vapor products and deter importers from continuing their unlawful conduct.

5. Dr. King, I would like more clarity about the taskforce and its practices and processes. Who at the FDA is directly responsible for the taskforce work? Who is the lead? Is it you?

    a. If it is not you who is it and how often do they report to you on progress being made by the taskforce?

    b. Who at CBP is responsible for directly interfacing with you, Dr. King, or your designee, to stop the importation of illicit e-cigarette products from China?

    c. Who at DOJ is responsible for directly interfacing with you, Dr. King, or your designee, to prosecute the importation of illicit e-cigarette products from China?

    d. When was the last strategy meeting you, or the FDA taskforce lead named above, personally had with the counterpart at CBP named above to stop the flood of illicit e-cigarettes from China? Please provide an overview to the committee of the content of that meeting.

    e. When was the last strategy meeting you, or the FDA taskforce lead named above, personally had with the counterpart at DOJ named above to prosecute the importation and sale of illicit e-cigarettes from China? Please provide an overview to the committee of the content of that meeting.

    f. When is the next strategy meeting between you and your counterpart at CBP? Please provide an overview to the committee of the agenda for the meeting and how you will measure progress against your last meeting.

    g. When is the next strategy meeting between you and your counterpart at DOJ? Please provide an overview to the committee of the agenda for the meeting and how you will measure progress against your last meeting.

    h. Please provide to the Committee the dates of all planned meetings with your CBP counterpart and your DOJ counterpart on the taskforce for the next 12 months.

6. Dr. King, public health risk communication is critically important. The majority of consumers and physicians think that all tobacco products have equal risk of harm. Will

the FDA commit to launching a public health communications campaign about the continuum of risk for tobacco products to educate consumers and physicians?

7. Dr. King, as a physician I have seem the harms of tobacco including long term complications such as an increased risks of many cancers. Over 6 million PMTAs were filed and only 49 modified risk tobacco product applications were filed and 12 marketing orders were granted, as industry responded to the FDA signals deprioritizing this pathway. Why has the FDA not proactively supported innovation and applicants in promoting modified risk tobacco products? Is the FDA not prioritizing tobacco harm reduction to reduce cancer risk in Americans and contravening the Cancer Moonshot?

The Honorable Dan Crenshaw

1. The Reagan-Udall foundation stated: "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." Regarding these "trade-offs," how does the FDA's authorization process weigh youth initiation of nicotine use vs. adult switching from cigarettes use?

    a. To receive authorization, how much adult switching from cigarettes use must a PMTA demonstrate to outweigh the risk of youth initiation of nicotine use?

2. If the FDA is not using a formula to determine whether the benefits to adults outweigh the risks to youth for each specific product submitted for review under the appropriate for the protection of public health (APPH) standard, is the FDA using an ad hoc approach?

    a. Is an ad hoc approach appropriate for a regulatory body?

    b. If the FDA is using an ad hoc approach, how can the FDA ensure the APPH standard is consistently, fairly, and repeatedly applied to different product applications and companies?

3. How many products has the Center for Tobacco Products authorized and denied in each category over the last decade? How is the CTP staff utilized in the review and processing of these applications?

4. Please provide a detailed breakdown of Center resources used for each application type by product category.

The Honorable Troy Balderson

I have been made aware that all 8 injunctions and all 70 civil money penalties that the CTP's Advisory and Enforcement Actions website says were issued to "manufacturers" were actually issued to individual vape shops (online or brick and mortar) that only technically qualify as manufacturers because they mix and label e-liquids.

1. Please identify all enforcement actions (as opposed to advisory actions such as warning letters) that the CTP has issued to:

    a. Manufacturers of illicit disposable e-vapor products (that are not individual vape shops); and,

    b. U.S. based distributors of illicit disposable e-vapor products.

2. What is the combined market share of all e-vapor manufacturers the FDA has taken enforcement actions against (do not include advisory actions like warning letters)?

3. In the recently published 2024 National Youth Tobacco Survey, 7 out of the 10 most popular e-vapor brands named by youth are illicit disposable products (Elf Bar, Breeze, Fume, Geek Bar, Esco Bars, SMOK, Lost Mary). How many of the manufacturers of these 7 brands has the FDA taken enforcement actions against? Please exclude advisory actions, such as warning letters.

4. Do you agree that because Chinese manufacturers are engaged in interstate commerce in the U.S., they are subject to the jurisdiction of the FDA and the federal courts?

    a. If yes, do you agree that the FDA and DOJ have all the statutory authority they need to secure injunctions, import seizures, and civil money penalties against these Chinese manufacturers?

    b. Please explain in detail how, if the FDA, DOJ, and the task force do not believe they can effectively impose penalties against Chinese manufacturers, the multi-agency task force will prevent the importation of illicit Chinese e-vapor products.

    c. Please explain whether the FDA, DOJ, and the task force intend to investigate directors, officers, executives, affiliates, and subsidiaries of the largest Chinese manufacturers who reside in or are domiciled in the U.S.

Dr. King, in your opening remarks you stated that the Tobacco Center works tirelessly using all the tools available to them to reduce the harm of tobacco use which remains the leading cause of preventable disease. As part of that work, you have reviewed more than 26 million applications for new tobacco products that are attempting to meet the standard of being "appropriate for the protection of public health." You stated that 99.5 percent of them (25.5 million of the applications) have been denied. I have some follow up questions:

5. Has the CTP issued 25.5 million market denial orders?

    a. 1 for each rejected application?

    b. If not, how many MDOs have been issued specifically? If an MDO sometimes covers more than one product or application, please explain.

6. Did the CTP meet the 180-day statutory review timeline with any of the above MDOs? If yes, please tell us which ones.

7. Did the CTP meet the 180-day statutory review timeline with any of the 34 products that have been granted market orders? If yes, please tell us which ones.

8. What is the updated review timeline for the remaining 500,000 PMTA applications still pending?

    a. Will the CTP meet the 180-day review deadline?

    b. Will it meet a deadline that is 180 days from the hearing we had on September 10th?

I have some follow-up questions regarding the new $110 million user fee request and the breakdown you gave on the intended distribution of the new funds – 50 percent towards enforcement, 25 percent towards application review, and 25 percent towards campaigns.

9. How does the CTP plan to use the 50 percent towards enforcement?

    a. More specifically, what enforcement activities are planned for that money?

10. Will the 25 percent towards application review go to hiring more application reviewers?

    a. How many FTEs do you have reviewing applications currently?
    b. How many additional FTEs would you hire with these funds? How many applications is each current FTE responsible for?

11. What will you do with the 25 percent increase in application review funding once the 500,000-application backlog is cleared?

    a. Once you complete the review of the 500,000 applications, what is the anticipated volume of applications moving forward?

12. Please provide detailed examples of the public education campaigns you had active in 2023 and 2024 and how much was spent on each for what avenues – TV, radio, social media, etc.

    a. What specific plans do you have for the 25 percent increase towards campaigns?

The Honorable Dianna Harshbarger

1. Dr. King, at the hearing on September 10, you publicly committed to clearing the backlog of pending PMTAs, but you also said there are currently 500,000 pending applications under review by the FDA. Many of these applications have been pending for several years, even though the deadline set by statute requires that the FDA decide each

application within 180 days. Could you confirm that, when you say there are 500,000 pending PMTAs, that means there are 500,000 individual products (or SKUs) subject to pending PMTAs? I understand that sometimes multiple SKUs can be included in one consolidated application.

a. If that's the case:

    i. How many consolidated e-vapor applications remain pending, rather than the number of individual products subject to such PMTAs?

    ii. How many total applicants or manufacturers have filed the PMTAs that remain pending?

b. Will the FDA commit to completing its review the backlog of "covered" vapor applications as projected in the FDA's court filing by December 31, 2024?

    i. If not, please indicate what measures the FDA has adopted to decide the applications as soon as possible, and when the FDA expects to finalize its review?

c. After the FDA clears this backlog, does the FDA have the processes in place to meet the statutory 180-day review period for future filed PMTA applications?

    i. What are these processes?

2. Despite the FDA's efforts, illicit Chinese vapes are seemingly available in every community in America. It seems like our tobacco regulatory apparatus is consistently being outmaneuvered, outsmarted, and simply beaten by the Chinese State Tobacco Monopoly. This is at the expense of American youth, adults seeking alternatives to smoking, and finally American companies. The FDA's lack of authorizations for new products from legitimate American companies effectively creates a monopoly for the Chinese vapor companies operating illegally in the open without any real consequences.

    a. Does the FDA have staff that understands the concepts of consumer demand on the tobacco marketplace, and the use of illicit flavored disposable products in the marketplace?

    b. Does the FDA incorporate that real-world data into its balancing of the benefits and harms associated with the potential authorization of flavored e-vapor products?

    c. Does the FDA believe that authorizations are a key tool to shift demand from illicit Chinese products to legal American products?

    d. Does the FDA believe that if it authorized e-vapor products in flavors other than tobacco, menthol, and mint, that consumers of current illicit products would instead switch to purchasing the authorized e-vapor products?

The Honorable Mariannette Miller-Meeks, M.D.

1. Director King, during your testimony at the September 10, 2024, Committee on Energy and Commerce hearing, it was evident that many lawmakers are frustrated by the stymied process to get lower risk, non-combustible products with appropriate youth safeguards to market. Additionally, it seems U.S. harm reduction efforts are falling behind those of other accountable and transparent governments, such as the United Kingdom (UK). The National Health Service of the UK states on its website, "While nicotine is the addictive substance in cigarettes, most of the harm from smoking comes from the thousands of other chemicals in tobacco smoke, many of which are toxic." Do you agree?

    a. The National Health Service of the UK also says, referring to Zyn pouches, vapes, or e-cigs, "they're far less harmful than cigarettes, and can help you quit smoking for good." Do you agree?

        i. How do your responses align with advancing harm reduction policy, which is congressionally mandated under the Tobacco Control Act of 2009?

2. Director King, the FDA has been criticized for creating widespread confusion among regulated wholesalers and retailers about its enforcement priorities. the FDA has said repeatedly that the "only" legal products that may be on the market are the 34 e-vapor products that have received marketing granted orders. But the FDA's actual enforcement practices do not appear to be consistent with these statements.

    a. For the sake of clarity and coherence, the FDA should be clear with regulated industry about the FDA's enforcement priorities. To that end, please explain in rank order how the FDA is currently prioritizing the removal of the following e-vapor product categories from the marketplace:

        i. Products that entered the market after 8/8/2016 and have not filed PMTAs at any time.

        ii. Products that filed an application but received a marketing denial order.

        iii. Products that received a marketing denial order now subject to judicial or administrative stays.

        iv. Products on the market after 8/8/2016 that are made or claimed to be made with synthetic nicotine? Is the answer any different for synthetic products that filed PMTAs in 2022.

        v. Products on the market as of 8/8/2016 that are made or claim to be made with tobacco-derived nicotine and had PMTAs filed as of 9/9/20 that are still under review by the FDA.

b. Will the FDA commit to identifying specific products that fall into the above-described categories for the newly formed multi-agency task force so it can prioritize its enforcement efforts in line with the FDA's enforcement priorities (e.g., against those actors that have not filed a PMTA or have had a PMTA denied without relief of a revocation, rescission, or stay)?

   i. Is the CTP prioritizing enforcement against all tobacco products made with synthetic nicotine, as required by the 2022 Consolidated Appropriations Act, regardless of whether such products are subject pending PMTAs (filed by the statutory deadline of 5/14/22)?

   ii. If so, please explain how the CTP is implementing prioritized enforcement as Congress intended against this category of synthetic nicotine products relative to tobacco-derived products (that filed PMTAs by 9/9/20).

   iii. If not, please explain how the CTP's failure to prioritize such enforcement is consistent with the provisions of the 2022 Consolidated Appropriations Act.

3. The Committee is aware of new products that do not contain nicotine but claim to mimic the effects of nicotine but are unregulated by the FDA. They are being called "nicotine analogues" and include nicotinamide and 6MN to name a few. To avoid the creation of another massive illicit market, what steps will the FDA take to regulate these products and how quickly will the FDA act?

The Honorable August Pfluger

1. Dr. King, during the hearing, I asked why the FDA's enforcement efforts seem to focus primarily on small retailers, and how the FDA plans to address Chinese manufacturers of illicit products. You mentioned that the CTP has issued civil monetary penalties to 65 manufacturers. However, upon reviewing the data, it appears that these entities were mostly small vape shops rather than significant manufacturers. What specific steps is the FDA taking to escalate enforcement against larger, more impactful manufacturers?

   a. Does your strategy include issuing civil monetary penalties (CMPs) and pursuing legal action, such as civil or criminal lawsuits through the DOJ, against major Chinese manufacturers producing illicit products?

   b. Furthermore, does the FDA have plans to take action against companies like iMiracle Shenzen, which dominate the illicit market and generate billions of dollars in sales annually?

2. Dr. King, the FDA has a responsibility to provide clear guidance to the industry on how it may comply with the law. Currently, there is widespread confusion, and industry participants have requested that the FDA publish a list of products that may continue to be sold while awaiting application decisions. The FDA has cited confidentiality concerns

as a reason for not publishing such a list but has previously acknowledged that these concerns do not apply to products already on the market.

In fact, the FDA published a list in May 2021 of over 6 million natural nicotine products with timely PMTAs filed by the September 2020 deadline. You testified that only 500,000 applications remain pending today, and very few of these are for products introduced before 2016, as required by the Deeming Rule. There seems to be no reason preventing the FDA from updating this list, given that nearly all the original products have already been denied authorization.

Will you commit to publishing an updated list of deemed tobacco products made with natural nicotine that were launched as of August 8, 2016, and for which PMTAs were timely filed by September 9, 2020, but have not yet been subject to negative action? These would be the only products legally allowed on the market, alongside the 34 already authorized.

3. How does the FDA's refusal to publish this list not benefit Chinese manufacturers of illicit products, who are taking advantage of the regulatory confusion?

4. Is it the FDA's position that products made by companies in full compliance with the 2016 Deeming Rule and 2020 Guidance still "risk enforcement" at any moment?

    a. Why has the FDA kept information about its enforcement priorities unclear for both manufacturers and retailers?

    b. What impact do you believe enforcing against domestic manufacturers, who have fully complied with all rules and guidance, would have on the dominance of illicit Chinese manufacturers in this market?

    c. Do you agree that illicit Chinese manufacturers are likely benefiting from the FDA's inaction, as removing U.S. competitors would leave them with a greater market share?

5. If Congress were to pass a law requiring the publication of this list, will you commit to ensuring the CTP complies within 90 days, without delays like those seen in other statutory requirements (e.g., the foreign manufacturer registration rule, the photo ID rule for tobacco purchasers under 30)?

The Honorable Frank Pallone, Jr.

1. In your testimony, you indicated that the FDA has pending for review roughly 500,000 PMTAs related to ENDS products. Will you please provide a breakdown of how many of these are for synthetic nicotine products and how many are for products with nicotine derived from tobacco? When does the FDA estimate that it will complete its review of the currently pending applications for ENDS products with nicotine derived from tobacco? When does the FDA anticipate it will complete its review of currently pending

applications for ENDS products derived from synthetic nicotine? How many synthetic nicotine marketing applications has the FDA acted on to date?

2. In your testimony, you indicated that the data source that the FDA uses suggest that about 85 percent of the U.S. ENDS market is U.S.-owned entities. Will you please provide the data source for this statistic? For each of the ENDS brands that are most popular with youth (according to the 2024 National Youth Tobacco Survey), will you identify which are made by U.S.-owned entities?

3. In your testimony, you stated that "simply submitting an application does not garner a safe harbor for that entity. If you don't have authorization, you are at risk of enforcement." While I understand that the FDA policy is that all products without a marketing granted order are subject to the FDA enforcement, has the FDA ever taken enforcement action against an ENDS product with a pending application? If so, for which product(s) has the FDA taken enforcement action? If the FDA has not taken action against a product with a pending application, why has the FDA not taken such enforcement action?

4. In 2022, Congress enacted legislation clarifying that synthetic nicotine products are to be regulated as tobacco products under the Tobacco Control Act. That law created a short window for manufacturers of synthetic nicotine products to submit premarket applications. But the law was clear that, 90 days after enactment, any synthetic product on the market that the FDA had not authorized -- "including such a tobacco product that is the subject of a pending application" -- would be in violation of the Tobacco Control Act. Has the FDA taken enforcement actions against any of the large number of synthetic nicotine products now on the market that have pending applications? If so, for which synthetic nicotine products with pending applications has the FDA taken enforcement action? If the FDA has not taken action against a synthetic nicotine product with a pending application, why has the FDA not taken such enforcement action?

The Honorable Anna Eshoo

1. The Center for Tobacco Products has several tools in its enforcement arsenal to ensure tobacco manufacturers and retailers follow the law, including warning letters, civil monetary penalties up to $1.2 million, and product seizures. Since February 2023, the FDA has levied civil monetary penalties against only 69 manufacturers and 148 retailers for selling unauthorized tobacco products. The penalties levied have largely been on individual products – with many fines being for only $20,678.

    a. Why is the FDA taking such a light-handed approach to enforcement – such as only issuing one fine per violation, and why not levy the highest penalty possible?

    b. How does the FDA determine when and if to levy civil monetary penalties?

    c. Is the FDA preparing a guidance document to allow for fines for multiple violations?

i. If yes, why is such guidance required when the statute is clear that the FDA already has that authority?

ii. When is this guidance document expected to be finalized?

d. Of the manufacturers and retailers who received warning letters from the FDA for selling unauthorized or illegal tobacco products, how many have voluntarily come into compliance?

2. The Reagan-Udall Foundation completed an assessment of the Center for Tobacco Products' processes and operations. The Foundation made 15 recommendations. Of the 15 recommendations, how many have been fully implemented? How many must still be addressed?

The Honorable Raul Ruiz

1. Dr. King, when the FDA identifies a violation, how does the FDA determine whether and when to seek civil monetary penalties, injunctive relief, or other remedies? Is the FDA required to issue a warning letter before pursuing other remedies?

2. Dr. King, would a greater focus on enforcement actions against other aspects of the supply chain – such as wholesalers or distributors – be more effective of clearing the market of unauthorized products rather than focusing on individual retailers?